U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. Copies of the filing and of any subsequent amendments also will be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-18084 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 18844; SR-OCC-82-6]

Options Clearing Corporation ("OCC"); Order Approving Proposed Rule Change

June 25, 1982.

On February 24, 1982, OCC filed with the Commission pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), (the "Act") and Rule 19b-4 thereunder, a proposed rule change that allows OCC to implement its pilot Escrow Receipt Depository ("ERD") program on a full-scale basis. ERD automates the processing of escrow deposits and allows related premium settlements between clearing members and ERD participating banks to be effected through OCC's facilities.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 18689, April 16, 1982) and by publication in the **Federal Register** (47 FR 18080, April 27, 1982). No letters of comment were received by the Commission.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to registered clearing agencies, and in particular, the requirements of Section 17A of the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 82-18085 Filed 7-1-82; 8:45 am]

BILLING CODE 8010-01-M

SMALL BUSINESS ADMINISTRATION

[License No. 06/06-0258]

Texas Commerce Investment Co.; Issuance of a License To Operate as a Small Business Investment Company

On March 26, 1982, a notice was published in the **Federal Register** (47 FR 13071), stating that Texas Commerce Investment Company, located at 712 Main Street, Houston, Texas 77002, has filed an application with the Small Business Administration pursuant to 13 CFR 107.102 (1982), for a license to operate as a small business investment company under the provisions of Section 301(c) of the Small Business Investment Act of 1958, as amended.

The period for comment expired on April 12, 1982, and no significant comments were received.

Notice is herey given that considering the application and other pertinent information, SBA has issued License No. 06/06-0258 to Texas Commerce Investment Company.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: June 25, 1982.

Robert G. Lineberry,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 82-18089 Filed 7-1-82; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Privacy Act of 1974; Proposed Revision of a System of Records

AGENCY: Internal Revenue Service, Treasury.

ACTION: Proposed Revision of a System of Records.

SUMMARY: Pursuant to the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), the Department of the Treasury, Internal Revenue Service, gives notice of proposed revisions to Treasury/IRS System of Records entitled, TDA (Taxpayer Delinquent Accounts)—Treasury/IRS 26.019. Treasury/IRS 26.019 is being modified to include child support obligation accounts which are collected by the Internal Revenue Service.

DATES: Public comments must be received on or before August 2, 1982. If no comments are received, to which the Department publishes a revision to incorporate comments, this system will become effective on August 31, 1982.

ADDRESS: Assistant Commissioner (Collection), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Goldsmith, Chief, Office of Planning and Management, Assistant Commissioner (Collection), Internal Revenue Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, (202) 566-4250.

Dated: June 22, 1982.

George Astengo,

Acting Assistant Secretary (Administration).

Notice of Revised System of Records

Treasury/IRS 26.019

The following system is revised:

TREASURY/IRS 26.019

SYSTEM NAME:

TDA (Taxpayer Delinquent Accounts) including subsystems: (a) Adjustment and Payment Tracer Files, (b) Collateral Files, (c) Seized Property Records, (d) Tax Collection Waiver (Form 900) Files, and (e) Accounts on Child Support Obligations, OP:C—Treasury/IRS.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Taxpayers on whom Federal tax assessments have been made and persons who owe child support obligations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Taxpayer name, address, taxpayer identification number, information about basis of assessment, including class of tax, period, dollar amounts, chronological investigative history, cancelled checks, amended returns, claims, collateral submitted to stay collection, copies of notices of Federal tax liens, revenue officer reports, waivers to extend statutory period for collection, etc., and similar information about persons who owe child support obligations. This system includes installment agreement files; Delinquent Account Inventory Profiles (DAIPs); Currently Not Collectible Registers; Currently Not Collectible Registers (over $25,000); advance dated remittance check files; currently not collectible accounts files; a file of taxpayer names entered in the Treasury Enforcement Communications System; and, a code identifying taxpayers that threatened or assaulted IRS employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and 26 U.S.C. 6305, 7801 and 7802.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine disclosure may be made to the extent provided by law or regulation (included 26 U.S.C. 6103 and 26 CFR 404.6103 where applicable). For additional routine uses, see Appendix AA.

RETRIEVABILITY:

By name of taxpayer or person who owes child support obligations.

SAFEGUARDS:

Access controls will be not less than that provided for by IRM 1(16)12, Manager's Security Handbook.

RETENTION AND DISPOSAL:

As specified in IRM 1(15)59.24, Records Control Schedule 204 for Collection, Taxpayer Service and Problem Resolution Program—District Offices, and IRM 1(15)59.26, Records Control Schedule 206 for Service Centers.

[FR Doc. 82-18094 Filed 7-1-82; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

During the period June 18 through June 24, 1982, the Department of Treasury submitted the following public information collection requirements to OMB, for review and clearance under the Paperwork Reduction Act of 1980, P.L. 96-511. Copies of these submissions may be obtained from the Treasury Department Clearance Officer, by calling (202) 634-2179. Comments regarding these information collections should be addressed to the Treasury Reports Management Officer, Information Resources Management Division, Room 309, 1625 I St. NW., Washington, D.C. 20220; *and* to the OMB reviewer listed at the end of each entry.

Date Submitted: June 23, 1982.

Submitting Bureau: Bureau of Government Financial Operations.

OMB Number: 1510-0019.

Form Number: TFS 1133.

Type of Submission: Revision.

Title: Claim Against the United States for the Proceeds of a Government Check.

Purpose: This form is used to record information pertaining to adjudicating the payee's request for payment for a lost, mutilated or stolen U.S. Government check.

OMB Reviewer: Suzanne Evinger, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: U.S. Customs Service.

OMB Number: 1515-0014.

Form Number: CF 4455.

Type of Submission: Extension.

Title: Certificate of Registration.

Purpose: The executed form certifies that the returned articles meeting Customs requirements are the same as those previously exported for the purpose of alterating, repair, use abroad, replacement, processing or other, and are therefore entitled to duty free entry.

OMB Reviewer: Suzanne Evinger, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0232.

Form Number: 6497.

Type of Submission: Extension.

Title: Information Return of Energy Grants or Subsidized Energy Financing.

Purpose: The form is to be filed by any governmental agency (Federal, State, or local) or its agent that makes grants or subsidized financing for energy conservation projects. The information is required to be reported under IRC section 6050D. The information is used to be sure that energy credits are not taken for government-financed projects.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 21, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0387.

Form Number: 4419.

Type of Submission: Revision.

Title: Application for Magnetic Media Reporting of Information Returns.

Purpose: 26 U.S.C. 6041 and 6042 require that all persons engaged in a trade or business and making payments of taxable income are required to file reports of this income with IRS. Payers who wish to file these returns on magnetic media instead of paper documents must complete Form 4419 to receive authorization for filing on tape.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Date Submitted: June 24, 1982.

Submitting Bureau: Internal Revenue Service.

OMB Number: 1545-0212.

Form Number: 5558.

Type of Submission: Revision.

Title: Application for Extension of Time to File Certain Employee Plan Returns.

Purpose: Used by employers to request extensions of time to file employee plan annual information returns and the employee plan excise tax return (Form 5330). The data supplied in this form is used to determine if such extension of time is warranted.

OMB Reviewer: Michael Abrahams, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Joy Tucker,

Departmental Reports Management Officer.

June 28, 1982.

[FR Doc. 82-18054 Filed 7-1-82; 8:45 am]

BILLING CODE 4810-25-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 128
Friday, July 2, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

	Items
Federal Deposit Insurance Corporation	1-5
Federal Reserve System	6, 7
Federal Trade Commission	8
Securities and Exchange Commission	9
Tennessee Valley Authority	10

1

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Tuesday, July 6, 1982, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,284-L—Franklin National Bank, New York, New York
Case No. 45,286-L—American City Bank & Trust Company, National Association, Milwaukee, Wisconsin
Case No. 45,287-SR—Farmers Bank of Petersburg, Petersburg, Kentucky
Case No. 45,290-SR—The Peoples Bank of the Virgin Islands, Charlotte Amalie, Virgin Islands
Case No. 45,292—The Greenwich Savings Bank, New York, New York

Recommendation with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Gibbs, Roper, Loots & Williams, Milwaukee, Wisconsin, in connection with the liquidation of American City Bank & Trust Company, National Association, Milwaukee, Wisconsin.

Memorandum and resolution re: Delegation of authority to administer petty cash funds.

Report of committees and officers:

Minutes of the actions approved by the standing committees of the Corporation pursuant to authority delegated by the Board of Directors.
Reports of the Division of Bank Supervision with respect to applications or requests approved by the Director or Associate Director of the Division and the various Regional Directors pursuant to authority delegated by the Board of Directors.
Report of the Director, Division of Liquidation:
Memorandum re: Morrice State Bank, Morrice, Michigan, Termination of Field Liquidation Office
Report of the General Counsel:
Memorandum re: Report of Actions Approved Under Delegated Authority: Settlements of Claims and Attorneys' Fees Approved for Payment
Reports of the Director, Office of Corporate Audits:
Memorandum re: Office of Corporate Audits' Quarterly Certification of Division of Liquidation Approvals Under Delegated Authority
Audit Report re: Project Review of the Accounts Receivable Subsystem—Interim Audit Report #2, dated June 1, 1982.

Discussion Agenda:

No matters scheduled.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 500 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389-4425.

Dated: June 29, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-971-82 Filed 6-30-82; 11:11 am]

BILLING CODE 6714-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:30 p.m. on Tuesday, July 6, 1982, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors pursuant to sections 552b (c)(2), (c)(6), (c)(8), and (c)(9)(A)(ii), of Title 5, United States Code, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured banks or officers, directors, employees, agents, or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Recommendations regarding the liqudiation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 45,272-NR—United States National Bank, San Diego, California
Memorandum and Resolution re: The Hamilton National Bank of Chattanooga, Chattanooga, Tennessee.

Memorandum re: Corporation policy regarding leave-without-pay for the purpose of obtaining an advanced degree or taking a sabbatical to teach or study in a job-related area.

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street, N.W., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 389–4025.

Dated: June 29, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-972-82 Filed 6-30-82; 11:11 am]

BILLING CODE 6714-01-M

3

FEDERAL DEPOSIT INSURANCE CORPORATION

Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 2:00 p.m. on Monday, June 28, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Memorandum and Resolution re: Proposed amendments to Parts 303, 304, and 347 of the Corporations's rules and regulations, entitled "Applications, Requests, Submittals, and Notices of Acquisition of Control," "Forms, Instructions, and Reports," and "Foreign Activities of Insured State Nonmember Banks," respectively, which would expedite the processing of applications for consent to establish foreign and domestic branches (including remote service facilities) and to relocate offices.

By the same majority vote, the Board further determined that no earlier notice of these changes in the subject matter of the meeting was practicable.

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-75-82 Filed 6-30-82; 3:40 pm]

BILLING CODE 6714-01-M

4

FEDERAL DEPOSIT INSURANCE CORPORATION

Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 2:30 p.m. on Monday, June 28, 1982, the Corporation's Board of Directors determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matters:

Discussion of an FDIC assistance agreement with an insured bank.

Discussion of a proposal regarding a branch of an insured bank.

The Board further determined, by the same majority vote, that no earlier notice of the changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), (c)(9)(A)(ii) and (c)(9)(B)).

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-976-82 Filed 6-30-82; 3:07 pm]

BILLING CODE 6714-01-M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Cancellation of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the special open meeting of the Corporation's Board of Directors scheduled for 2:00 p.m. on Wednesday, June 30, 1982, at which the Board was to take up the following matter, has been cancelled:

Petition of the Investment Company Institute seeking a public hearing and certain other relief in connection with the creation and operation by The Boston Five Cents Savings Bank, Boston, Massachusetts, of two wholly-owned subsidiaries to advise and distribute shares in a mutual fund.

No earlier notice of the cancellation of the meeting was practicable.

Dated: June 30, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-977-82 Filed 6-30-82; 3:08 pm]

BILLING CODE 6714-01-M

6

FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 11 a.m., Wednesday, July 7, 1982, following a recess at the conclusion of the open meeting.

PLACE: 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Federal Reserve Bank and Branch director appointments.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 29, 1982.

James McAfee,

Associate Secretary of the Board.

[S-969-82 Filed 6-30-82; 8:50 am]

BILLING CODE 6210-01-M

7

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Wednesday, July 7, 1982.

PLACE: Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Proposals with respect to contemporaneous reserve requirements. (Proposed earlier for public comment: Docket No. R–0371)
2. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: June 29, 1982.

James McAfee,

Associate Secretary of the Board.

[S-968-82 Filed 6-30-82; 8:49 am]

BILLING CODE 6210-01-M

8

FEDERAL TRADE COMMISSION

TIME AND DATE: 2 p.m., Tuesday, July 6, 1982.

PLACE: Room 432, Federal Trade Commission Building, 6th Street and Pennsylvania Avenue, NW., Washington, D.C. 20580.

STATUS: Open.

MATTER TO BE CONSIDERED: Policy Review Session on Civil Penalties.

CONTACT PERSON FOR MORE INFORMATION:

Susan B. Ticknor, Office of Public Information: (202) 523-1892; Recorded Message: (202) 523-3806.

[S-970-82 Filed 6-30-82; 10:34 am]

BILLING CODE 6750-01-M

9

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: To be published.

STATUS: Closed meeting.

PLACE: Room 825, 500 North Capitol Street, Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: Tuesday, June 22, 1982.

CHANGES IN THE MEETING: Additional meeting. The following item will be considered at a closed meeting scheduled for Tuesday, June 29, 1982, at 5:30 p.m.:

Settlement of injunctive actions.

Chairman Shad and Commissioners Evans, Thomas and Longstreth determined by vote that Commission business required consideration of this matter and that no earlier notice thereof was possible.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Bob Zutz at (202) 272-2091.

June 29, 1982.

[S-973-82 Filed 6-30-82; 11:41 am]

BILLING CODE 8010-01-M

10

TENNESSEE VALLEY AUTHORITY

TIME AND DATE: 10:15 a.m. (e.d.t.), Wednesday, July 7, 1982.

PLACE: TVA, West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Action Items

A—Project Authorizations

1. Project Authorization No. 3241.4—Amendment to project authorization for wet-process phosphoric acid pilot-plant processes.

B—Purchase Awards

1. Request for delegation of procurement authority for negotiation of discounted enrichment services.
2. Amendment to contract 80K34-827436 with The Babcock & Wilcox Company, Barberton, Ohio, for boiler balanced-draft conversion at Paradise Steam Plant units 1 and 2.
3. Proposed contracts with the Louisville & Nashville Railroad for unit-train transportation of coal.

C—Power Items

*1. Proposed uranium loan to Urangesellschaft U.S.A., Inc.
*2. Cogeneration agreement with Weyerhaeuser Company, Columbus, Mississippi.
3. Lease and amendatory agreement with Cumberland Electric Membership Corporation covering arrangements for lease of TVA's Ashland City, Green Brier, Lone Oak, Orlinda, and Shady Grove 69-kV substations to permit higher voltage service.
4. Deed covering conveyance of TVA's Hamilton 46-kV Substation property to Kerr-McGee Chemical Corporation at Hamilton, Mississippi.
5. Adoption of supplemental resolution authorizing 1982 Series C power bonds.
6. Resolution authorizing the Chairman and other executive officers to take further action relating to issuance and sale of 1982 Series C power bonds.

D—Personnel Items

1. Renewal of consulting contract with John M. Kellberg, Knoxville, Tennessee, for advice and assistance in connection with design and construction of hydro and thermal power plants, requested by the Office of Engineering Design and Construction.
2. Renewal of consulting contract with Roland A. Kampmeier, Chattanooga, Tennessee, for advice and assistance in connection with TVA's power programs and energy-related programs, requested by the Office of Power.
3. Amendment to personal services contract with Wyle Laboratories, Huntsville, Alabama, for engineering and related services, requested by the Office of Engineering Design and Construction.
4. Personal services contract with Allied Nuclear, Inc., Freemont, California, for services of health physics technicians, requested by the Office of Power.
5. Personal services contract with Sasser's Consulting Services, Inc., Tavares, Florida, for services of health physics technicians, requested by the Office of Power.

F—Unclassified

1. Revised budget plan for fiscal year 1982—midyear review.

CONTACT PERSON FOR MORE INFORMATION: Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632-3257, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245-0101.

Dated: June 30, 1982.

[S-974-82 Filed 6-30-82; 2:09 pm]

BILLING CODE 8120-01-M

---

*Items approved by individual Board members. This would give formal ratification of the Board's action.

federal register

Friday
July 2, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Orthopedic Devices; General Provisions and Classification of 77 Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 78N-2830]

Orthopedic Devices; General Provisions and Classification of 77 Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of orthopedic devices in commercial distribution. The Medical Device Amendments of 1976 require the agency to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble, FDA describes the development of the proposed regulation classifying 77 orthopedic devices. The preamble also describes the activities of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Orthopedic Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of orthopedic devices.

DATES: Comments by October 1, 1982. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James G. Dillon, Bureau of Medical Devices (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Orthopedic Device Classification Panel (the Panel) was originally chartered on April 25, 1972, as the Panel on Review of Orthopedic Devices. FDA placed a report of the Panel's tentative classification recommendations on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of June 25, 1976 (41 FR 26245). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments. Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of orthopedic devices. The Panel also invited experts to testify and sought information from the published literature on many devices.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the Dockets Management Branch are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in this proposal.

On April 28, 1978, the agency terminated all of the device classification panels and then reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Orthopedic Device Classification Panel was terminated, and its functions are now conducted by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel.

Most of the Panel classification recommendations published in this preamble are those made in 1977 by the earlier Orthopedic Device Classification Panel. But recommendations on the following nine orthopedic devices are

those made on November 19, 1980, by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel (Ref. 1):

Section	Device	Docket No.	Class
888.3300	Hip joint metal constrained prosthesis.	78N-3070...	III.
888.3310	Hip joint metal/polymer constrained prosthesis.	78N-3071...	III.
888.3370	Hip joint (hemi-hip) acetabular metal prosthesis.	78N-3076...	III.
888.3400	Hip joint femoral (hemi-hip) resurfacing prosthesis.	78N-3080...	II.
888.3510	Knee joint femorotibial metal/polymer constrained prosthesis.	78N-3084...	II.
888.3680	Shoulder joint glenoid (hemi-shoulder) prosthesis.	78N-3058...	III.
888.5940	Cast components	78N-3123...	I.
888.5960	AC-powered cast removal instruments.	78N-3124...	II.
888.5980	Manual cast application/removal instruments.	78N-3125...	I.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which device classification will be published in the **Federal Register.** The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register.** FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of Orthopedic Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of orthopedic devices. The Panel supplemented the list using its members' knowledge of orthopedic devices in use. Devices that were solely for experimental or investigational use, that were not generally available, or that had been regarded as new drugs were not included. Additional orthopedic devices, which were not included in this list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 888 in Title 21 of the Code of Federal Regulations. Part 888 will consist of sections identifying each orthopedic device with a brief narrative description and stating the classification of that device. The list of orthopedic devices appears elsewhere in this preamble.

Orthopedic Device Classifications

FDA is proposing to classify 77 orthopedic devices. The agency is proposing to classify 15 orthopedic devices into class I (general controls), 38 orthopedic into class II (performance standards), and 24 orthopedic devices into class III (premarket approval). The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513 (c)(2) and (d)(1) of the act (21 U.S.C. 360c (c)(2) and (d)(1)).

Panel Recommendations

The Panel recommendation concerning an orthopedic device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification include a brief narrative identification of the generic type of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 888.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 (21 CFR Part 807) of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a newly offered device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

Some products have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Composition of materials used in orthopedic prosthetic devices: The Panel believed that the generic chemical formula of materials should be omitted from the proposed name of the device, although material specifications may be placed in the device's identification. Use of the general term "metal" in the proposed name of the device means that a component of the device is made of one or more kinds of metal or metal alloys. Use of the general term "polymer" in the proposed name of the

device means that a component is made of one or more kinds of synthetic compounds, usually of high molecular weight, consisting of up to millions of repeated, linked units, each a relatively low molecular weight molecule.

Resurfacing technique: Because of resurfacing techniques, certain joint prostheses require far less bone resection than other devices intended to repair or replace the same joint. The amount of bone resection may or may not affect the safety and effectiveness of the implantation of the prosthesis. When a resurfacing technique is used, the proposed name of the prosthesis includes this information.

Degree of constraint: Certain joint prostheses provide more constraint of joint movement than others. FDA believes that the degree of constraint is an important factor affecting the safety and effectiveness of orthopedic prostheses. Consequently, FDA considered the degree of constraint imposed by the prosthesis when determining whether to propose classification of the device into class II or class III. Because of the lack of consistent descriptive terminology in the literature, FDA is proposing the following standard terms for categorizing the degree of constraint, based on concepts developed by Chao and Mullen (Ref. 2).

(a) A *constrained* joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

(b) a *semi-constrained* joint prosthesis is used for partial or total replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

(c) A *non-constrained* joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

Standardized names of orthopedic prosthetic devices intended for joint replacement. Based on recommendations made by Panel members and on current terminology used in the medical literature, FDA is proposing that certain information be included in the names of the generic types of orthopedic prosthetic devices intended for joint replacement. FDA proposes that the generic names of devices intended for joint replacement identify:

(1) The joint or tissue being replaced and, if appropriate, the articulating bone surfaces;

(2) The general type of materials used in the device, if appropriate;

(3) The degree of constraint being imposed by the device, if appropriate;

(4) When a resurfacing technique is used;

(5) When the device is not implanted into the bone with a polymethylmethacrylate-type luting agent (bone cement), if appropriate; and

(6) That the device is a prosthesis.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I, class II, or class III.

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act; section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), the good manufacturing practice (GMP) requirements). The Panel recommended that the manufacturers of several devices be exempted from section 510, section 519, and section 520(f) of the act. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and Class III Devices," however, the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f).

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgement when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refer not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgements of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94-853, 94th Congress, 2d Session 40 (1976)). FDA has determined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the section for each orthopedic device under the heading "Panel Recommendations and FDA's Proposed Classifications."

The agency is adopting as its statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in FDA's proposed classifications.

5. *Risks to health.* In identifying the risks to health presented by orthopedic devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified risks to health presented by a device in addition to those listed by the Panel. These additional risks are set out for each device in the preamble under the heading "Panel Recommendations and FDA's Classifications."

In addition to those hazards explicitly mentioned, the Panel and FDA recognize that there are general hazards associated with orthepedic prosthetic devices, such as risk of infection, risk of thromboemboli generation, risk of corrosion of metal implants, risk of

reoperation, and other possible complications due to use of bone cement and metal alloys. Specifically, Rae (Ref. 3) has shown that ingested particles of orthopedic alloys induce cellular damage. His work demonstrates that the alternations in phagocytic activity could be a factor in the development of late infections complicating joint replacement. This inhibition is one of several virulence enhancement mechanisms postulated by Elek and Conen (Ref. 4) to explain the 10,000-fold enhancement of infection in humans by the presence of a foreign body. A recent study by Johnson and Fromm (Ref. 5) corroborates the importance of a foreign body in decreasing a host's resistance to infection. Merritt and coworkers (Ref. 6) believe that the frequently occurring fibrous encapsulation of a prosthesis results in an avascular zone in which pathogens (disease-producing organisms) can grow; and both groups confirm experimentally that the presence of an implant inhibits the host's ability to combat infection.

Swanson, et al. (Ref. 7) performed laboratory testing of an orthopedic implant that is composed of cobalt-chromium-molybdenum, a widely used alloy. Swanson showed that wear debris was evident for the device examined. When the wear debris produced was injected into rats, tumorogenesis was observed among a significant proportion of the rats. The tests by Swanson showed that the wear debris from this device had a cancer-causing effect in rats. The clinical significance of this finding is unknown. Recent preliminary investigations by Memoli, et al. (Ref. 8) indicate a trend suggesting that animals with metal implants, especially those containing nickle, may be at a greater risk for the increased development of malignancy, especially sarcomas and lymphoreticular neoplasms.

Berger and Salzman (Ref. 9) provide a review of the nature and mechanisms of the complications subsequent to thromboemboli generation. They note that the surface of an implanted prosthesis can initiate or enhance the formation of thromboemboli. Walldius (Ref. 10) summarizes a portion of the literature enumerating deaths attributable to lipoemboli released from medullary cavities during prosthesis implantation. Walldius also notes hypotension, cardiac arrest, and other cardiovascular disturbances that result from the local and systemic toxicity of the polymethylmethacrylate (bone cement) monomer.

Also, polymethylmethacrylate bone cement, which generates heat during polymerization, is considered by some authors (Refs. 10, 11, and 12) to cause thermal damage, bone death, and subsequent bone resorption, which could be important factors in device loosening (Refs. 12 and 13). However, others (Refs. 14 and 15) believe that the heat of cement polymerization during implantation procedures is not great enough to cause permanent damage. These researchers believe that use of the cement and the revascularization of bone leads to the formation of a fibrous membrane which is a factor in loosening. When a joint is replaced with a prosthesis, the patient may have, over time, an increased risk of mutagenesis (Ref. 16), carcinogenesis (Refs. 17 through 26), and teratogenesis (Refs. 27, 28, and 29). The clinical significance of these increased risks is unknown.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by orthopedic devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each section for an orthopedic device under the heading "Panel Recommendations and FDA's Proposed Classifications," states whether or not FDA agrees with the Panel's recommendation and describes the agency's proposed classification of the device.

FDA is proposing to classify into class III 11 orthopedic prosthetic devices that the earlier Orthopedic Device Classification Panel had, in 1976 and 1977, recommended be classified into class II. As explained in greater detail below in the preambles to these proposals, the agency has determined that performance standards will not adequately assure the safe use of these devices, because their designs, or the materials used in the devices, have not had sufficient clinical use to establish fully the persons for whom the devices are intended and the proper conditions of use.

After receiving the Panel recommendations, FDA in 1980 reviewed all data on orthopedic devices and prepared summaries based on this review. At FDA's request (Ref. 30), these summaries were reviewed for scientific completeness and accuracy, but not for regulatory recommendations, by individual orthopedic surgeons specializing in the use of the devices being classified, through the assistance of the American Academy of Orthopedic Surgeons.

Based on this review and reassessment of the device classifications recommended by the earlier Panel, FDA has made the present proposed classifications. On November 19, 1980, these proposed classifications as well as the reasons for the changes, were presented to the Orthopedic Device Section. At that time the current panel made general recommendations regarding certain generic types of devices (Ref. 30). FDA is proposing to classify into class II several orthopedic devices for which various complications have been reported. The majority of the complications involved were determined not to be device-related, such as failures due to the design of or materials used in the devices. Instead, these complications were determined to be primarily attributable to various nondevice related factors for which premarket approval would not necessarily provide additional assurance of safety and effectiveness. For example, orthopedic devices usually are implanted in aged patients with progressive diseases, particularly osteoarthritis and rheumatoid arthritis. Also, the skill of the orthopedic surgeon performing the implant procedure is an important variable in clinical outcomes. FDA believes that requiring additinal studies on these devices to be undertaken in support of a PMA would not result in new information that would help reduce the risks to health presented by use of these devices. Moreover, FDA believes that sufficient data already exist to establish the persons for whom these devices are intended and the proper conditions of their use. In proposing that these devices be classified into class II, FDA relied heavily on the scientific and clinical judgment of the members of the advisory panel, who are knowledgeable about the history and development of these devices.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, FDA's reconsideration of existing data and information, and FDA's consideration of new data and information.

Priorities for Class II and Class III Devices

When the Panel recommends classification of a device into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a

priority for establishment of performance standards for the device or premarket approval requirements. In developing its advice concerning the priorities ("high," "medium," or "low") to be accorded devices recommended for classification into class II or class III, the Panel compared each device with other orthopedic devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device.

The Panel recommended assignment of a "high priority" only to those class II or class III devices which the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489 and 45 FR 7493), FDA published notices identifying the class II devices the agency determined to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the panel's recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

FDA intends to proceed as quickly as the agency's and the Panel's resources permit to require premarket approval of devices classified into class III. Two factors affect the length of time before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may, at the same time, publish regulations under section 515(b) of the act requiring premarket approval for any of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification. During this 30-month period a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is authorized by section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports, and section 520(f) (21 U.S.C. 360j(f)), good manufacturing practice.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519 of the act, including final regulations requiring reports to FDA of experiences with medical devices. (A proposed regulation to require such reports was published in the **Federal Register** of November 18, 1980 (45 FR 76183).) Until final records and reports regulations are issued, FDA believes that it cannot properly issue exemptions from them. Whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the earlier Orthopedic Device Classification Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufacturers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or by routine testing, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce during the manufacturing process the bioburden (number of microorganisms) on the device and in its components. This reduction is accomplished through adherence to a comprehensive quality assurance program, such as that required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to maintenance of complaint files. The agency believes that granting exemptions from these sections would not be in the public interest and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, is able to investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and can determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under section 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, occasionally FDA has proposed to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the prescribed exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation is consistent with the criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance from the Device GMP Regulation for Devices Classified into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

List of Orthopedic Devices

The following is a list of orthopedic devices that FDA is proposing to classify, the section and subpart of Part 888 in Title 21 of the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Orthopedic Diagnostic Devices		
888.1100	Arthroscope	78N-3041	II.
888.1240	AC-powered dynamometer	78N-3300	II.
888.1250	Nonpowered dynamometer	78N-3042	I.
888.1500	AC-powered goniometer	78N-3043	II.
888.1520	Nonpowered goniometer	78N-3044	I.
	Subpart D—Orthopedic Prosthetic Devices		
888.3000	Bone cap	78N-3046	II.
888.3010	Bone fixation cerclage	78N-3051	II.
888.3020	Intramedullary fixation rod	78N-3056	II.
888.3025	Passive tendon prosthesis	78N-3098	II.
888.3030	Single/multiple component metallic bone fixation appliances and accessories.	78N-3049	II.
888.3040	Smooth or threaded metallic bone fixation fastener.	78N-3053	II.
888.3050	Spinal interlaminal fixation orthosis.	78N-3047	II.
888.3060	Spinal intervertebral body fixation orthosis.	78N-3048	II.
888.3100	Ankle joint metal/composite semi-constrained prosthesis.	78N-3059	III.
888.3110	Ankle joint metal/polymer semi-constrained prosthesis.	78N-3060	II.
888.3120	Ankle joint metal/polymer non-constrained prosthesis.	78N-3061	III.
888.3150	Elbow joint constrained prosthesis.	78N-3062	III.
888.3160	Elbow joint semi-constrained prosthesis.	78N-3063	II.
888.3170	Elbow joint radial (hemi-elbow) prosthesis.	78N-3064	II.
888.3180	Elbow joint humeral (hemi-elbow) uncemented prosthesis.	78N-3065	III.
888.3200	Finger joint metal/metal constrained uncemented prosthesis.	78N-3066	III.
888.3210	Finger joint metal/metal constrained prosthesis.	78N-3301	III.
888.3220	Finger joint metal/polymer constrained prosthesis.	78N-3067	III.
888.3230	Finger joint polymer constrained prosthesis.	78N-3068	II.
888.3300	Hip joint metal constrained prosthesis.	78N-3070	III.
888.3310	Hip joint metal/polymer constrained prosthesis.	78N-3071	III.
888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	78N-3072	III.
888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.	78N-3073	III.
888.3340	Hip joint metal/composite semi-constrained prosthesis.	78N-3074	III.
888.3350	Hip joint metal/polymer semi-constrained prosthesis.	78N-3075	II.
888.3360	Hip joint femoral (hemi-hip) metallic prosthesis.	78N-3077	II.
888.3370	Hip joint (hemi-hip) acetabular metal prosthesis.	78N-3076	III.
888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.	78N-3078	III.
888.3390	Hip joint femoral (hemi-hip) metal/polymer prosthesis.	78N-3079	II.
888.3400	Hip joint femoral (hemi-hip) resurfacing prosthesis.	78N-3080	II.
888.3410	Hip joint metal/polymer semi-constrained resurfacing prosthesis.	78N-3081	III.
888.3480	Knee joint femorotibial metallic constrained prosthesis.	78N-3082	II.
888.3490	Knee joint femorotibial metal/composite non-constrained prosthesis.	78N-3083	III.
888.3500	Knee joint femorotibial metal/composite semi-constrained prosthesis.	78N-3302	III.
888.3510	Knee joint femorotibial metal/polymer constrained prosthesis.	78N-3084	II.
888.3520	Knee joint femorotibial metal/polymer non-constrained prosthesis.	78N-3085	II.
888.3530	Knee joint femorotibial metal/polymer semi-constrained prosthesis.	78N-3086	II.
888.3540	Knee joint patellofemoral polymer/metal semi-constrained prosthesis.	78N-3087	III.
888.3550	Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.	78N-3088	II.

Section	Device	Docket No.	Class
888.3560	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.	78N-3090	II.
888.3570	Knee joint femoral (hemiknee) metallic uncemented prosthesis.	78N-3091	III.
888.3580	Knee joint patellar (hemiknee) metallic resurfacing uncemented prosthesis.	78N-3092	II.
888.3590	Knee joint tibial (hemiknee) metallic resurfacing uncemented prosthesis.	78N-3093	II.
888.3640	Shoulder joint constrained prosthesis.	78N-3094	III.
888.3650	Shoulder joint non-constrained prosthesis.	78N-3095	III.
888.3660	Shoulder joint semi-constrained prosthesis.	78N-3096	III.
888.3680	Shoulder joint glenoid (hemi-shoulder) prosthesis.	78N-3058	III.
888.3690	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.	78N-3097	II.
888.3720	Toe joint constrained uncemented prosthesis.	78N-3099	II.
888.3730	Toe joint phalangeal (hemi-toe) prosthesis.	78N-3100	II.
888.3750	Wrist joint carpal lunate prosthesis.	78N-3101	II.
888.3760	Wrist joint carpal scaphoid prosthesis.	78N-3102	II.
888.3770	Wrist joint carpal trapezium prosthesis.	78N-3304	II.
888.3780	Wrist joint polymer constrained uncemented prosthesis.	78N-3103	II.
888.3790	Wrist joint metal constrained prosthesis.	78N-3305	III.
888.3800	Wrist joint semi-constrained prosthesis.	78N-3104	II.
888.3810	Wrist joint ulnar (hemiwrist) prosthesis.	78N-3105	II.
	Subpart E—Orthopedic Surgery Devices		
888.4150	Calipers for clinical use	78N-3106	I.
888.4200	Cement dispenser	78N-3107	I.
888.4210	Cement mixer for clinical use.	78N-3108	I.
888.4220	Cement monomer vapor evacuator.	78N-3109	I.
888.4230	Cement ventilation tube	78N-3110	I.
888.4300	Depth gauge for clinical use.	78N-3111	I.
888.4540	Orthopedic manual surgical instrument.	78N-3114	I.
888.4580	Sonic surgical instrument and accessories/attachments.	78N-3116	II.
888.4600	Protractor for clinical use	78N-3117	I.
888.4800	Template for clinical use	78N-3118	I.
888.5850	Nonpowered orthopedic traction apparatus and accessories.	76N-3120	I.
888.5890	Noninvasive traction components.	78N-3122	I.
888.5940	Cast components	78N-3123	I.
888.5960	AC-powered cast removal instruments.	78N-3124	II.
888.5980	Manual cast application/removal instruments.	78N-3125	I.

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device panels. The Orthopedic Device Section of the Surgical and Rehabilitation Devices panel and the other sections or panels listed below made classification recommendations concerning the following devices:

Device	Other sections or panel(s)
Clamp	General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel.
Hemostat	Do.
Elevator	Do.
Forceps	Do.
Guide	Do.
Knife	Do.
Mallet	Do.
Rasp	Do.
Retractor	Do.
Spatula	Do.
Staple	Do.
Surgical table with orthopedic accessories.	Do.
AC-powered surgical table with orthopedic accessories.	Do.
Air pressure tourniquet	Do.
Hip prosthesis acetabular mesh	Do.
Hip prosthesis cement restrictor	Do.
Curette	Do.
Bone hook	Do.
Cutting instrument	Do.
Osteotome	Do.
Surgical pliers	Do.
Powered orthopedic surgical instrument motors and accessories/attachments.	Do.
Pneumatically powered orthopedic surgical instrument motors and accessories/attachments.	Do.
Diaphram stimulator	Neurological Device Section of the Respiratory and Nervous System Devices Panel.
Internal peroneal extremity stimulator.	Do.

The agency is not at this time publishing the recommendations of the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel to classify the devices listed above. The agency has published these recommendations and proposed classification regulations along with the recommendations of other Panels that reviewed the devices. These other Panel's recommendations have already been published in the **Federal Register.** The following table shows the current structure of the advisory committees involved with classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/Section Name and Publication Date in **Federal Register**

Circulatory Systems Devices Panel—March 9, 1979 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).

Clinical Chemistry and Hematology Devices Panel:
- Clinical Chemistry Device Section—February 2, 1982, 47 FR 4802–4929 (proposals).
- Clinical Toxicology Device Section—February 2, 1982, 47 FR 4802–4929 (proposals).
- Hematology and Pathology Device Section—September 11, 1979, 44 FR 52950–53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations).

General Medical Devices Panel:
- General Hospital and Personal Use Device Section—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations).
- Gastroenterology-Urology Device Section—January 23, 1981, 46 FR 7562–7641 (proposals).

Immunology and Microbiology Devices Panel:
- Obstetrics-Gynecology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulation).
- Microbiology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals).

Obstetrics-Gynecology and Radiologic Devices Panel:
- Obstetrics-Gynecology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals): February 26, 1980, 45 FR 12682–12720 (final regulations).
- Radiology Device Section—January 29, 1982, 47 FR 4406–4451 (proposals).

Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel:
- Ophthalmic Device Section—January 26, 1982, 47 FR 3694–3749 (proposals).
- Ear, Nose, and Throat Device Section—January 22, 1982, 47 FR 3280–3325 (proposals).
- Dental Device Section—December 30, 1980, 45 FR 85962–86168 (proposals).

Respiratory and Nervous System Devices Panel:
- Anesthesiology Device Section—November 2, 1979, 44 FR 63292–63426 (proposals).
- Neurological Device Section—November 28, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations).

Surgical and Rehabilitation Devices Panel:
- Physical Medicine Device Section—August 28, 1979, 44 FR 50458–50537 (proposals).
- Orthopedic Device Section—(*Insert date of publication in the* **Federal Register**) (proposals).
- General and Plastic Surgery Device Section—January 19, 1982, 47 FR 2810–2853 (proposals).

Panel Recommendations and FDA's Proposed Classifications

§ 888.1100; Docket No. 78N–3041; Arthroscope.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arthroscopes:

1. Identification: An arthroscope is a type of electrically powered endoscope that is intended to make visible the interior of a joint. The arthroscope may be combined with accessories to permit surgency in selected anatomic locations.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel

recommends that arthroscopes be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard. The Panel also recommends that the device's labeling include instructions for the proper care of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator. (b) Infection: The introduction of microbes associated with a nonsterile device may cause infection. (c) Tissue Trauma: Defective components or faulty construction of the device could result in breakage of the arthroscope while inside the joint, resulting in tissue trauma.

EDA agrees with the Panel recommendation and is proposing that arthroscopes be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by use of the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

§ 888.1240; Docket No. 78N–3300; AC-powered dynamometer.

The Orthopedic Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of AC-powered dynamometers:

1. Identification: An AC-powered dynamometer is an electrically powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

2. Recommended classification: Class II. The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that AC-powered dynamometers be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Anesthesiology Device Classification Panel also believes that the accuracy and reproducibility of the device must be controlled by a performance standard to prevent the generation of erroneous grip-strength data that may lead to inaccurate estimates of neuromuscular blockage. The Panels believe that general controls alone will not provide sufficient control over these characteristics. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator. (b) Misdiagnosis and inappropriate therapy: Failure of the device to provide accurate data may lead to error in the estimates of neuromuscular function or blockage in the patient. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

FDA agrees with the recommendations of the Orthopedic Device Classification Panel and the Anesthesiology Device Classification Panel and is proposing that AC-powered dynamometers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device, and sufficient information exists to establish a performance standard. The agency has reviewed both Panels' recommendations for AC-powered dynamometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1250; Docket No. 78N–3042; Nonpowered dynamometer.

The Orthopedic Device Classification Panel, the Neurology Device Classification Panel, and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonpowered dynamometers:

1. Identification: A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

2. Recommended classification: All three Panels recommend that nonpowered dynamometers be classified into Class I. The Orthopedic Device Classification Panel recommends that this device be exempt from the premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The Neurology Device Classification Panel and the Physical Medicine Device Classification Panel recommend that there be no exemptions.

3. Summary of reasons for recommendation: The three Panels recommend that nonpowered dynamometers be classified into class I because general controls are sufficient to provide reasonable assurance of the saftey and effectiveness of the device. The Orthopedic Panel recommends that the manufacturer be exempt from premarket notification procedures and the GMP regulation because it believes that adherence to the regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' knowledge of, and clinical experience with, nonpowered dynamometers.

5. Risks to health: None identified.

FDA agrees with the recommendations of the three Panels and is proposing that nonpowered dynamometers be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Orthopedic Device Classification Panel's recommendation that manufacturers of nonpowered dynamometers be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a

manufacturer from section 510 only if it finds that compliance with the section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of nonpowered dynamometers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning nonpowered dynamometers. The agency does not anticipate at this time that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Orthopedic Device Classification Panel's recommendation that manufacturers of nonpowered dynamometers be exempt from the device GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that these manufacturers be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of nonpowered dynamometers should be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of nonpowered dynamometers should be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. See the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

The agency has reviewed the three Panel's recommendations for nonpowered dynamometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1500; Docket No. 78N–3043; AC-powered goniometer.

The Physical Medicine Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered goniometers:

1. Identification: An AC-powered goniometer is an AC-powered measuring and recording device intended to evaluate joint function by measuring ranges of motion, acceleration, or forces exerted by a joint.

2. Recommended classificatioin: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered goniometers be classified into class II because the electrical properties of the device must be controlled by a performance standard to prevent electrical shock to the patient or operator. The Panel believes that general conrols alone will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Electrical shock: Excessive current leakage from this device may cause electrical shock to the patient or operator.

FDA agrees with the Panel recommendation and is proposing that AC-powered goniometers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to minimize the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. FDA has reviewed the recommendation of the Physical Medicine Device Classification Panel for AC-powered goniometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.1520; Docket No. 78N–3044; Nonpowered goniometer.

The Orthopedic Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonpowered goniometers:

1. Identification: A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

2. Recommended classification: Both Panels recommend that nonpowered goniometers be classified into class I. The Orthopedic Device Classification Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act. The Physical Medicine Device Classification Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that nonpowered goniometers be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Orthopedic Device Classification Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the GMP regulation in manufacturing the device because it believes that adherence to these regulations would not improve the safety and effectiveness of the device. The Orthopedic Device Classification Panel believes that this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the recommendations of the Orthopedic Device Classification Panel and the Physical Medicine Device Classification Panel and is proposing that nonpowered goniometers be classified into class I. The agency believes that general controls are sufficient to provide

reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of nonpowered goniometers be exempt from section 510(k) and 520(f) of the act, FDA is proposing that manufacturers of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA is proposing that a manufacturer of these devices be exempt from all requirements in the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 886.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

The agency has reviewed the Panels' recommendations for nonpowered goniometers and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.3000; Docket No. 78N–3046; Bone cap.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bone caps:

1. Identification: A bone cap is a mushroom-shaped implanted device made of either silicone elastomer or ultra-high molecular weight polyethylene. It is intended to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bone caps be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although bone caps are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that bone caps be classified into class II. FDA has reviewed the data on which the Panel recommendation is based and has sought additional information on the safety and effectiveness of these devices. Silicone bone caps have been used since 1963 to control the bone overgrowth phenomenon in juvenile amputees. They have been found to successfully control bone overgrowth and provide a pain-free amputation stump (Ref. 31). Implantation of the device in animals has shown that the bone end heals and contours to the inside surface of the device (Ref. 32).

Although bone caps are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3010; Docket No. 78N–3051; Bone fixation cerclage.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bone fixation cerclages:

1. Identification: A bone fixation cerclage is an implanted device that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon of flat sheet or a wire. When implanted, the device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bone fixation cerclages be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, nonunion or malunion of bone, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although bone fixation cerclages are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, bone fixation cerclages and on a review of the recent

medical literature, which indicates that there are few device-related complications. Buhler (Ref. 33) reported one case of infection and two cases of delayed unions out of a total of 198 cases. There were no reported implant failures.

Fenyo (Ref. 34) reviewed cases of fractures treated with bone fixation cerclages over a 12-year period and reported that there were no reported device failures. Two authors (Refs. 35 through 37) reported that nonunion or malunion, a risk associated with the use of this device, may be due to improper application of the cerclage wire.

5. Risks to health: (a) Adverse tissues reaction: Inadequate biologial or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials from the device to the surrounding tissues and systemic circulation. (b) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (c) Nonunion or malunion: Delayed or malunion of the bone fracture may occur due to inappropriate tension on the device, inadequate mechanical strength, or other mechanical imperfections, leading to device failure and loss of fracture fixation.

FDA agrees with the Panel recommendation and is proposing that bone fixation cerclages be classified into class II. Although bone fixation cerclages are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., infection and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3020; Docket No. 78N–3056; Intremedullary fixation rod.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intramedullary fixation rods;

1. Identification: An intramedullary fixation rod is an implanted device that consists of a rod made of alloys, such as cobalt-chromium-molybedenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

2. Recommended classification: Class II. The Panel recommends that establishment of a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that intramedullary fixation rods be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although intramedullary fixation rods are implanted devices, the Panel believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel also recommends that the labeling of the device provide information on the dimensions and mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on a review of the medical literature. Bohles (Ref. 38) reported that, of 283 patients with closed fractures treated with an intramedullary rod, 8 (2.8 percent) developed infections. In addition, of 25 patients with open fractures (4 percent) treated by implanting the device, 1 developed an infection. Despite these infections, union of the fracture was accomplished in all cases. Schneider (Ref. 39) concluded that, after 18 years of experience with more than 260 cases of open reduction and internal fixation of the femur with four-flanged self cutting intramedullary fixation rods, it is his opinion that the operation is safe and effective. Clawson, et al. (Ref. 40), reported that intramedullary reaming and implantation of an intramedullary fixation rod is a safe method for treating most femoral shaft fractures and for obtaining early functional recovery. He stated that, regardless of the severity of injury, 20 percent of the patients he treated by intramedullary reaming and implantation of an intramedullary fixation rod were fully weight-bearing in 1 week, and 73 percent were fully weight-bearing within 2 months. Cristensen (Ref. 41) concluded that the Kuentscher method provides remarkably rapid consolidation and restoration of function even in difficult cases of nonunion of shaft fracture, particularly of the femur. Allen, et al. (Ref. 42), reported that excellent fixation was achieved and very early weight-bearing was possible in 40 patients with traumatic and pathological fractures and osteotomies of the femur. In all fresh fractures and uninfected nonunions, union occurred promptly, and, in most instances, bone grafting was not required.

5. Risks to health: (a) Loss or reduction of limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or rigidity, may result in nonunion or malunion of the bone due to flexing, fracture, or deformation of the device and subsequent loss of limb function. Migration of the fractured device may cause damage to adjacent hard and soft tissues. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or corrosion of the device and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that intramedullary fixation rods be classified into class II. Although intramedualllary fixation rods are implanted devices, FDA has determined that premarket approval is not necessary because suffcient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and

assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls will greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3025; Docket No. 78N–3098; Passive tendon prosthesis.

The Orthopedic Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of passive tendon prostheses:

1. Identification: A passive tendon prosthesis is an implanted device made of silicone elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

2. Recommended classification: Class II. Both Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both Panels recommend that passive tendon prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of hand function, adverse tissue reaction, or infection. The Panels believe that general controls alone will not provide sufficient control over these characteristics.

Although passive tendon prostheses are implanted devices, the Panels believe that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the pertinent medical literature. The device is used when the tendon injury is so severe that good results would not be expected with conventional tendon grafting (Refs. 43 through 45). Weinstein, et al. (Ref. 45), reported on 28 cases of device implantation and noted that while there were frequent complications after both stages of the two-stage surgical procedure used in tendon reconstructions, the device was valuable in the treatment of severely damaged fingers. Hunter, et al. (Ref. 46), reported on 74 cases of implantation of the device. Hunter noted that the satisfactory results obtained using the device were distinctly better than results previously obtained without the use of the device. Animal studies (Ref. 47) and histological examination of tissue removed from patients receiving the device (Ref. 43) indicated that the device was well tolerated by the body.

5. Risks to health: (a) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (b) Adverse tissue reaction: Inadequate biological properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution and the release of materials from the device to the surrounding tissues and systemic circulation.

FDA agrees with the recommendations of both Panels and is proposing that passive tendon prostheses be classified into class II. Although passive tendon prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., infection and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and the device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

The agency has reviewed the recommendations of both Panels for passive tendon prostheses and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.3030; Docket No. 78N–3049; Single/multiple component metallic bone fixation appliances and accessories.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of single/multiple component metallic bone fixation appliances and accessories:

1. Identification: Single/multiple component metallic bone fixation appliances and accessories are implanted devices, consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that is made of alloys, such as cobalt-chromium-molybdenum, stainless steel, or titanium, that is intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are intended to be used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The device is intended to be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the device be classified into class II because the

design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent nonunion of fractures, bone necrosis, infection, or adverse tissue reaction. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although single/multiple component metallic bone fixation appliances and accessories are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the labeling for the device include information on the device dimensions and mechanical properties and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its review of the medical literature. Elliott (Ref. 48) reported his clinical experience using a femoral condyle blade/plate on 17 patients. All fractures healed without infections, and there were no instances of nonunion of the fractures and no bending or breakage of the device. Chiron, et al. (Ref. 49), reported on 72 fractures of the distal third of the femur treated by condylar plates. He reported that all fractures healed, and that excellent or good results were obtained with 72 percent of the fractures. Banks (Ref. 50) concludes that the incidence of nonunion in displaced intracapsular femoral neck fractures may be decreased by accurate reduction, adequately placed internal fixation, and carefully supervised postoperative care.

Brown, et al. (Ref. 51), reported that in 17 supracondylar and 5 intercondylar fracture cases, all but 2 of the patients regained 65 degrees of flexion within 10 to 12 weeks. Shelton, et al. (Ref. 52), reported that among 14 supracondylar fractures, excellent restoration was obtained in almost every instance. There were 2 instances of slight plat malalignment resulting in 5 degrees varus and 5 degrees valgus angulation. Each patient achieved rapid clinical union and satisfactory knee movement. The average patient had at least 90 degrees flexion by the third month, and after 1 year had achieved an average of 125 degrees flexion. Two patients had a very slight radiographic malunion. Shelton, et al., concluded that the two malunions were clinically insignificant and were due to improper positioning of the plate.

Burwell (Ref. 53) conducted a survey of 181 fractures of the tibial shaft that were treated by implantation of rigid fixation plates. After 1 year followup, there were three delayed unions (about 2 percent) and eight nonunions (about 4.4 percent). Infection developed in 12 patients (about 6.6 percent). No mechanical failures of the implant were reported, and no patient had residual stiffness of the knee after implantation. Berkin and Marshall (Ref. 54) reported an overall postoperative infection rate of 4.8 percent in 135 tibial fixations and 1.7 percent infection rate in 57 femoral fixations. All the infections eventually healed and the fractures achieved solid union 4 to 24 months after operation.

Scales and Perry (Ref. 55) analyzed 393 bone plates out of 4,769 implanted plates that had been removed from patients. Several clinical reasons for removal were given: one hundred and seventy-eight plates were removed routinely, 126 because of pain, and 14 because of defects in the plates. At no time was corrosion stated by the surgeon to be the reason for removal of the implant.

Ruedi, et al. (Ref. 56), reported that, among over 400 tibia fractures, good to very good results were obtained in 90 percent of the open fractures and in 97 percent of the closed fractures.

Reported complications relating to use of bone fixation screws include: (a) screw loosening (Refs. 53 and 56 through 60) often resulting in loss of fracture fixation and, in one instance, limb paralysis due to traumatization of an artery (Ref. 60); (b) formation of a bursa (a cyst caused by friction or other mechanical cause) over the head of the screw (Ref. 59); and (c) screw fracture (Ref. 53). Several authors (Refs. 53, 61, and 62) noted that if screws cannot be properly tightened, micromotion between the screw and the bone may occur and may lead to bone resorption and loosening of the device. Scales and Perry (Ref. 55) reported that the fracture rates of screws were 0.85 percent for stainless steel screws, 6.0 percent for cobalt-chromium-molybdenum screws, and 7.7 percent for titanium screws.

A review of the recent medical literature on implanted bolts, nuts, and washers revealed that complications associated with these articles include fracture of devices (Refs. 55 and 63), corrosion of the metal at contacting surfaces (Refs. 55 and 64), and bone weakening due to the presence of holes drilled for bolts (Ref. 65).

5. Risks to health: (a) Nonunion of fractures: Improper design or performance of the device may result in nonunion of a fracture. (b) Bone necrosis (destruction): The presence of the device may sever the blood supply to a significant segment of bone. Since bone tissue, especially cortical bone, requires the integrity of its canalicular mechanism for nutrition, any permanent interruption of the vasculature leads to irreversible necrosis (Ref. 66). (c) Infection: The presence of the prothesis within the body may lead to an increased risk of infection. Improper configuration of the device or the finish on the device's surfaces can also lead to infection. (d) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials to the surrounding tissues and systemic circulation. (e) Loss or reduction in limb function: Inadequate mechanical properties, such as its lack of strength, rigidity, or improper design of the device, may result in nonunion or malunion due to flexing, fracture, or deformation of the device and subsequent loss or reduction of limb function. Migration of the fractured device may cause damage to adjacent hard and soft tissues.

FDA agrees with the Panel recommendation for single/multiple component metallic bone fixation appliances and accessories and is proposing that these devices be classified into class II. FDA has sought additional data and documentation on the use of these devices. Black (Ref. 67) reported that this treatment of hip fractures is generally a successful procedure, with a small number of clinical failures, a small number of device failures, and a still smaller number of device failures that result in clinical failure. Black summarized several clinical studies that reported an average failure rate of 6 percent.

Holt (Ref. 68) reported that, after 16 years of use, the Holt nail offers distinct advantages in the management of trochanteric fractures in both young and old patients. The incidence of complications is low, and mechanical failures of the implant have been virtually eliminated.

Fielding (Ref. 69) reported that, from 1955 to 1971, the telescoping Pugh nail was used in 256 displaced intracapsular fractures with known end results. Ninety percent united and avascular necroses were seen in 18.5 percent of the united fractures. Since many of the patients

with avascular necrosis had no pain, they were considered satisfactory results.

Ecker, et al. (Ref. 70), reported the results of sixty-two intertrochanteric hip fractures treated with a compression screw. Three nonunions and one malunion gave the technique a failure rate of only 6.4 percent. Seinsheimer (Ref. 71) reported no failures of bone fixation in a total of 47 cases. Banks (Ref. 50) reported that, with adequate reduction, impaction and accurate internal fixation, intracapsular fracture of the femoral neck can be expected to heal in at least 90 percent of the patients. Friedmann (Ref. 72) reported that the Massie nail has been used in 25 cases, with satisfactory results in 23 cases.

Harrington, et al. (Ref. 73), reported that a sliding compression screw-plate combination was used in 72 patients who were followed for more than 12 months after surgery. Sixty-seven fractures progressed to rapid union with good valgus reduction maintained. The average time to fracture union was 3.5 months. Jacobs, et al. (Ref. 74), reported that, of 101 patients treated with a sliding screw-plate developed by Pohl, 2 cases failed because of loss of fixation, 3 cases because of symptomatic penetration, and 1 case because of malunion, with a total failure rate of 6 percent. Hansen, et al. (Ref. 75), reported that, in 42 out of 48 cases (88 percent), fractures were united successfully after a single operative procedure. Six patients (12.5 percent) experienced nonunion and required further surgery. Baker (Ref. 76) reported that overall end results were rated excellent in 67.7 percent and poor in 32.3 percent of the fractures. Massie (Ref. 77) reported that nonunion has not been observed where the patient was completely immobilized.

Cohen, et al. (Ref. 78), reported that corrosion of cobalt-chromium implants is rare, despite widespread use of alloys with slightly different composition and forming techniques between plates and screws. The authors concluded that corrosion may be present to some degree but may not cause clinical problems. Rose, et al. (Ref. 79), reported that analysis of a broken vitallium nail/plate device used to fix an intertrochanteric fracture of the hip revealed that the nail was composed of cast vitallium and the plate of wrought vitallium. The condition of the fracture surface led the authors to believe that brittle failure had occurred and that the fracture crack had initiated from the region of nail/plate contact. These authors suggested that wrought and cast vitallium should not be used in combination.

Zickel (Ref. 80) reported that the Zickel devices obtain an adequate anchor in both proximal and distal fragments of the femur. He stated that the devices provide strong immobilization, permit early ambulation, and control angulation and rotation of fragments. Mickelson, et al. (Ref. 81), reported that of 21 patients who were treated with a Zickel nail for neoplastic pathological fracture or impending pathological fracture, 19 patients were restored to bed-chair status by the third postoperative day and 20 were able to walk. Failure of fixation did not occur in any patient, and there were no infections. Cuthbert, et al. (Ref. 82), reported excellent results with use of the Kuntscher Y Nail in the treatment of intertrochanteric and subtrochanteric fractures of the femur.

Although single/multiple component metallic bone fixation appliances and accessories are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device and device design, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3040; Docket No. 78N–3053; Smooth or threaded bone fixation fastener.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of smooth or threaded metallic bone fixation fasteners:

1. Identification: A smooth or threaded metallic bone fixation fastener is an implanted device that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed or have a formed, slotted head on the end. It is intended to be used for fixation of bone fractures, bone reconstructions, as a guide pin for insertion of other implants, or to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that smooth or threaded metallic bone fixation fasteners be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although smooth or threaded bone fixation fasteners are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and the mechanical properties of the device, and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the recent medical literature.

The medical literature regarding smooth metallic bone fixation fasteners reveals that there a few implant-related complications or implant failures associated with the device. A review by Fenyo (Ref. 83), covering a 12-year period and 41 cases, revealed no fractures of implants. Jones and Esah (Ref. 84) reported on six cases of radial fracture fixation in which there were no implant-related complications. Green

(Ref. 85) reported on 75 cases of intraarticular fractures treated with pin fixation, in which the results were evaluated as "good to excellent" in 86 percent of the cases. The most common complication Green reported was failure to maintain the restoration of radial length and inclination achieved by the initial reduction. He noted that up to 5 millimeters of radial length was lost due to bending of the device.

Another report (Ref. 86) noted that when the device was used in 30 patients to fuse shoulder joints, 20 patients (66 percent) attained a primary fusion, and 5 patients (17 percent) required a third operation to achieve a solid fusion. Once fusion was attained, 86 percent of the patients had excellent or good results. The chief cause of failure of arthrodesis was immoblization for too short a period of time.

Device-related complications were reported by Flynn, Matthews, and Benoit (Ref. 87) in a review of a series of 52 supracondylar fractures of the humerus in children. Both smooth and threaded pins were used. During long-term followup, the authors concluded that satisfactory results were achieved in 98 percent of the cases. They reported the following complications: vascular complications (18 percent), vascular and neuropathy complications (8 percent), muscular complications (1 percent), loss of fracture reduction (3 percent), and pin extrusion (1 percent). There were no instances of device fracture. Other reports in the medical literature involving bone fixation screws list the following device-related complications: (a) screw loosening (Refs. 57, 88, and 90 through 93) often resulting in loss of fracture fixation and, in one instance, limb paralysis due to traumatization of an artery (Ref. 93); (b) formation of a bursa (a cyst caused by friction or other mechanical cause) over the head of the screw (Ref. 92); and (c) device fracture (Ref. 94). Several authors (Refs. 62, 88, and 95) noted that if screws cannot be properly tightened, micromotion between the screw and the bone may occur and may lead to bone resorption and loosening of the device. Scales and Perry (Ref. 94) reported that the fracture rates of screws is 0.85 percent for stainless steel screws, 6.0 percent for cobalt-chromium-molybdenum screws, and 7.7 percent for titanium screws.

5. Risks to health: (a) Loss or reduction of limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or rigidity, may result in nonunion or malunion due to flexing, fracture, or deformation of the device and subsequent loss of limb function. When the device is used as a guide pin for other implants, device failure due to inadequate mechanical properties could lengthen the time of surgery and result in an increased risk of operative complications. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and the release of materials to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk infection. (d) Nonunion or malunion of a fracture: Improper design or faulty performance of the device could result in a loss of traction and nonunion or malunion of a fracture.

FDA agrees with the Panel recommendation and is proposing that smooth or threaded metallic bone fixation fasteners be classified into class II. Although smooth or threaded metallic bone fixation fasteners are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices.

In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., breakage, plastic deformation, and excessive elastic deformation, are bulk-material mechanical property failures of the device and the risks are attributed primarily to the device design and/or material and secondarily to host-tissue effects upon the device/material. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risk to health presented by these devices.

§ 888.3050; Docket No. 78N-3047; Spinal interlaminal fixation orthosis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of spinal interlaminal fixation orthoses:

1. Identification: A spinal interlaminal fixation orthosis is an implanted device made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also has been used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that spinal interlaminal fixation orthoses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent adverse tissue reaction, infection, or paralysis. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a spinal interlaminal fixation orthosis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device provide information on the strength of the device and identify the materials used in the device by both their common names and engineering classifications.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the medical literature.

5. Risks to health: (a) Adverse tissue reaction: Inadequate properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or corrosion of the implant and a release of materials from the device to the surrounding tissues and the systemic circulation. (b) Infection: The presence of the orthosis within the body may lead to an increased risk of infection. (c) Paralysis:

Paralysis may occur with loosening, migration, or breakage of the device.

FDA agrees with the Panel recommendation and is proposing that spinal interlaminal fixation orthoses, such as the Harrington device, be classified into class II. FDA has sought additional data on the use of the devices. The most common spinal interlaminal fixation orthosis is the Harrington device. As shown by the quantity of published literature, the Harrington device is widely used in the correction of scoliosis (lateral curvature of the spine). Reports in the literature differ as to whether untreated scoliosis causes significant problems, such as pain, disability, cardiopulmonary decompensation, and death. Nachemson (Ref. 97) reported that scoliotic patients had a mortality rate double that of the general population and that those patients with a severe thoracic curve had a mortality rate four times that of the general population. Nachemson also indicated that patients generally exhibited increasing respiratory troubles with increasing age and an increasing spinal curve. In contrast, Collis and Ponsetti (Ref. 98) found a death rate in untreated scoliotics similar to that of the normal population.

In studies reviewed by the Panel, the success of the Harrington device in maintaining a surgical reduction in spinal curvature was suggested. In 1962, Harrington (Ref. 99) reported on a study of use of the device in three clinical groups. Group I showed 58 percent reduction in spinal curvature, Group II showed 59 percent, and Group III, 84 percent. In 1973, Harrington and Dickson (Ref. 100) reported the results of an 11-year investigation of 578 cases. This study was divided into 8 consecutive study groups. With each of the 8 groups, the study took "a step in the evolution of the design of the device and a corresponding change either in spinal fusion procedure or the postoperative management." The investigators reported an average spinal curvature reduction of about 63 percent. Dickson and Harrington (Ref. 101), reported an average spinal curve reduction of 65.3 percent. O'Brien and Yau's (Ref. 102) clinical studies showed an 88 percent reduction of spinal curvature.

When Harrington reported the initial results of implantation of the device in 129 patients, complications were high (Ref. 99). Twenty-seven instrument fractures were reported. Bone erosion occurred in 28 percent of the cases. Nonunion (failed fusion) was reported in 10 cases. Fifty-eight percent of the device fractures occurred in the first 19 of the 129 cases. Failures of the device were minimized through changes in the design of the device, surgical technique, and postoperative care.

In the 11-year investigation of 578 cases reported by Harrington and Dickson (Ref. 100), the major complications included: nonunion (3 percent), broken rod with overlap (10 percent), hematoma (1 percent), wound infection (1 percent), hepatitis (one case), and death (one case). The overall major complication rate started with a 29 percent occurrence in group 1, and gradually diminished, with no major complications reported in group 8.

Dawson, et al. (Ref. 103), used the Harrington device in a study of 82 adult scoliotic patients. With an average followup of 3.5 years, Dawson reported the following complication rates: nonunion—27 percent, infection—21 percent (subsequently lowered to 2 to 3 percent when prophylactic antibiotics were used) with no chronic infection, and death—6 percent; however, all patients who died had severe pulmonary disease.

Kostuik, et al. (Ref. 104), used the Harrington device in 107 patients and reported the following late complication rates: nonunion (10 percent), chronic infection (0 percent), painful instrumentation (4 percent), loose rods (1 percent), donor site numbness (1 percent), neuroma (1 percent), and loss of lumbar lordosis (1 percent).

Dickson and Harrington (Ref. 101) reported on use of the device in 384 patients. Genitourinary infection (5 percent) was the most prevalent early complication, and device fracture (6 percent) was the most prevalent late complication.

Bonnet and Brown (Ref. 105) reported one rod fracture in 150 cases. Nonunion was the most prevalent complication in Bonnet's study. This complication occurred initially in 38 percent of the cases, but was reduced to 27 percent in the latest clinical group.

Goldstein reported no device fractures in 107 patients (Ref. 106). Dolan and MacEwen (Ref. 107), in a review of 173 cases involving the Harrington device, reported nonunion in 15 patients and only 3 device fractures.

Spinal interlaminal fixation orthoses are implantable devices purported or represented for a use which is of substantial importance in preventing impairment of human health. FDA believes that clinical experience with the designs of these devices and the materials used in them have established the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices outweighs any likelihood of illness or injury resulting from their use. FDA believes that informative labeling will help minimize the risks to health associated with the use of these devices.

Although spinal interlaminal fixation orthoses are implanted devices, FDA believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3060; Docket No. 78N-3048; Spinal intervertebral body fixation orthosis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of spinal intervertebral body fixation orthoses:

1. Identification: A spinal intervertebral body fixation orthosis is an implanted device made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is intended to apply force to a series of vertebrae to correct "sway back", scoliosis (lateral curvature of the spine), or other conditions.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations: The Panel recommends that spinal intervertebral body fixation orthoses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent adverse tissue reaction, infection, or paralysis. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling

for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (b) Infection: The presence of the orthosis within the body may lead to an increased risk of infection. (c) Paralysis: Paralysis may occur with loosening, migration, or breakage of the device.

FDA agrees with the Panel recommendation and is proposing that spinal intervertebral body orthoses, such as the Dwyer device, be classified into class II. The agency has obtained additional data and information describing the use of spinal intervertebral body fixation orthoses (Refs. 108 through 119). The device is intended primarily for use in the treatment of scoliosis, but it is also intended for fixation of the spine so that bone grafts can unite properly. Because the device is implanted on the front of the spine, implantation requires a more extensive surgical exposure than required for the implantation of spinal interlaminal fixation orthoses (§ 888.3050).

The safety and effectiveness of implantation of spinal intervertebral body fixation orthoses in the treatment of scoliosis is still being assessed (Ref. 114). Recent studies (Refs. 114, 116, and 117) report use of the device for a variety of treatments, i.e., idiopathic thoracolumbar and lumbar spinal curves, spinal curves associated with deficient posterior elements, spinal curves with marked forward curve of the lumbar spine (lordosis), and spinal curves associated with muscle paralysis. Because the device may be placed on the front of the spine, it is implanted to treat "sway back." Paralytic scoliosis is a lateral curvature of the spine caused by muscle paralysis on one side of the spinal column. Paralytic spinal curves usually involve a series of vertebra, and bone grafts inserted to correct such curves have a higher incidence of nonunion (Ref. 114). Although spinal intervertebral body fixation orthoses are indicated for use alone in the treatment of paralytic spinal curves, the preferred method of treatment is the combined use of both spinal intervertebral body fixation orthoses and spinal interlaminal fixation orthoses (§ 888.3050), a posteriorly placed compression or distraction rod (Refs. 113, 114, 116, 117, and 118). Use of spinal intervertebral body fixation orthoses is contraindicated for use in treatment of both high thoracic curves and "hunchback" (Refs. 114, 116, and 117).

FDA's search of the medical literature revealed only three studies showing long-term use of spinal intervertebral body fixation orthoses (Refs. 110, 111, and 114). Dwyer (Ref. 110) reported use of the device in 51 patients. The major complication reported involved the patients' respiratory system and two instances of nonunion of bone grafts. Most of the respiratory complications are attributed to the extensive surgery required to implant the device, and not to problems with the device itself. Dwyer, et al. (Ref. 111), reported use of the device in 77 patients with an overall complication rate of 43 percent. The complications reported included progressive "hunchback" in 18 patients, loss of correction in 22 patients, nonunion of bone grafts in 15 patients, device failure in 5 patients, deep paravertebral infection in 3 patients, and retroperitoneal fibrosis (fibrosis between the lining of the intestinal cavity and the spine) in one patient. Hall (Ref. 113) reported use of the device in 77 patients and the major complication involved nonunion of bone grafts. Twelve percent of the patients had a major nonunion resulting in reoperation. Fourteen percent had a minor nonunion with implant failure, but without serious impairment of function of the patient.

Two recent case reports in the literature (Refs. 112 and 115) provide information on complications associated with use of spinal intervertebral body fixation orthoses. Eisenstein and O'Brien (Ref. 112) reported chylothorax (an accumulation of chyle, a milky fluid, in the pleural cavity). Silber and McMaster (Ref. 115) reported a case of retroperitoneal fibrosis with hydronephrosis (a collection of urine in the distended pelvis of the kidney caused by obstructed outflow—pressure of the urine in time causes atrophy of the kidney structure, and the whole organ is converted to a large cyst). Both of the above complications may be caused by the demanding surgery involved with implanting the device, and not from the device itself. Additionally, Schafer, et al. (Ref. 119), reported that improper crimping of the head of the eye-screw inserted into the intervertebral body could shred the cable, eventually resulting in cable failure. The authors noted that 5 out of 6 heads of eye-screws and 2 out of 4 heads of eye-screws were found to be cracked following improper crimping.

Thus, spinal intervertebral body fixation orthoses are implanted devices that are purported or represented to be for use in relieving disabling pain and restoring or minimizing further loss of functional use of the spine. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA further believes that clinical experience with these devices or the materials used in these devices has established the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices outweighs any likelihood of illness or injury resulting from their use. FDA further believes that informative labeling will help minimize the risks to health associated with the use of these devices.

Although spinal intervertebral body fixation orthoses are implanted devices, FDA believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3100; Docket No. 78N-3059; Ankle joint metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ankle joint metal/composite semi-constrained prostheses:

1. Identification: An ankle joint metal/composite semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from a carbon fiber reinforced ultra-high molecular weight polyethylene composite, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/composite semi-constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing futher loss of functional use of a joint or limb. The Panel believes these users are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations to the Panel (Refs. 120 and 121). Dr. Robert Johnson (Rensselaer Polytechnic Institute) compared the physical properties of the carbon fiber reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethlene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon-fiber-reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of toxicity tests on the carbon fiber reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up on 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; that systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The results of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon fiber reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from a patient who had received an ultra-high molecular weight polyethylene prosthesis in one ankle and a carbon fiber reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon fiber reinforced material. Dr. Volz concluded that the carbon fiber reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 121), Robert Fuson, M.D. (Zimmer-USA), summarized the clinical experience with prostheses made from the carbon fiber reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the ankle joint metal/composite semi-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3110; Docket No. 78N–3060; Ankle joint metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ankle joint metal/polymer semi-constrained prostheses:

1. Identification: An ankle joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/polymer semiconstrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although ankle joint metal/polymer semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on three oral presentations to the Panel, and the Panel members' knowledge of the medical literature. On July 15, 1977, oral presentations to the Panel were made by Drs. Harry Groth, Theodore Waugh, and Arthur Steffee (Ref. 122). Dr. Groth discussed the clinical results obtained following implantation of 31 Oregon design ankle prostheses. Seventeen of these devices had been implanted for 1 year or more. The maximum time of implantation was reported as 2 years. The clinical results were reported as "fair" in 4 patients, and as "good" or "excellent" in the remaining 27.

Dr. Waugh presented the clinical results obtained using the University of California at Irvine (UCI) design ankle prosthesis. This prosthesis had been implanted in 63 patients, 35 to 40 of whom had had the devices implanted for more than 2 years.

Dr. Steffee discussed the clinical results obtained following implantation of 37 Bech-Steffee design ankle prostheses. The minimum time of implantation of these devices was reported as 2 months, and the maximum time was 46 months.

Drs. Groth, Waugh, and Steffee reported the following total complications associated with use of the three prosthesis designs they studied: five cases of device loosening, two cases of joint infection, one case of joint instability, two cases of malpositioning of the prosthesis, eight cases of wound healing problems, and two cases of pulmonary embolism.

In another oral presentation before the Panel on November 19, 1980 (Ref. 123), Dr. Paul Thompson discussed the results he obtained using the TPR® ankle prosthesis. He said that the device had been implanted in 43 patients over a 6-year period and that excellent or good results were obtained in 75 percent of these patients, and poor results were obtained in 25 percent. Complete freedom from pain was achieved in 32 percent. Sixty-five percent of the patients complained of mild discomfort and 7 percent had constant pain. Reoperations were done on eight patients (19 percent) for loosened prostheses; two patients of the eight had two reoperations, the remaining six had one reoperation.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: the presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Several publications (Refs. 124 and 125) were available describing the biomechanics of the ankle joint prosthesis and the rationale behind a number of ankle prosthesis designs. Other publications (Refs. 126 through 129) presented clinical results obtained using the devices.

Stauffer (Ref. 126) reported that the early results obtained with the Mayo design prosthesis were favorable. He stated that, of 20 patients in whom the Mayo design ankle prosthesis was implanted, six complications occurred: 3 cases of fracture of the medial malleolus; 1 case of impingement of the lateral malleolus or the talus; 1 case of loosening of the tibial component, following a patient's fall, and 1 case of rotation of the subtalor joint by the anchoring fins of the talar component. In a subsequent publication (Ref. 127), Stauffer reported the clinical results obtained from 72 patients involving 76 implantations. In 63 of these patients, the devices had been implanted for more than 6 months. Of these 63 patients, good results were obtained in 52, fair results in 6, and poor results in 5. A number of complications were reported: one case of deep infection requiring removal of the components; five cases of delayed wound healing; one case of thrombophlebitis; five cases of fracture of the medial malleolus; and three cases of device loosening. Reoperations were required in five patients due to impingement of the lateral malleolus or the talus.

Evanski and Waugh (Ref. 128) reported on ankle prostheses that had been implanted in 29 patients. Twenty-five patients received the UCI design ankle prosthesis and four received the Smith design ankle prosthesis. The authors stated that sufficient data were available to evaluate the results in 28 patients. The average period of followup for these patients was 9 months. Significant improvement was noted in function, pain relief, and range of motion. Complications included: three cases of wound healing problems and two cases of malalignment of the components, one requiring reoperation. There were two failures: one patient required a joint fusion and the other an

amputation following postoperative occlusion of the posterior tibial artery.

Scholz (Ref. 129) reported on the implantation of 31 devices of his design in 30 patients who were candidates for ankle arthrodesis. The devices were implanted over a 2-year period. It was reported that, in general, pain was eliminated or reduced, function was improved, and motion of the joint was generally sufficient to allow normal heal-toe gait without a limp. It was also reported that there were no major complications associated with the device. However, reoperation was necessary in one patient to reposition a tibial component that had been incorrectly aligned and had loosened. Scholz stated that no devices had been removed to arthrodese the joint, but that arthrodesis was possible if the components had to be removed at a future date.

Although ankle joint metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Thrombophlebitis and infection are risks of any serious operation and are not necessarily caused by poor performance of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3120; Docket No. 78N–3061; Ankle joint metal/polymer non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA Advisory committee, made the following recommendation regarding the classification of ankle joint metal/polymer non-constrained prostheses:

1. Identification: An ankle joint metal/polymer non-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ankle joint metal/polymer non-constrained prostheses be classified into class III because these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls of performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on the available medical literature. According to Freeman (Ref. 130), "It is still too early to say whether this operation (total ankle joint replacement) offers any advantages over arthrodesis * * *. It would appear a comfortable mobile ankle can be produced but how reliably this can be done and how long the results will last is impossible to say."

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrouding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that ankle joint metal/polymer non-constrained prostheses be classified into class III. The agency has reviewed the Panel recommendation and has sought additional information describing the safety and effectiveness of these devices. The only available clinical study on the device has been done by S. E. Newton (Ref. 131). Since 1973, 50 patients have had this prosthesis implanted. There have been 20 (40 percent) reported failures. FDA believes these data are insufficient to establish the safety and effectiveness of ankle joint metal/polymer non-constrained prostheses.

FDA finds that ankle joint metal/polymer non-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the ankle joint metal/polymer non-constrained prosthesis presents an

unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3150; Docket No. 78N–3062; Elbow joint constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint contrained prostheses:

1. Identification: An elbow joint constrained prosthesis is an implanted device made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys and ultra-high molecular weight polyethylene, that is intended to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together (or affined). The generic type of device is limited to those prostheses intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on an oral presentation to the Panel and their knowledge of the medical literature. On April 14, 1977, the Panel heard an oral presentation by Dr. Rowland Pritchard (Ref. 132). Dr. Pritchard summarized his experience with the Pritchard-Walker prosthesis which has a metallic ulnar component and a polyethylene humeral component. Dr. Pritchard reported that he had implanted 25 of the devices and that 18 (72 percent) of the patients were free from pain. Dr. Pritchard indicated that the devices had been implanted for as little as 2 years in some patients and as long as 3 years in others. Dr. Pritchard stated that the polyethylene humeral component of two of the devices (8 percent) had fractured and that there were two other complications, one case of infection and one case of radial nerve palsy (paralysis).

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity.

(b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that contrained elbow joint prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of the device. The agency has reviewed the current medical literature pertinent to elbow joint constrained prostheses. The literature reviewed pertains to both the earlier designs of constrained elbow prostheses, the "rigid-hinge" devices such as the St. George and Coonrad designs, and the more recent "loose-hinge" devices, such as the Schlein, Ewald, Pritchad-Walker, and Mayo designs.

Although good results with the rigidly hinged devices were found initially, several investigators (Refs. 132 through 134) reported that serious complications were associated with long-term implantation of these devices. Souter (Ref. 134) described three serious long-term complications associated with the use of these devices: (1) loosening of the devices resulting in joint instability, (2) bone erosion and resorption resulting in fracture of the bone surrounding the devices, and (3) the difficulty in salvaging the joint if the device is removed.

A high incidence of complications, particularly loosening, was reported by many investigators using a variety of constrained elbow designs. Dee (Ref. 133) evaluated 40 patients 2 to 5 years after they had received an elbow joint metallic rigid-hinged prosthesis. Eleven (27.5 percent) of the prostheses had loosened; the majority of these loosening 2 or more years after surgery. Only two cases of loosening had been evident 1 year after implantation, and only six after 3 years. Souter (Ref. 134) reported that 12 out of 25 prostheses (48 percent) had loosened after an average time of implantation of 5 years and 3 months. Eleven (44 percent) of the patients had unstable joints. Devas (Ref. 135) used a rigid-hinged device with metallic humeral and ulnar components and a polyethylene bushing in nine patients. He reported that four out of nine (44 percent) of the devices had loosened or were suspected of being loose and concluded that the long-term results did not warrant continuing the procedure.

Gshwend, Sheier, and Bahler (Ref. 136) and Ewald (Ref. 137) reported on their clinical results with the G.S.B metallic rigid-hinged device. Gshwend, et al. (Ref. 136), reported that one-third of the 40 prostheses implanted in their study were subject to loosening 1 to 5 years after implantation. Ewald (Ref. 137) reported that in his study, 2 out of 13 (15 percent) of the devices had loosened 10 to 21 months after implantation. Other reported hazards and complications include fracture of the polyethylene components of devices due to inadequate mechanical strength of the material (Ref. 138), metal sensitivity in patients with metallic prostheses due to the accumulation of metallic wear debris (Ref. 133), and the potential for extensive bone infection related to the long intramedullary stems of the devices (Ref. 134). The high incidence of complications with these devices has been attributed to the inability of a "rigid" hinge to accommodate the torque forces that

occur during axial rotation of the forearm (Refs. 134, 138, and 139). FDA recognizes that the "loose" hinge elbow prosthesis (e.g., Pritchard-Walker) is designed to allow some side-to-side motion and thus reduce the rate of loosening found with the "rigid" hinged devices. Dr. Pritchard reported to the Panel that there were no cases of devices loosening in 25 patients, 2 to 3 years after implantation of the devices.

Schlein (Ref. 140) reported that over 400 loose-hinged elbow prostheses were implanted over a 3-year period. Schlein reported the following complications in the series of 400 implantations: 11 cases of device loosening (2.75 percent); 4 cases of infection (1 percent); 2 cases of device fractures (0.5 percent); and 6 cases of bone fractures (1.5 percent). FDA notes that: (1) The high incidence of device loosening associated with the constrained elbow prostheses (i.e., Dee, Shiers, McKee, modified McKee, Coonrad, and G.S.B. designs) has been attributed to inadequate device design (Refs. 133 through 135, 139, and 141 through 143); (2) the biomechanics of the elbow joint are reportedly not well understood (Refs. 144 and 145); and (3) biomedical analysis is reportedly needed to establish design criteria for development of optimum design for the prosthesis (Ref. 141).

FDA finds that elbow joint constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that uncontrolled use of the elbow joint constrained prosthesis presents an unreasonable risk of illness or injury.

Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3160; Docket No. 78N–3063; Elbow joint semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint semi-constrained prostheses:

1. Identification: An elbow joint semi-constrained prosthesis is an implanted device intended to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficent control over these characteristics.

Although elbow joint semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction in joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that elbow joint semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of the device. Cavendish and Elloy (Ref. 144) discuss 10 Liverpool prostheses that had been implanted from 18 months to 3 years. One failed due to infection and one due to bone fracture. The other eight cases resulted in an adequate range of motion and the patients were pain free. Ewald, et al. (Ref. 147), reported on 50 implantations of the Ewald prosthesis. The maximum followup was reported as 2 years and 9 months, the minimum as 6 months, and the median as 18 months. Pain relief and functional improvement were reported to have been uniformly excellent. Complications included: two cases (4 percent) of dislocation of the device; two cases (4 percent) of infection; two cases (4 percent) of ulnar nerve palsy, one of which was permanent; and one (2 percent) unstable elbow attributed to the failure of a previous operative procedure. The authors concluded that the angle of the device stem caused inherent elbow instability and dislocation in some patients. These complications prompted the authors to design four additional stem angles. The biomechanics of the elbow joint are still being characterized (Refs. 144, 145, and 150), and continuing studies are needed to optimize the design of the device (Refs. 150 through 153).

Although elbow joint semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that

will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3170; Docket No. 78N–3064; Elbow joint radial (hemi-elbow) prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint radial (hemi-elbow) prostheses:

1. Identification: An elbow joint radial (hemi-elbow) prosthesis is an implanted device made of medical grade silicone elastomer intended to replace the proximal end of the radius. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint radial (hemi-elbow) uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although elbow joint radial (hemi-elbow) prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissue and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that elbow joint radial (hemi-elbow) prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Swanson (Ref. 154) reported on the implantation of the devices in 44 patients, including 9 patients who were operated on bilaterally. Of these 53 implanted devices, 28 were followed for 6 months to 2 years, and 25 were followed for 2 to 5 years. Results were evaluated with regard to pain relief, stability, and mobility of the elbow joint. Pain was reported to have been relieved in all 53 elbows, and stability was reported to be good. There was also a reported increase in range of motion of the joint, especially in pronation and supination. Roentgenograms made 6 months to 5 years after surgery were used to evaluate the condition of the bone surrounding the implant. Examination of the roentgenograms demonstrated good acceptance of the implant. In one case, the bone around the stem of the implant was found to have resorbed, and the implant was noted to have loosened. However, there were no adverse clinical effects associated with this anomaly. The advantages of the use of the prosthesis over simple resection of the radial head (without use of an implant) were summarized by the researcher to be: (1) better pain relief; (2) increased range of motion; (3) preservation of joint alignment and prevention of migration of the radial shaft; and (4) prevention of bone overgrowth and spiking at the resected end of the radius.

Although elbow joint radial (hemi-elbow) protheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3180; Docket No. 78N–3065; Elbow joint humeral (hemi-elbow) uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of elbow joint humeral (hemi-elbow) uncemented prostheses:

1. Identification: An elbow joint humeral (hemi-elbow) uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that

establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that elbow joint humeral (hemi-elbow) uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that elbow joint humeral (hemi-elbow) uncemented prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. The agency has reviewed the available medical literature pertaining to elbow joint humeral (hemi-elbow) uncemented prostheses. A recent publication (Ref. 155) reported that the devices have been implanted in over 100 patients worldwide. However, the only available clinical data are the results of 2 surgeons who implanted 18 devices over a 10-year period (Ref. 155). An earlier publication (Ref. 156) discusses the clinical results in what appears to be the first 10 of these 18 implantations. The devices had been implanted in nine patients (one patient had prostheses implanted bilaterally). These patients were evaluated 1 to 7 years later and only four patients (44 percent) had stable, pain-free elbows with a functional range of motion. New bone growth restricted or totally blocked elbow joint motion in three patients. The device was removed in two other patients; because of joint pain and swelling in one; and because the device had dislocated and was eroding through the skin in the other.

FDA finds that elbow joint humeral (hemi-elbow) uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the elbow joint humeral (hemi-elbow) uncemented prosthesis presents an unreasonable risk of illnes or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3200; Docket No. 78N–3066; Finger joint metal/metal constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/metal constrained uncemented prostheses:

1. Identification: A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made by alloys, such as cobalt-chromium-molybdenum, or prostheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended to be implanted without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/metal constrained uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although finger joint metal/metal constrained uncemented prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectivness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper

design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or lossening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/metal constrainted uncemented prostheses he classified into class III. FDA has reviewed the available medical literature pertaining to these prostheses. The only finger joint metal/metal constrained uncemented proshtesis discussed in the literature is a two-pronged stainless steel hinged prosthesis which was developed by Flatt for use in the metacarpophalangeal (MCP) and the proximal interphalangeal (PIP) joints of the fingers.

Flatt presented clincial results with the Flatt finger prosthesis in a series of publications over a 12-year period (Refs. 157 through 162). Thirty-one prostheses had been implanted for 6 months or more (6 months to 34 months); 23 in the PIP joint and 8 in the MCP joint (Ref. 157). In the earliest of these reports (Ref. 157), Flatt noted that despite early encouraging clinical results, the long-term outlook for the device did not look favorable. In particular, Flatt noted that the bone absorption which occurs around the neck of the prosthesis may possibly lead to obstruction of flexion. Flatt also noted that possible complications from use of the device might be: (1) Bone erosion in patients in whom the intramedullary prongs have been forced together in the medullary canal, and (2) metal fatigue and fracture of the intramedullary prongs.

Subsequent publications by Flatt (Refs. 161 and 162) show that the predicted complications did, in fact, occur. Flatt and Ellison (Ref. 161) reported on the implantation of 242 prostheses (167 in the MCP joint and 75 in the PIP joint) with an average followup of 6.2 years (range 1 to 12 years). Twenty-six (10.7 percent) of the prostheses (15 MCP and 11 PIP) had to be removed for the following reasons: periarticular fibrosis (bone resorption) and settling, 14; failure (i.e., fracture) of both intramedullary prongs, 2; failure of the screw holding the hinge together, 2; breakdown of the skin over the prosthesis, 5; and infection, 3. The author reported that of the prostheses that required removal, more than half were removed because of settling within the recipient bones. Bone absorption around the intramedullary prongs, scarring, or heterotrophic bone formation around the hinge caused sufficient mechanical difficulties to necessitate removal of the prosthesis. Flatt and Ellison noted that the gradually progressing periarticular fibrosis (bone resorption) resulted in a decreased range of joint motion and was related to very active use of the hand.

Girzados and Clayton (Ref. 163) reported on the implantation of 23 Flatt finger prostheses in 11 patients with an average followup of 44 months (range 24 to 73 months). Of the 23 prostheses implanted, 11 were in the MCP joints of the fingers, 8 were in the PIP joints of the fingers, and 4 were in the MCP joints of the thumb. Bone absorption around the neck and stems of the prosthesis occurred in 16 of the 23 (69 percent) joints. Six prostheses (26 percent) were rated as poor results: three had no motion postoperatively; one was grossly unstable; and two were implanted in a patient with active rheumatoid disease who, over a period of 64 months, had intermittent swelling and pain over the joints that had been replaced with the prostheses. The authors reported that "good" or "fair" results were obtained in 13 (56 percent) of the joints. However, the number of patients having pain-free stable joints with a useful range of motion (defined as "good") as opposed to those with limited motion, minimal pain, and instability (defined as "fair") could not be determined.

Problems associated with the Flatt finger prosthesis have been recognized by many authors (Refs. 164 through 170). Several authors (Refs. 164 and 165) reported that these prostheses have not been generally accepted because of the accompanying bone resorption. McFarland (Ref. 166) reported that the Flatt prosthesis has been only moderately successful, that complications are frequent and include bone overgrowth with loss of motion, migration of the prosthesis due to bone erosion, and metal failures (i.e., device fractures). Smith and Broudy (Ref. 170) and Goldner and Urbaniak (Ref. 168) noted that the bone resorption and subsequent migration of the devices is caused by the use of a rigid material in osteoporotic bone. Smith and Broudy (Ref. 170) also noted that the intramedullary prongs frequently migrate through the cortex and occasionally the hinge will break or the overlying skin will ulcerate, causing tendon rupture and infection.

FDA finds that finger joint metal/metal constrained uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury of illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the finger joint metal/metal constrained uncemented prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3210; Docket No. 78N-3301; Finger joint metal/metal constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/metal constrained prostheses:

1. Identification: A finger joint metal/metal constrained prosthesis is an implanted device intended to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and is limited

to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/metal constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/metal constrained prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of these devices and has reviewed the available medical literature pertaining to these devices. Two types of these prostheses were discussed in the literature: (1) The Link prosthesis, a metallic hinge intended to replace the metacarpophalangeal joint of a finger or thumb, and (2) the Biomedical Laboratories of the University of Cincinnati (BLUC) prosthesis, a hinged metallic prosthesis intended to replace the metacarpophalangeal joint of the thumb.

Devas and Shah (Refs. 171 and 172) reported on the implementation of 51 Link prostheses in 25 patients with an average postoperative followup of 4 years (range 2 to 6 years). In 15 (30 percent) of these implantations, the patient had persistent pain in the joint and what was described as a useless finger. The authors believed that the proportion of patients with pain was far too large to make the treatment method freely available. They noted that the main cause of failure was due to loosening of the prostheses with disruption (erosion) of the bone. They also noted that in most of the joints with good and fair results the prosthesis had become loose but that the patients were free from symptoms at the time of evaluation. It was believed that prosthesis loosening may have been caused by fixation of the components by injecting the cement into the metacarpal and phalangeal bone shafts, and it was noted that a modified prosthesis with a different technique of insertion was being considered (Ref. 172). Several papers (Refs. 173 and 174) described the design and testing of the BLUC thumb prostheses. Clinical results, however, were not presented. FDA believes that the data available on the devices, the clinical results of the use of the devices in 25 patients with a reported failure rate of 30 percent, and the recommendation by the authors that the procedure not be made freely available, do not establish the long-term safety and effectiveness of finger joint metal/metal constrained prostheses.

FDA finds that finger joint metal/metal constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a finger joint. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA also believes that insufficient clinical experience exists to establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that the use of finger joint metal/metal constrained prostheses presents an unreasonable risk of illness or injury.

Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3220; Docket No. 78N–3067; Finger joint metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint metal/polymer constrained prostheses:

1. Identification: A finger joint metal/polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those devices that are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint metal/polymer constrained protheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or

infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that finger joint metal/polymer constrained prostheses be classified into class III. FDA has sought additional information on the safety and effectiveness of these devices and has reviewed six references which discuss the device. Two (Refs. 175 and 176) discuss the design criteria for these devices; two (Refs. 177 and 178) review the evolution of the design of these devices; and four (Refs. 175, 176, 179, and 180) describe new prosthesis designs. The prosthesis designs discussed in the literature include: the St. George, Steffee, Schultz, Nicolle, Schetrumpf, Vari-Axle, and load stabilizing prostheses, all of which were designed for the metacarpophalengeal (MCP) joint. Smith and Broudy (Ref. 177) reported that a device similar in design to the Steffee prosthesis had been developed for the proximal interphalangeal (PIP) joint.

Clinical results were available for only two prosthesis designs, the Vari-Axle and the Nicolle designs (Refs. 175 and 179). Long-term clinical results, however, are not available for any of the designs. Walker, et al., reported on 21 patients with Vari-Axle prostheses (Ref. 175). The average postoperative time was 15 months (range 6 months to 3 years). While pain relief was noted to be good, the range of motion dropped from 33 degrees preoperatively to 22 degrees, a reportedly disappointing result. These authors noted that short-term and long-term mechanical tests were performed on the device because of the potential distortions which occur in polyethylene intramedullary stems. Based on the results of these tests, the authors concluded that the polyethylene stems of the Vari-Axle prosthesis might fail over the long term. Nicolle (Ref. 179) evaluated 20 patients with Nicolle prostheses. The average postoperative time was 12 months. The range of joint motion was not reported. The author reported that the degree of ulnar drift (joint deformity) was improved by surgery and improved further with postoperative rehabilitation, but that from 12 months on a progressive ulnar drift was observed, the reason for which was not clear. Nicolle noted that a longer followup and additional patients are required before the reported results can be regarded as statistically significant.

Smith and Broudy reported that the various designs of finger joint metal/polymer constrained prostheses are undergoing clinical and laboratory trials (Ref. 177). Walker (Ref. 178) noted that the advantages of the metal/polymer designs need to be shown. Problems associated with other designs of this prosthesis were identified by several authors (Refs. 175, 177, and 178). Walker, et al. (Ref. 175), reported that the postoperative range of motion with the St. George design was often limited due to the ingress of fibrous tissue into the joint. Smith and Broudy (Ref. 177) reported that while satisfactory results had been obtained in 80 percent of the patients with the Steffee prosthesis, the active range of motion was limited to only 50 percent of normal and deformity recurred in some patients, prompting a revision of the prosthesis design. Walker (Ref. 178) commented on the design of the Schultz prosthesis, stating that it allows too must rotation and there is an inadequate bearing between the metal and plastic components.

FDA finds that finger joint metal/polymer constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a finger joint. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use these devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the finger joint metal/polymer constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. FDA believes that insufficient information exists to support the conclusion that general controls will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3230; Docket No. 78N-3068; Finger joint polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of finger joint polymer constrained prostheses:

1. Identification: A finger joint polymer constrained prosthesis is an implemented device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prosthesis that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination of polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve. These prostheses are intended to be implanted with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that finger joint polymer constrained prostheses be classified into class II because the design, material composition, and mechanical properties

of the device, such as its flexibility, rigitity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a finger joint polymer constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that finger joint polymer constrained prostheses be classified into class II. FDA has sought additional data and information on these prostheses. Clinical results on three designs of finger joint polymer constrained prostheses were presented in the literature: the Calnan-Nicolle prosthesis, intended for use in the metacarpophalangeal (MCP) and proximal interphalangeal (PIP) joints of the fingers; the Niebauer prosthesis also intended for use in the MCP and PIP joints of the fingers; and the Swanson prosthesis intended for use in the MCP and PIP joints of the fingers and for the MCP joint of the thumb.

1. *Calnan-Nicolle Prosthesis.* This device has two components, an across-the-joint component having intramedullary stems and a flexible hinge made of polypropylene, and a silicone rubber sleeve which encapsulates the flexible hinge portion of the device (Ref. 181). Griffiths and Nicolle (Ref. 182) reported on the clinical results 8 to 37 months (average of 20 months) after implantation of the Calnan-Nicolle device in 112 MCP joints in 31 patients. Complete relief from pain was obtained in four (13 percent) patients. There was much improvement over preoperative pain status in 13 (42 percent), moderate pain relief in 10 (32 percent), and little pain relief in 4 (13 percent) patients. These authors reported that a deterioration in the performance of the prosthesis occurred in up to half of the patients between 1 and 2 years after insertion of the prosthesis; and that part of the deterioration in function was due directly to mechanical failure of the prosthesis. The range of joint motion had deteriorated over time in 33 of the 40 (82.5 percent) hands on which surgery was performed. Joint deformity was "corrected and held" in 10 of 31 hands (32 percent), was corrected initially but recurred in 14 of 31 (45 percent) hands and worsened in 7 of 31 (23 percent) hands. The silicone capsule (sleeve) had fractured in 31 of the 112 prostheses (28 percent). The polypropylene stems had fractured in five joints (5 percent). Nicolle (Ref. 179) noted that time and experience had shown that the polypropylene hinge of the Calnan-Nicolle prosthesis does not appear to be strong enough to fully withstand the compression and torsional stresses that may occur in the use of the hand.

2. *Niebauer Prosthesis.* This device consists of a single, flexible, across-the-joint component. The intramedullary stems and the flexible hinge portion of the device are made of silicone to allow tissue penetration and fixation of the stems. Beckenbaugh, et al. (Ref. 184), reported clinical results 12 to 65 months (average 32 months) after implantation in the MCP joints of 68 Niebauer prostheses and found a fracture rate of the device of 38.2 percent (26 devices), recurrence of clinical deformity in 44.1 percent (30 devices) and recurrence of pain in 2 percent. Goldner, et al. (Ref. 185), reported a fracture rate of 29.7 percent in 37 prostheses implanted for 6.5 years and a 17.5 percent fracture rate in 143 prostheses implanted 4 to 6 years. These authors believe that the silicone-polyester material used in the device may absorb lipids and become brittle, and that eventual fracture of the prosthesis is a possibility, but that fracture does not preclude a good functional result. Goldner, et al. (Ref. 186), evaluated 103 patients over a 4-year period. Pain was relieved or greatly diminished postoperatively in all but 8 of the 103 patients. The average active range of motion in these patients was 51 degrees. The range of motion was noted to increase up to about 1 year postoperatively; and then thought to decrease slightly, possibly due to enlarged bony outgrowths from the surface of the bone and impingement of peripheral bone on the hinge of the device. In two (2 percent) of patients, the device had fractured, which was accompanied by deformity and a moderate amount of pain.

Hagert (Ref. 187) conducted x-ray examinations on 41 joints with Niebauer implants. This author reprted that of the 41 prostheses studied, 26 (63.4 percent) were found to be damaged (i.e., cracked within the implant mid-section, fragmented at the midsection, or fractured at the hinge), 1 to 36 months postoperatively. This author believed that the Niebauer implant might be too weak to withstand forces in the MCP joints, and that a possible contributing factor was the use of materials (polyester fiber and silicone rubber) with differing elasticity. This author noted that the Niebauer implant was reported to have withstood 100 million flexions during mechanical tests bending it around a fixed axis, but not exposing it simultaneously to shearing type forces which are present in the MCP joint. These shearing forces were reportedly most probably responsible for the deformation of the implant and the subsequent damage observed. Niebauer, et al. (Ref. 188), reported that destruction of the bone around the hinge of the device had occurred in a few cases and that this atrophy may be the result of pressure from the prosthesis. In an evaluation by x-ray of the 41 Niebauer prostheses, Hagert (Ref. 187) observed bone resorption in 23 of the 41 joints (56 percent). The cortex of the one was penetrated in 13 (32 percent) of these joints. It was reported that the observed erosion of the bone is most likely caused by motion of the intramedullary stems within the medullary cavity, and is exaggerated by the rough polyester surface of the device.

3. *Swanson Prosthesis.* This device is made entirely of silicone rubber and is designed to act as an internal mold, maintaining joint alignment, becoming encapsulated and stabilized by fibrous tissue, and gliding or moving within the medullary cavity rather than being fixed to the bone (Ref. 189). A number of reports (Refs. 184, and 189 through 195) were found describing the use of the Swanson prostheses in the MCP joints

of the fingers, but few reports (Refs. 196 through 199) were available describing the use of this device in the MCP joint of the thumb, or the PIP joints of the fingers. In 1976, it was reported that a new "high performance" silicone elastomer material had been developed for use in the Swanson prosthesis. With the exception of one report (Ref. 198), the available clinical data was obtained using prostheses made from the "conventional" silicone elastomer. Fracture of implants made of the "conventional" silicone elastomer appears to be the most frequently reported failure. Beckenbaugh, et al. (Ref. 184), reported that of 186 Swanson prostheses implanted in the MCP joint for an average of 32 months (range 12 months to 65 months) 26.3 percent (49) had fractured. Hagert, et al. (Ref. 191), reported that of 104 Swanson implants evaluated, 25 percent (26) had failed, either by cracking or fragmenting and fracturing within the followup period of 1.5 to 5 years. Mannerfelt, et al. (Ref. 192), reported a fracture rate of 2.8 percent in 144 joints evaluated 1.5 to 3.5 years (average 2.5 years) after implantation. Ferlic, et al. (Ref. 193), reported a 9 months (average 3.2 years) after implantation. Swanson (Ref. 189) reported the lowest rate of fracture, 0.88 percent, in a field clinic series involving over 3,000 implants with a followup of from 6 to 30 months.

The effects of fracture of the device on the clinical results were evaluated by several authors. Aptekar, et al. (Ref. 194), described the occurrence of detritic synovitis (inflammation of the synovial tissue) due to shards of silicone rubber found in relation to a broken prosthesis. Beckenbaugh, et al (Ref. 184), noted that recurrence of deformity was associated with implant fracture, i.e., ulnar drift, in 14 percent; weakness or instability in 21 percent; hyperextension in 11 percent; and some clinical deformities in 43 percent; but that while the recurrence of deformity implied that soft tissue balance was not present after the implant fractured, it was not clear whether the imbalance caused the fracture or developed because of it.

Hagert (Ref. 195) believed that the increased displacement (i.e., ulnar deviation) noted in some joints with fractured implants may indicate insufficiency of the fibrous capsule surrounding the implant to restrain the forces occurring at the MCP joint. This pressure, combined with movement of the implant within the medullary canal was reportedly found to cause a moderately progressive bone resorption throughout the followup period in all of the 36 joints examined. Resorption was observed around the midsection of the prosthesis where the implant was in close contact with bone and around the intramedullary stems of the device. Erosion of bone around the midsection of the device led to various degrees of migration of the device in 28 out of 36 (78 percent) of the joints examined. The author found that decreased joint flexion was observed due either to the distal migration of the implant or a growing volar bony spur in 13 out of the 39 (33 percent) joints examined. He concluded that the design of the device may be insufficient to fully restrain the volarly and proximally directed forces in the MCP joint and the serious decrease of flexion. Hagert, et al. (Ref. 191), reported that while it is generally accepted that silicone rubber absorbs lipids and other substances, the effects on material changes and degradation is not adequately known. Weightman, et al. (Ref. 196), noted that lipid absorption could contribute to mechanical failure of the prostheses, as chemical deterioration is known to be a prime initiator of fatigue failures of polymers. Other clinical results have been reported in the literature (Refs. 189, 192, 196, and 198) on the use of this prosthesis in large numbers of patients. These results were very similar to those summarized previously.

Although finger joint polymer constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA had identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., fracture, loosening, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology. Clinical experience with these devices has established the persons for whose use the devices are intented and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweights any likelihood of injury of illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3300; Docket No. 78N–3070; Hip joint metal constrained prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of hip joint metal constrained prostheses:

1. Identification: A hip joint metal constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a acetabular component made of an alloy with an ultra-high molecular weight polyethylene insert, and is limited to those devices intended for implantation with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls of performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The Panel identified the following risks to health: (a) Loss or reduction of joint function: Improper

design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device, or loosening of the device in the surgical cavity. (d) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in and adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of material from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal constrained prostheses be classified into class III. The agency has obtained additional data and information describing the use of hip joint metal constrained prostheses. Sivash (Ref. 200) reported on implantation in 164 patients; followup time was 1 to 9 years. Breakage of the prosthesis was reported in 13 (8 percent) of the patients.

FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA also believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they can be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3310; Docket No. 78N–3071; Hip joint metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/polymer constrained prostheses:

1. Identification: A hip joint metal/polymer constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/polymer constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/polymer constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of hip joint metal/polymer constrained prostheses presents an unreasonable risk of illiness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, the agency believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3320; Docket No. 78N–3072; Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of a hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses.

1. Identification: A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, regidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary becuase sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature. Wilson, et al. (Ref. 201), reported on 100 McKee-Farrar total hip replacements performed in 86 patients. Substantial improvements were observed in walking function and mobility of hips for periods of 2 to 4 years following implantation. Wilson also noted that patients have been so satisfied with the devices, that continued use and further development of this type of operation is warranted. Prosthesis loosening in 20 percent of patients was the main complication.

Bentley, et al. (Ref. 202), performed hip replacements using 101 McKee-Farrar prostheses and 128 Charnley prostheses, both of which have the two components of the device fixed in place with bone cement. Total pain relief was obtained in 83 percent of the patients with the McKee-Farrar hip replacement compared with 96 percent of the patients with the Charnley hip replacement. Range of hip movement of more than 100 degrees was obtained by 88 percent of the patients with the McKee-Farrar hip replacement and 89 percent of the patients with the Charnley prosthesis. However, the Charnley prosthesis allowed an average of over 40 degrees more total range. During followup of patients from 1 to 4 years, complications included three deep wound infections and three cases of loosening of the femoral component of the McKee-Farrar compared with none with the Charnley. Bentley determined that the Charnley prosthesis gave superior results to the McKee-Farrar.

Using radiology, Mendes (Ref. 203) evaluated 100 hips replaced with cemented McKee-Farrar prostheses. A 12 percent failure rate was reported after 2 to 4 years of followup. Also reported was a 4 percent incidence of various radiologic signs which were associated with a high incidence of failure, such as new periosteal bone formation at the level of the prosthetic stem; progressive resorption of the neck stump; line of bone density surrounding the cemented implant; extensive heterotopic ossification; infection; and incidence of sterile (i.e., not associated with an infection) loosening.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presense of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses be classified into class III. The agency believes that a performance standard is necesary for these devices because general controls alone are sufficient to minimize the risks to health presented by these devices.

FDA finds that hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal/metal semi-constrained, with a cemented acetabular component, prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3330; Docket No. 78N–3073; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee,

made the following recommendation regarding the classification of hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses:

1. Identification: A hip joint metal/metal semi-constrained, with an uncemented acetabular component, proshtesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended to be used without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectivness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their review of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strenth and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device's components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses be classified into class III. FDA has obtained additional information regarding these devices. Ring (Ref. 204) has implemented about 1,000 of the devices using an uncemented acetabular component during an 8-year period with 942 devices available for followup. The early implants (169) had a followup time ranging from 5 to 8 years. In this group, 45 percent had excellent results, 29 percent had good results, 10 percent fair results, and 16 percent poor results. The second group (535) had a followup time of 1 to 5 years with excellent results being obtained in 69 percent of the cases, 21 percent good, 6 percent fair, and 4 percent poor. The remaining 238 cases were the most recent with followup time of less than 1 year. In the 942 cases reviewed, there were 35 revisions performed due to loosening. In the initial series, the revision rate was 14 percent, whereas the revision rate for the second series was only 2 percent. The third series had not had any revisions. Lindholm (Ref. 205) used the Ring prostheses with an uncemented acetabular component and reported 20 percent of the patients had little or no improvement after the device was implanted.

The agency has reviewed the pertinent engineering and clinical literature and has determined that insufficient information exists to establish a performance standard for hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses. FDA has found a lack of correlation(s) between pertinent preclinical mechanical tests (i.e., wear rates, fracture resistance, etc.) of this device and clinical findings. The agency notes that there is little information on the devices with an uncemented acetabular component available from investigators other than reports from the inventor/developer of the original design of this device (Ring). FDA believes that the initial clinical experiences of investigator Ring have not been shown to be representative of the anticipated general clinical experience with these devices, and that the available data and information are not sufficient to assure the safety and effectiveness of the device with an uncemented acetabular component.

FDA finds that hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of a substantial importance in preventing impairment of human health.

FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint metal/metal semi-constrained, with an uncemented acetabular component, prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3340; Docket No. 78N–3074; Hip joint metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/composite semi-constrained prostheses:

1. Identification: A hip joint metal/composite semi-constrained prosthesis is an implanted two-part device

intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of carbon fiber reinforced ultra-high molecular weight polyethylene. Both components are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: The Panel recommends that hip joint metal/composite semi-constrained prostheses be classified into class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/composite semi-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's clinical experience with similar devices and a series of presentations to the Panel (Refs. 206 and 207). Dr. Robert Johnson (Rensselaer Polytechnical Institute) compared the physical properties of the carbon fiber reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethylene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon fiber reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of toxicity tests on the carbon fiber reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up to 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; the systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The result of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon fiber reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from the patient who had received an ultra-high molecular weight polyethylene prosthesis in one ankle and a carbon fiber reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon fiber reinforced material. Dr. Volz concluded that the carbon fiber reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 207), Robert Fuson, M.D. (Zimmer-USA), summarized the clinical experience with prostheses made from the carbon fiber reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of joint function due to excessive wear, fracture, deformation of the device's components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of hip joint metal/composite semi-constrained prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug,

and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, the agency believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3350; Docket No. 78N–3075; Hip joint metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint metal/polymer semi-constrained prostheses:

1. Identification: A hip joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint metal/polymer semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint metal/polymer semi-constrained prostheses be classified into class II. FDA has obtained additional data and information on the use of hip joint metal/polymer semi-contsrained prostheses. The following device-related risks to health were either identified by the Panel or reported in the literature: (a) Device loosening, (b) calcar resorption, (c) femoral component fracture, (d) excessive acetabular component wear, and (e) adverse tissue reaction to the wear debris produced by the device.

(a) *Device loosening:* Device loosening has been reported as a complication that results in pain and inability to walk (Ref. 208). FDA notes that the etiology of this complication is not known. Several postulated causes are: (1) sepsis; (2) cancellous bone fatigue; (3) prosthetic failure due to the device design; (4) bone resorption; (5) concentration of stresses due to the varying modulus of elasticity of bone, cement, and prosthesis; (6) granulomatous reaction to wear particles; and (7) bone necrosis and tissue reactions caused by thermal effects of bone cement. Reports in the literature indicate that aseptic loosening of cemented acetabular and femoral components occurs in a significant number of cases (Refs. 209 and 210), and that the rate of loosening may increase over time (Refs. 211 and 212). In a 1977 review of the experience with total hip prostheses, Wilson, et al. (Ref. 213), concluded that further research was needed in preventing the breakdown of the bone/bone cement interface.

A number of writers have discussed the association between device loosening and the presence of a radiolucent line observed as a demarcation between the bone cement that is holding the prosthetic component in place and the underlying supporting bone. Several authors believe that radiolucent lines observed at the bone/bone cement interface do not always signify looseness or implant failure (Refs. 214 through 217). Some writers, however, such as Desemet, et al. (Ref. 215), believe that while radiolucent lines at the edge of the bone cement in the femur are not necessarily associated with clincial evidence of loosening (e.g., severe pain on walking), they do indicate a lack of firm bonding which may predispose the patient to loosening at a later date. Other authors (Refs. 218 and 219) suggest that the progressive development of a radiological separation of the convex curve (lateral border) of the prosthesis from the cement is the first sign of femoral component loosening.

A number of authors (Refs. 220, 221, and 222) identified resorption of bone in the region of the calcar at the proximal end of the femur as contributing factor in device loosening. Simon, et al. (Ref. 223), reported that fatigue of the cancellous bone in the acetabulum is a possible explanation for device lossening. Still other investigators (Refs. 224 and 225) believe that eventual loosening of the prosthesis is due to a foreign body reaction to particles of polyethylene material that leads to replacement by soft tissue of bone at the bone/bone cement interface.

(b) *Calcar resorption:* Resorption of bone in the region of the calcar has been reported (Refs. 222, 226, and 227) as a probable contributing cause of cement failure, prosthesis loosening, or fracture of the femoral component of hip prostheses. The etiology of this complication is not known, but several possible causes have been discussed in the medical literature. Oh and Harris (Ref. 222), for example, reported that calcar resorption may be due to disuse atrophy of the bone in this region, causing increased cement failure, prosthesis loosening, and stem fracture. These authors also noted that the design of the prosthesis affects the transfer of forces to the bone in the calcar region and could contribute to the resorption of the calcar femorale observed after total

hip replacement. Marmor (Ref. 218) described 10 cases of femoral component loosening occurring in patients who were overweight. This author suggested that collapse of the cancellous bone in the region of the calcar and femoral component loosening may be a result of the stress of excessive body weight on the femoral component. Harris, et al. (Ref. 228), described four cases of extensive bone resorption in the region of the calcar occurring 33 months to approximately 5 years postoperatively. These authors noted that while the cause of bone resorption in these cases is not known, they believe that the lysis was secondary to loosening and fragmentation of the bone cement. Charnley and Cupic (Ref. 230) reported that, in some cases of calcar resorption, there may be evidence of harmful tissue reaction to particles of polyethylene worn away from the hip socket. In a subsequent publication, Bocco, Langan, and Charnley (Ref. 220) reported that while the role that wear particles of polyethylene play in destructive changes in the calcar are unknown, there is no doubt that these particles are frequently found during histological examinations of the calcar region.

(c) *Femoral component fracture:* Fracture (fatigue failure) of the femoral component of a hip prosthesis is believed to be a product of repetitive cyclic load (such as occurs during walking), usually initiated at a point of high tensile stress (such as the lateral surface of the stem). Cracks form in the material and grow slowly across the stem until the reamining metal cannot support the body weight and fractures completely (Ref. 227). A number of device-related factors which may predispose an implant to fracture were identified in the literature, including: (1) the use of materials with inadequate mechanical properties (Refs. 227, 231, 232, and 233); (2) inadequate quality controls in manufacture and metallurgical defects in the device (Refs. 227, 233, 234, 235, 236, and 269); (3) device design (Refs. 227 and 236); and (4) mechanical loosening of the femoral component following loss of cement support in the calcar region (Refs. 222, 226, 227, 238, and 270). A number of authors (Refs. 231, 234, 237, and 238) have reported the incidence of femoral stem fracture in their patients to range from 0.23 percent to 11 percent in the first 5 years. Some authors (Refs. 236 and 239) believe that the incidence of fracture increases with longer postoperative followup.

The role of calcar resorption in femoral stem failure was discussed by several authors. Andriacchi, et al. (Ref. 226), found that the loss of proximal stem support at the region of the calcar femorale will result in fatigue failure of the device component. Markolf and Amstutz (Ref. 236) report that a minimal degree of loosening may result in a marked increase in tensile stress imposed on the device. Charnley (Ref. 237) believed that erosion of the bone in the region of the medial femoral neck (i.e., the calcar femorale) leading to defective cement support of the device in this area was possibly the predominant factor leading to fracture of the prosthesis. Marmor (Ref. 218) described the following sequence of events in the patients whose prostheses eventually fractured: bony resorption in the region of the medial femoral neck, followed by fracture of the bone cement, medial displacement of the femoral implant components and, ultimately, bending or breakage of the device.

(d) *Acetabular component wear:* An increased wear rate of the acetabular component of the device is believed to be due to the presence of trapped particles, such as polyethylene wear debris, bone, or bone cement (Refs. 225, 240, 241, and 242). Several aspects of prosthesis design (i.e., the size of the head of the femoral prosthesis) and quality control of the components (i.e., properties of the polyethylene material, and the surface finish of the metallic component) were noted to affect the rate of polyethylene wear (Refs. 241 and 243). Clarke, et al. (Ref. 244), and other authors (Refs. 240, 245, and 246) have examined acetabular components that had been removed from patients. They believe that the in vivo wear rate could be as low as 0.01 millimeter per year but it can increase to as high as 0.5 millimeters per year if bone cement particles are present and induce wear of these components. Dowling, et al. (Ref. 240), believe that laboratory tests alone are not sufficient to predict the long-term wear and deformation of the polyethylene component in the human body. They have found that the device wear rates are higher in the body than laboratory tests predict and believe that this increase is due to the presence of joint fluid and the temperature of the hip joint and may lead to stress corrosion and creep of the polyethylene material.

(e) *Adverse response to wear debris:* A number of authors discussed the possible long-term effects of wear debris. Winter (Ref. 247) noted that the material characteristics responsible for biological reactivity of foreign bodies are size, shape, chemical composition, surface properties, and the number of particles present. While the physical properties of the implant inserted by the surgeon can be specified (i.e., standards on material composition), inevitable wear and corrosion produce undefined soluble and insoluble materials whose potential effects are largely unknown. Bullough (Ref. 248) commented that the physical size of the particles may be very important. This author states that medical experience with particulate wear debris from joint implants is relatively limited compared to experience with other implants such as bone nails and bone plates. Other investigators (Refs. 210 and 224) believe that a foreign body reaction to particles of polyethylene material will lead to replacement by soft tissue of bone at the bone-cement interface and eventually to loosening of the prosthesis.

Summary of clinical results: Clinical results of less than 5 years were available for the following designs of the hip joint metal/polymer semi-constrained prosthesis (Refs. 249 through 268); Charnley-Muller, Aufranc-Turner, Harris, Minneapolis, Leinbach, St. George, Bechtol, Brunswick, and the Trapezoidal-28. Clinical results from use of the devices for 5 or more years were available for only two of these designs, the St. George and the Charnley (Refs. 229, 230, 261, 272, 273, and 274).

Buchholz and Noack (Ref. 261) reported results following implantation of the St. George design prosthesis. They reported followup for over 5 years for 271 cases, followup between 2 to 5 years for 1,731 cases, and less than 2 years followup for 1,203 cases. The average age of the patients at the time of surgery was 61 years (range 17 to 95 years). These authors found that pain was reduced and gait distance and mobility of patients had improved more than 100 percent when compared to the preoperative conditions. The following complications and complication rates were found: aseptic loosening—1.09 percent; fracture of the prosthesis—0.06 percent; transitory nerve damage—1.52 percent; permanent nerve damage—0.41 percent; dislocation of the device components—1.15 percent; periarticular calcification and ossification—7.64 percent; deep infection—2.3 percent; and pulmonary embolism—0.4 percent. There were 248 deaths (7.4 percent). The cause of 13 (0.4 percent) of these deaths was identified and reported to be due to pulmonary embolism.

Results of use of the Charnley prosthesis for over 5 years were reported by Nicholson (Ref. 229) and by Charnley and his coworkers (Refs. 230, 272, 273, and 274). Nicholson reported on the implantation of 900 Charnley prostheses with followup ranging from 1

to 6 years. Results of use for 5 or more years were reported on 30 of these 900 device implantations. The author calculated the incidence of mechanical problems occurring in prostheses which had been implanted for 3 to 4 years. Thirteen (8.5 percent) of the devices (seven femoral components and six acetabular components) had loosened, and the femoral component of one device had fractured. The author also reviewed the radiological results in 250 consecutive cases. The clinical followup times of these cases were not given. Resorption of 5 to 8 millimeters of bone at the proximal end of the femur (calcar femorale) was observed in 57 hips (22.8 percent). The femoral component was observed to have settled in nine (3.6 percent) of the cases.

Charnley and Cupic (Ref. 230) reported on the implantation of 106 Charnley prostheses with a clinical followup of 9 to 10 years. The average age of the patients in this series was reported to be 65 at the time of the operation. Pain, function, and mobility were evaluated in these patients. Eighty-eight hips (83 percent) were rated free of pain and eight others (7.5 percent) were reated as having slight or transient pain. Function was evaluated in 53 hips, and was rated as normal in 45 hips (85 percent), taking into account the advanced-age of a number of patients. Mobility was assessed in 75 hips. Fourteen hips (18.6 percent) were rated normal and 45 (60 percent) as having a total range of motion of between 161 and 120 degrees. The total failure rate was reported as 9.6 percent, three failures (3.0 percent) due to mechanical lossening of the device components, and eight failures (6.6 percent) due to infection.

Griffith, Seidenstein, el al. (Ref. 274), reviewed the long-term results of the Charnley prosthesis used in 461 patients, 86 of whom had hip prostheses implanted in both hips for a total of 547 hip replacement operations. Pain, function, and mobility were evaluated in these patients and of the 547 operated hips, 472 (86 percent) were free of pain; 61 (11 percent) had slight or intermittent pain; 11 (2 percent) had pain; and 3 (0.5 percent) had severe pain. Function and mobility were evaluated in all cases and the operation was reported to be 80 to 85 percent successful. The following complications and complication rates were reported: Three cases of fracture of the femoral component; seven cases of femoral component loosening; five cases of acetabular component loosening; eight cases of device dislocation; and a 2.2 percent incidence of infection. In addition, the authors evaluated the incidence of pathological changes at the cement-bone interface and reported: cavitation of the bone of the calcar in 25 hips (4.5 percent); cavitation of the acetabulum in 1 case; the presence of endosteal cysts in the femur in 2 patients; and subsidence of the femoral component in 49 hips (8.9 percent). There was some degree of cement demarcation of the femqral component in 44 cases (7.9 percent) and of the acetabular component in 294 cases (53.7 percent). The agency reviewed additional publications, but they lacked sufficient information on either the number of patients in whom the devices had been implanted for 5 or more years or the results obtained in these patients (Refs. 258, 259, 260, and 271).

Although hip joint metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health that have been associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use, except the uncertainty of predicting in which patients bone cement problems will arise. FDA has determined that the probable benefit to health from proper use of these devices outweights any likelihood of injury or illness resulting from the use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3360; Docket No. 78N-3077; Hip joint femoral (hemi-hip) metallic prosthesis.

The Orthopedic Device Classification Panel, an advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) metallic prostheses:

1. Identification: A hip joint femoral (hemi-hip) metallic prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with a polmethylmethacrylate luting agent (bone cement), as well as designs which have large window-like holes in the stem of the device and which are intended to be used without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) metallic prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss of reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a hip joint femoral (hemi-hip) metallic prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from

the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) metallic prostheses be classified into class II. FDA believes that the hip joint femoral (hemi-hip) metallic prosthesis presents essentially the same risks to health as that of the femoral component alone, of the hip joint metal/polymer simi-constrained prosthesis used for total hip replacement (see § 888.3350; Docket No. 78N–3075). Therefore, the discussion and references cited in § 888.3350 are incorporated by reference to support the proposed classification of hip joint femoral (hemi-hip) metallic prostheses into class II.

Although hip joint femoral (hemi-hip) metallic prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses to the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3370; Docket No. 78N–3076; Hip joint (hemi-hip) acetabular metal prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of hip joint (hemi-hip) acetabular metal prostheses:

1. Identification: A hip hoint (hemi-hip) acetabular metal prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint (hemi-hip) acetabular metal prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint (hemi-hip) acetabular metal prostheses be classified into class III. The agency finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the hip joint (hemi-hip) acetabular metal prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3380; Docket No. 78N–3078; Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses:

1. Identification: A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated

cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis stem is intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendations: The Panel recommends that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and on a presentation to the Panel. Dr. Ian Goldie (University of Goteborg) (Ref. 285) presented the results of several Norwegian studies with these prostheses. Dr. Goldie referred to Christiansen's series of 241 hips in which excellent results were obtained in 57 percent of the cases and good results in 33 percent. In this series, there were five infections, seven cases of loosening of the acetabular cup, two dislocations shortly after operation, two cases of femoral perforation, and three cases of heterotopic ossification. Dr. Goldie then presented the results of his own series of 61 patients. In the 19 patients with 2 years followup, and in the 28 patients with 6 months followup, there were no complications. However, in the remaining 14 patients with a followup of 1 year, there were the following complications: 2 dislocations between the head and the cup, 2 cases of heterotopic ossification, and 2 patients with inexplicable pain.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechnical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction in joint function due to excessive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. A review of the medical literature revealed a disagreement regarding the resistance to wear of polyacetal materials. McKellop, et al. (Ref. 286), report that laboratory wear rates for polyacetal range from 70 percent lower than polyethylene to 540 percent higher. Dumbleton (Ref. 287) reports wear in the trunnion sleeve of the device and that polyacetal exhibits a low resistance to wear. Because of the potential problems involving its resistance to wear, the long-term effectiveness of this device is questionable. The initial investigator and his associates have been the primary users of this device. Long-term followup data available only from the initial investigator. Clinical cases documenting effectiveness and safety of the device involving usage of less than 3 years.

FDA finds that hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that uncontrolled use of hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified in class III, unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support a conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3390; Docket No. 78N-3079; Hip joint femoral (hemi-hip) metal/polymer prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) metal/polymer prostheses:

1. Identification: A hip joint femoral (hemi-hip) metal/polymer prosthesis is an implanted device intended to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with a polymethyl-methacrylate luting agent (bone cement) or implanted by impaction.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) metal/polymer prostheses be classified into class II because the design, meterial compostion, and mechanical properties of the device,

such as its flexibility, rigidity, strength, and surface finish should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that performance standard will control the risks associated with the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendations is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, their knowledge of the medical literature, and presentations of clinical data made before the Panel.

Drs. Richard Strauss and Andrew Schildhous (Bronx-Lebanon Hospital Center) made a presentation before the Panel on the clinical performance of the Bateman hip prosthesis (Ref. 288). Dr. Strauss outlined his 5-year experience with the Bateman prosthesis in 84 patients. The primary diagnosis in these patients was intracapsular fracture of the proximal femur. Dr. Strauss stated that the of question of whether the femur stem of the implant should be cemented or noncemented was decided at the time of surgery. The complications reported during the clinical study were for dislocations and two superficial infections. Dr. Strauss pointed out that, to date, there has been no clinical evidence of acetabular wear in any of the cases.

Dr. William Weat (San Leandro, CA) presented to the Panel his experience with the Bateman prosthesis on a series of 55 hips in 53 patients. Complications in the clinical study included two dislocations. In addition, five patients died of unrelated causes, three were converted to total replacement, and two could not be traced. The followup period averaged 19½ months for 43 patients, representing 45 hips. Pain was absent in 36 patients, mild in 6, and significant enough to limit function in 1. Gait was normal in 27 patients, limited by some unrelated problem in 12, and limited by some problem related to the hip prosthesis in 6. The range of motion was considered functional in 39 patients and limited in 6. Overall, the results were considered excellent in 69 percent of the patients, good in 22 percent, and poor in 4 cases (9 percent). Dr. West concluded that the Bateman design of the hip joint femoral (hemi-hip) metal/polymer prosthesis is a satisfactory method of treatment for a number of disorders of the femoral head and neck and that these results will stand the test of, at least, and intermediate period of time. Dr. West commented that fluoroscopic examination of the hip during walking indicated that the prosthesis is capable of functioning as designed for at least 30 months postoperatively.

5. Risks to health: (a) Loss or reduction of joint function: Improper design of inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) metal/polymer prostheses be classified into class II. The agency has obtained additional data and information describing the use of the hip joint femoral (hemi-hip) metal/polymer prostheses. The most common problems associated with use of the device that have been reported in the literature are device dislocation and related complications. Anderson (Ref. 289) reported on two cases of dislocation and component separation of the Bateman hip prosthesis, which he believed were due to inadequate immobilization of the patient after surgery. Barmada (Ref. 290) has also reported two cases of dislocations, which he attributes to impingement of the outer cup within the acetabulum while the hip was forced into flexion, adduction and internal rotation. Drinker and Murray (Ref. 291) compared 101 Bateman hemiarthroplasties with 160 cemented Thompson hemiarthroplastics with respect to complications and short-term results. Ten patients with the Bateman implant and 10 with a Thompson device were examined an average of 3.0 and 3.4 years postoperatively. The differences in the mean Harris-hip rating score were significant and probably resulted from the mean differences in their mean ages (74.4 and 81.1 years). There were nine dislocations for seven patients with the Bateman prostheses. Five of the nine could not be rectified by closed reduction. In the Thompson series, 12 dislocations occurred in 7 patients. All were successfully treated via closed reduction. Drinker and Murray believe that motion at the low-friction inner bearing of the Bateman prosthesis, which was expected to provide added stability and lower rates of dislocation compared to conventional single-bearing designs, either does not occur in vivo as predicted or that other more important factors are operative in determining the potential for dislocation. These authors performed motion studies in thirteen patients at 2.0 and 3.4 years postoperatively, and found that far less inner bearing motion existed than is allowed by the implant itself. In half of the patients, there was a reduction in inner bearing motion over time, and in almost all patients studied at any given time there was a marked reduction in inner bearing motion with weight-bearing compared with the supine unloaded position. The reduction in inner bearing motion on weight bearing was believed to be caused by an increase in inner bearing friction when the concentric artificial bearing surfaces of the device are compressed, lose lubricant, and become relatively less mobile, while the less concentric outer bearing surfaces (i.e., the acetabular cartilage and the cobalt-chromium surface of the device) may retain lubricant and remain relatively more mobile.

Langan (Ref. 292) reported on 90 Giliberty bipolar prostheses that he implanted. Sixty-five prostheses were available for followup. The average followup time was 19 months. Eighty-six percent of the operated hips had very good or excellent motion. Roentgenograms were taken immediately after the operations. The cups of the prostheses were seen to be in neutral orientations with the patients own pelvis (i.e., approximately 45 degrees to the transverse axis of the pelvis). By 1 year followup, however, only 12 percent were noted to be in the neutral position; the remainder had gone into a vertical position. Also, four dislocations occurred, which Langan attributed to poor surgical technique or judgment. Langan reported that the short-term clinical results were excellent, but longer term clinical data are needed.

Although hip joint femoral (hemi-hip) metal/polymer prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health

accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, dislocation, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health accompanying the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3400; Docket No. 78N–3080; Hip joint femoral (hemi-hip) resurfacing prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hip joint femoral (hemi-hip) resurfacing prostheses:

1. Identification: A hip joint femoral (hemi-hip) resurfacing prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that hip joint femoral (hemi-hip) resurfacing prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint femoral (hemi-hip) resurfacing prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. In addition, the Panel reviewed literature pertaining to the device. Aufranc and Sweet (Ref. 293) reported on the clinical results obtained from use in 171 patients. Results were classified as excellent, good, or satisfactory in 164 hips (82 percent) and unsatisfactory in 37 (22 percent). Johnson and Larson (Ref. 294) reported the results of followup of 251 patients with a minimum followup of 3 years. Overall improvement occurred in 90 percent of the patients; pain relief occurred in 67 percent and pain was reduced in 90 percent.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that hip joint femoral (hemi-hip) resurfacing prostheses be classified into class II. Although hip joint femoral (hemi-hip) resurfacing prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3410; Docket No. 78N–3081; Hip joint metal/polymer semi-constrained resurfacing prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of hip joint metal/polymer semi-constrained resurfacing prostheses:

1. Identification: A hip joint metal/polymer semi-constrained resurfacing prosthesis is an implanted two-part device intended to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral cap component made of alloy, such as cobalt-chromium-molybdenum, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the device be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although hip joint metal/polymer semi-constrained resurfacing prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a

performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the devices, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excesive wear, fracture, deformation of the device components, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that hip joint metal/polymer semi-constrained resurfacing prostheses be classified into class III. The agency has obtained additional data and information on the use of hip joint metal/polymer semi-constrained resurfacing prostheses. Total surface replacement hip arthroplasty developed as a result of experience gained with conventional hip replacement and Smith Petersen's cup arthroplasty. In 1951, Charnley (Ref. 295) carried out the first double cup replacement of the hip utilizing polytetrafluoroethylene. These prostheses were fixed to the bone without bone cement. It is now known that polytetrafluoroethylene is an unsatisfactory material when it articulates against itself. The resultant debris leads to a low grade inflamatory response in which granulation tissue invades the boneprosthesis interface and loosens the prosthesis. Failure, therefore, was not inherent in the concept but resulted from the absense of satisfactory materials and bonding techniques. In 1960, Townley used polyurethane to anchor a metal cup to the femoral head and to resurface the acetabulum. The material and the results were so unsatisfactory that the procedure was abandoned (Ref. 295). The third attempt to modify conventional cup arthroplasty was carried out by Muller in 1968 (Ref. 295). Muller employed components fabricated from cobalt-chrome alloy. The symptomatic results were unsatisfactory and the prostheses were not stable on the femur. As a result, he abondoned the procedure. In 1970, Gerard used cups composed of cobalt-chrome alloy that were not cemented. The results were not fully satisfactory and Gerard therefore introduced a prosthesis in which the acetabular component was made of high density polyethlene and the fermoral component of metal. The high density polyethylene acetabular component moved against both the metal femoral component and the bone, generating polyethlene wear debris. Bone resorption resulted and, hence, Gerard abandoned this prosthesis. Gerard then introduced his third and present prosthesis in which the acetabular component had a metal outer surface moving against the bone of the acetabulum and an inner surface fashioned of polyethylene which moved against the metal femoral component.

During 1970–1977, Gerard (Ref. 296) implanted various designs of his device in 337 hips. He reported that the results in 289 hips which had been followed for over 6 months were excellent in 114, good in 124, fair in 41, and poor in 10. The failures, with the exception of cases of infection or periarticular calcification, were attributed to the early material combinations and to the surgical technique.

In 1971, Trentani at the Rizzoli Institute in Bologna (Ref. 297) and Furuya (Ref. 298) in Tokyo independently carried out a cemented double cup arthroplasty. Trentani reported excellent results in 76 percent of his cases over a 2 to 6 year followup. He reported a total of 9 failures (12 percent) out of 70 patients. Four of the cases were breakage at the base of the neck of the femur following violent trauma. In the other five cases, the femoral component loosend. Furuya (Ref. 298) performed the operation on 13 hips with followup ranging from 3 to 6 years. In seven of these cases, revision was required within a period of 1 through 5 years. The reasons for the failure were fracture of the femoral neck secondary to osteonecrosis in one hip and loosening of the acetabular socket in six hips.

Freeman (Ref. 299) began work on double cup arthroplasty in 1970. From 1972 through 1974, 32 hips were replaced. Fourteen of these devices failed. These failures were attributable to loosening. The first 16 prostheses consisted of a polyethylene femoral component and a metal acetabular component. In five of these hips, one or both components loosened. Freeman believed that the high incidence of loosening in this group of hips was due to the fact that convex polyethylene wears rapidly and thus generates large quantities of intra-articular polyethylene debris. Freeman postulated that eight femoral neck fractures could be attributed to varus placement of the prosthesis and the making of a notch in the superior cortex. The prosthesis was then redesigned so that the femoral component was metal. From November 1974 to December 1977, 116 hips were implanted with the new design. Range of motion was improved in 90 percent of cases. Complications were minimal. One femoral neck fracture was reported along with one incidence of loosening.

Capello (Ref. 300) reported on use of the device in 66 cases. These cases were followed over an average of 22 months. According to the Iowa Hip Rating Scale that Capello employed, an average score of 91.4 out of 100 was reported. The average range of motion was 105 degrees. He reported eight femoral neck fractures and loosening of eight acetabular components.

Wagner (Ref. 301) performed 322 metal resurfacing operations. His results were generally favorable, with only a total of six components loosening. Tanaka (Ref. 302) performed 37 surface replacements on 57 joints. The average followup was 2 years. Seventy-three percent of the hips were pain-free. Walking ability improved in 31 patients. In 1975, Amstutz (Ref. 303) developed a further variant of a cemented double cup prosthesis. In 100 procedures with an average followup of 8 months, only 3 cases required revision. Walking function, arc of flexion, and rotation improved after the operation.

FDA finds that hip joint metal/polymer semi-constrained resurfacing prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare

favorably with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectivenesss of these implanted devices, FDA believes that uncontrolled use of the hip joint metal/polymer semi-constrained resurfacing prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3480; Docket No. 78N–3082; Knee joint femorotibial metallic constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metallic constrained prostheses:

1. Identification: A knee joint femorotibial metallic constrained prosthesis is an implanted device intended partially to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metallic constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint femorotibial metallic constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device, and its review of the medical literature. Results from using the device in more than 720 cases have been reported in the medical literature in the United States during the past 3 years (Refs. 304, 310, and 313). There are also reports in the medical literature documenting use of the device in several thousand cases worldwide during the past 10 years. The Panel believes that this extensive clinical use has revealed the usual mechanical problems, implant loosening and settling. The Panel determined that the overall risks resulting from use of the prosthesis were no worse than the risks associated with major knee surgery without implantation of a prosthesis.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metallic constrained prosthesis be classified into class II. The agency believes that there is sufficient information to establish a performance standard for this device. Of the 957 patients reviewed by the Panel who have had this prosthesis implanted and who were discussed in the worldwide medical literature (Refs. 304 through 314), 108 (11 percent) suffered implant failure, 233 (24 percent) of the cases had complications, and 104 (11 percent) had loosening of the prosthesis.

FDA has sought additional data on the safety and effectiveness of this device. Kettelkamp (Ref. 315) reported that the failure rate for the device ranges from 5 percent to 24 percent for the hinged metal knee prosthesis, with a short followup time. Kettlekamp (Ref. 315) and Chand (Ref. 316) both believe that excessive forces may be applied to the intramedullary stem bone cement interface because the constrained prosthesis hinge prevents medial/lateral joint movement. Kettlekamp believes that if the stem loosens the cement may rub away and destroy the surrounding bone, causing a larger cavity and making revision difficult or impossible.

Kettlekamp reviewed reports in the medical literature on use of 576 Walldius hinged knee prostheses. In one group of 144 implantations, complications occurred in 29 cases (13 percent). In the remaining 432 cases, 89 (20 percent) were classified as failures, 33 (7 percent) required reoperations, and 53 (12 percent) had loosening. Fractures occurred in 11 cases (2 percent) and deep infection was reported in 35 knees (8 percent). Kettlekamp reported that the incidence of complication increased with the length of reported followup. Brady (Ref. 313) reviewed results of implanting the Shiers design of this device in 288 knees. He reported poor results in 71 knees (24 percent), reoperation was required in 33 knees (11 percent), and loosening observed in 56 knees (19 percent). Brady states that the major problems involved with use of this prosthesis are the absence of axial (medial) rotation, the necessary resection of large amounts of bone, and the creation of physiologic dead space.

Kettlekamp (Ref. 315) and Deburge, et al. (Ref. 317), report that the major problem with the Shiers design prosthesis is loosening. Deburge reported a loosening rate of 15 percent (22 patients) during a 5-year followup of the request of implanting the Guepar contrained knee prosthesis in 152 patients. However, less than half of these instances of device loosening were

symptomatic (10 of 22 patients). Reoperations were peroformed on the 10 patients. Other authors (Ref. 310) believe that the rate of loosening of the prosthesis is higher, possibly around 80 percent, but that only a small percentage of those patients with device loosening are symptomatic.

Arden and Kamdar (Ref. 318) reported followup for 7 years on implantation of 193 Shiers design prostheses. They reported that 11 percent of the patients had aseptic loosening. Kaushal (Ref. 319) reported followup examination of a series of 30 knees about 42 months following implantation of the prosthesis. The examination revealed that 13 knees (46 percent) had phlebothrombosis, 8 knees (11 percent) and asymptomatic loosening, 4 knees (5.4 percent) had deep infections, and 3 knees (4.3 percent) had symptomatic loosening. The major problems with use of the prosthesis were settling, loosening, and limitation on the range of joint motion allowed. In preliminary data, Van Camp (Ref. 320) showed that stress loading appeared to cause mechancial loosening of the device.

Walker (Ref. 321) stated that the valgus angle of the knee was ignored in the older designs of this prosthesis. Walker said this design problem resulted in lateral stress on the intramedullary stems of the device. This theory was verified experimentally by Wagner and Bourgois (Ref. 322). Wagner and Bourgois also showed that, in both the Walldius and Shiers designs of the prosthesis, the prosthesis' axis of rotation was not equivalent to the axis of the anatomic joint it replaced. These researchers said the pin in the Shiers prosthesis was turned down on the axis and that it might loosen if the prosthesis were overstressed. Because the axle pin of the Walldius prosthesis is clamped on one side, the location of the axis causes localized wear.

Although infection immediately following implantation of a prosthesis is primarily a result of surgical technique, Swanson, et al. (Ref. 323), state that the design of the prosthesis may minimize the rate of infection associated with implantation. Swanson found that the infection rate was lower when less bone was removed for insertion of the device. Phillips and Taylor (Ref. 308) report that most groups of patients who have received this prosthesis have suffered about a 10 percent higher incidence of infection than patients in whom other generic types of knee prostheses have been implanted.

In cases of total failure of implantation of a joint prosthesis, the prosthesis may be removed and the joint fused (arthrodesis). The rate of success is performing arthrodesis is related to the amount of bone that was removed to implant the device. Arthrodesis is difficult following implantation of a constrained joint replacement device (Ref. 324).

Although knee joint femorotibial metallic constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the devices. In addition, FDA has indentified and assessed the major risks to health accompaning the use of the devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illiness resulting from their use. FDA further believes that information labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necesssary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3490; Docket No. 78N–3083; Knee joint femorotibial metal/composite non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of knee joint femorotibial metal/composite non-constrained prostheses:

1. Identification: A knee joint femorotibial metal/composite non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon-fibers composite and are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/composite non-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations made to the Panel (Refs. 325 and 326). Dr. Robert Johnson (Rensselear Polytechnic Institute) compared the physical properties of the carbon-fiber-reinforced ultra-high molecular weight polyethylene composite material with the physical properties of conventional polyethylene material. He found that the reinforced material was superior to the conventional polyethylene material regarding compressive deformation, flexural stress, compressive creep, modulus of elasticity, and fatigue. Dr. Johnson also noted that the technology of composite materials such as carbon-fiber-reinforced polyethylene is in its infancy with regard to engineering in general.

Dr. Jack Lemons (University of Alabama) presented the results of

toxicity tests on the carbon-fiber-reinforced material. The results of in vitro tests showed the material, and extracts from the material, to be noncytotoxic to monolayers of cells and nonhemolytic to rabbit blood. The results of in vivo tests indicated that the material was nonirritating, nontoxic, and did not produce adverse effects after up to 15 months of implantation. The results of subacute toxicity tests indicated that intracutaneous extracts of the material were nonirritating when injected into rabbits; that systemic injections produced no adverse effects in mice; and that when the material was implanted along the backs of rabbits, it was nontoxic when it was evaluated at 6 and 12 weeks. The results of the chronic toxicity tests indicated that polyethylene material reinforced with carbon fibers was noncytotoxic, nontoxic, nonirritating, and produced no adverse effects when it was injected into the knee spaces of four rabbits and evaluated 15 months later. Dr. Lemons determined that these tests show that the carbon-fiber/reinforced material is biocompatible.

Dr. Joel Schilling (Portland, OR) presented a report on the histological examination of pieces of tissue removed from a patient who had received an untra-high molecular weight polyethylene prosthesis in one ankle and a carbon-fiber-reinforced ultra-high molecular weight polyethylene composite prosthesis in the other. Dr. Schilling found that there was minimal tissue reaction to either type of material and that there seemed to be very little reaction to the carbon fragments.

Dr. Robert Volz (University of Arizona) presented a comparison of the effect of temperature on the conventional ultra-high molecular weight polyethylene and on the carbon-fiber-reinforced material. Dr. Volz concluded that the carbon-fiber-reinforced material offered considerable improvement in its resistance to deformation at body temperatures (i.e., 37° C) and at 96° C, the temperature reached during polymerization of methylmethacrylate cement.

At the July Panel meeting (Ref. 326) Robert Fuson, M.D., (Zimmer-USA) summarized the clinical experiences with prostheses made from the carbon-fiber-reinforced material. A total of 86 acetabular components for total hip prostheses, 18 tibial components for total knees, and 23 tibial components for total ankles have been implanted. Of these, 65 hip, 18 knee, and 22 ankle components have been implanted for more than 6 months. Only 61 hip components, 11 knee components, and 12 ankle components have been implanted for over 1 year. Only five implantations (ankle) had been clinically followed for 2 years. No adverse reactions related to these prostheses were reported.

5. Risks to health: (a) Loss or reduction of joint function: Improper design, or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/composite non-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. Because these devices have not been studied for more than 2 years, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended an the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femorotibial metal/composite non-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3500; Docket No. 78N-3302; Knee joint femorotibial metal/composite semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/composite semi-constrained prostheses:

1. Identification: A knee joint femorotibial metal/composite semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fiber composite and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/composite semi-constrained prostheses be classified into class III because these devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' clinical experience with similar devices and a series of presentations to the Panel (Refs. 325 and 326). A discussion of these presentations is given in this preamble under § 888.3490.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to a dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/composite semi-constrained prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femorotibial metal/composite semi-constrained prosthesis presents a potential unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3510; Docket No. 78N–3084; Knee joint femorotibial metal/polymer constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer constrained prostheses:

1. Identification: A knee joint femorotibial metal/polymer constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit onto the metallic tibial component. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint femorotibial metal/polymer constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device. Long-term followup data are not available for this generic device. The only clinical data available on use of this device is reported by Matthews, Kaufer, and Sonstegard, the inventors/developers (Ref. 327). These data have shown 22 patients having 25 prosthesis implanted with a followup of 1 to 1.5 years.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/polymer constrained prostheses be classified into class II. The agency believes that there

is sufficient information to establish a performance standard for this device. FDA notes that clinical results after long-term (5 or more years) implantation of the devices have not been reported. Matthers, et al. (Ref. 328), report that the recipients of the implants have only been followed for up to 2 years. FDA notes that the only available pertinent publications (Refs. 328 and 329) are those of the initial investigations of the new prosthesis design.

Despite the absence of published reports of long-term clinical followup, FDA has determined that premarket approval of knee joint femorotibial metal/polymer constrained prostheses is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Short-term clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health accompanying the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3520; Docket No. 78N–3085; Knee joint femorotibial metal/polymer non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer non-constrained prosthesis:

1. Identification: A knee joint femorotibial metal/polymer non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as combalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene, and are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer non-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although knee joint femorotibial metal/polymer non-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and its proposing that knee joint femorotibial metal/polymer non-constrained prostheses be classified into class II. FDA has sought additional data and documentation of the safety and effectiveness of these devices. Marmor (Refs. 330 and 331) reported early results from use of the device. In 1977 (Ref. 332), Chand reported Marmor's results with 103 patients (21 bilateral) with a followup range of 24 to 42 months. The reported incidence of complications ranged from: general—none reported; remote—6 deaths (5.7 percent) from causes reportedly unrelated to the device; systemic—one thrombophlebitis (less than 1 percent); and local—at least 29 percent. The most frequent complication early in the series of patients was immediate postoperative infection with an incidence of 28.8 percent (21 of 73). The next most frequent complication was tibial component loosening, with a reported incidence of 11.6 percent (12 of 102). The reoperation rate for this series was reported as 12 of 123 knees or 9.8 percent.

FDA's review of available literature (Refs. 333 through 337) failed to disclose device experience which would significantly alter the trends already suggested, with the exception of the report of Sneppen, Fredensborg, et al. (Ref. 336), who reported 6 postoperative dislocations out of 50 implantations for a patellofemoral complication incidence of 12 percent.

It has been reported that hundreds of surgeons in the United States and many other parts of the world are implanting the generic knee joint femorotibial metal/polymer non-constrained prosthesis (Ref. 338). Reports of grating, dislocation, or pain associated with the device (Refs. 330, 334, 335, 336, and 339) are attributed by Carlova (Ref. 338) to an "inadvertent" design change of the most widely used size of femoral component. Marmor also recommended not using the 6-millimeter-thick hemitibial components because the polyethylene tended to buckle and loosen (Ref. 339).

As an example of a series of patients with intermediate-term followup, Cracchiolo, et al. (Ref. 340), reported on 118 Gunston/Cracchiolo prostheses that had been implanted in 93 patients. General complications reported were: 1 incidence each of hepatitis and drug allergy; remote complications consisted of 1 patient with cholecystitis and 26 cases of catheter-associated urinary tract infection. The principal systemic intraoperative complication reported was 9 arrhythmias or other

cardiopulmonary events. Local complications included 2 nerve palsies (presumably chronic), 1 femoral artery occlusion necessitating emergency reoperation, 6 prosthesis subluxations, 5 component loosenings, 1 bone fracture, 4 patients with persistent disabling pain, and 22 patients whose postoperative ability to walk unaided was less than fair. The presumed failure incidence during a mean followup of 40 months (range: 24 to 75 months) was 19.4 percent (18 of 93, excluding the "poor" status patients noted above) for this series; including at least a 12.9 percent reoperation incidence.

The following intermediate-term complications have been reported: device loosening/bone resorption (Refs. 341 and 342); design-associated recurrence of musculotendinous contractures or soft tissue deformities (Ref. 343); loss of function associated with pain or change in joint biomechanics (Refs. 334, 339, 343, and 344), and complications relating to tribologic properties, such as friction, lubrication, or wear (Refs. 345 through 359).

Although knee joint femorotibial metal/polymer nonconstrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3530; Docket No. 78N–3086; Knee joint femorotibial metal/polymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femorotibial metal/polymer semi-constrained prostheses:

1. Identification: A knee joint femorotibial metal/polymer semi-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consists of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene, and is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femorotibial metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel belives that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kineamatics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint femorotibial metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. The following data is representative of clinical experience within the immediate postoperative and short-term followup interval reported by users other than the inventor/developers of the prosthesis. The incidence of complications reported by Holman and Tyer (Ref. 360) was: remote—(2 percent); systemic—(5.7 percent); and local—(not determinable). The failure rate was approximately 15 percent (8 of 53) for this series of semi-constrained knee prostheses, with a followup range of 1 to 10 months. The incidence of complications reported by Insall, et al. (Ref. 361), was: remote—none reported; systemic—(7 percent); and local—(20 percent). The device failure rate was approximately 22 percent (11 of 50 cases) for this series, with a followup of less than 14 months. At least 6 of the clinical failures required a minimum of 1 reoperation and 4 required removal of the prosthesis. Fox (Ref. 362) reported that over a period of 33 months, 74 prostheses were implanted in 62 patients, of which 29 were included in the author's clinical statistics. Local complications included 6 tibial component loosenings, 2 loose tibial markers, and 8 malpositionings of components. Thirty-one knees in an unknown number of patients had at least 1 complication; 9 patients had 2 or more complications. The clinical failure rate was at a minimum of 16 percent (10 of 62) for this series, assuming that each reoperation not otherwise identified was performed upon a different patient, with a followup range of a few days up to 34 months.

Riley and Hungerford (Ref. 363) reported that care in patient selection combined with strict attention to

operative detail can minimize complications caused by surgical procedure. These authors reported that during a period of 41 months, 58 prostheses were implanted in 48, reheumatoid arthritic patients. Three patients died less than 24 months following implantation of the prosthesis and were excluded from the data tabulations. Systemic complications reported were one death from cardiac arrest. Local complications included 1 palsy (transient), 1 residual flexion contracture requiring reoperation, at least 2 confirmed component loosenings, 4 patients with persistent disabling pain, and 1 patient with prominent patellofemoral symptons requiring reoperation. The failure rate was 27.1 percent (13 of 48) for this series—including 8.3 percent reoperation incidence—with a median followup of 36 months (range: 2 weeks to 64 months).

Cracchiolo, et al. (Ref. 364), reported that 92 Geometric prostheses had been implanted in 81 patients. General complications reported were 1 incidence each of hepatitis and pneumonia and 5 of drug allergy; remote complications consisted of 30 cases of catheter-associated urinary tract infection (an incidence of 37 percent). The principal systemic intraoperative complication reported was 6 arrhythmias or other cardiopulmonary events. Local complications included 1 nerve palsy (presumably chronic), 4 deep wound infections (necessitating reoperation), 2 bone fractures, 1 presumed component fracture, 1 dislocation, 9 component loosenings, at least 3 patients with persistent, disabling pain (2 necessitating reoperation) and 25 patients whose postoperative ability to walk unaided was less than fair. The presumed failure incidence was 21 percent (17 of 81, excluding the patients with poor walking status noted above). Only 1 or 2 of the failures occurred later than the first postoperative year. There was at least an 18.5 percent reoperation incidence, with a mean followup of 41 months (range: 24 to 78 months).

Larsson and Ahlgren (Ref. 365) reported on 29 Geometric prostheses that had been implanted in 27 patients. General complications reported were limited to 1 incidence of pneumonia; no remote complications were identified. The principal systemic complication was 1 death attributed to cardiovascular disease sometime after a 12-month postoperative visit. Local complications included 3 deep-wound infections (1 immediate and 2 later than 6 months postoperatively), 3 tibial component loosenings (11.1 percent incidence at 2.5, 3, and 3.5 years postoperatively), 15 patients with less than a 90° flexion/extension arc, 4 patients with radiologic evidence of bone resorption around the tibial component, 5 with persistent swelling, and 6 patients who required support to enable walking.

The following intermediate-term complications have been reported: bony or soft-tissue necrosis (Refs. 9 and 89); design-induced recurrence of musculotendinous contractures or soft-tissue deformities (Refs. 343 and 96); device loosening/bone resorption (Refs. 89, 341, and 342); infection (Refs. 146, 148, 149, 183, 323, and 408); loss of function associated with pain or change in joint biomechanics (Refs. 344 and 360); and complications relating to tribologic properties, such as friction, lubrication, or wear (Refs. 241 through 243 and 345 through 359).

Although knee joint femorotibial metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3540; Docket No. 78N–3087; Knee joint patellofemoral polymer/metal semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemoral polymer/metal semi-constrained prostheses:

1. Identification: A knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint in the treatment of primary patellofemoral arthritis or chondromalcia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It as no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement). The patellar component is designed to be implanted only with its femoral component.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemoral polymer/metal semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel has limited the indications for use of the device to treatment of primary patellofemoral arthritis or chondromalacia (Ref. 366). The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, despite the risk of infection, the rate of clinical success associated with implantation of these prostheses surpasses that achieved with more established procedures.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, similar devices and a presentation made to the Panel (Ref.

366). James Fox reported on his clinical experience with this generic type of device. Fox stated that patellofemoral joint replacement was performed in more than 60 knees, with followup since 1974. He reported that he, as well as his patients, were pleased with the results.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution of wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA disagrees with the Panel recommendation and is proposing that knee joint patellofemoral polymer/metal semi-constrained prostheses be classified into class III. Other than the presentation to the Panel made by James Fox (Ref. 366), FDA is not aware of any clinical data of this device. Moreover, because Dr. Fox provided no details regarding the device or its implantation procedure, FDA is not certain that the devices Dr. Fox implanted belong to this generic class.

FDA has reviewed the pertinent engineering and clinical literature to determine whether sufficient information exists to permit the establishment of a performance standard for this device. FDA has found that the literature discussing the most crucial information needed to establish a standard is inadequate. For example, the correlation between pertinent preclinical mechanical tests and clinical findings are unknown.

FDA finds that knee joint patellofemoral polymer/metal semi-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint of limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of knee joint patellofemoral polymer/metal semi-constrained prostheses prevents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3550; Docket No. 78N–3088; Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemorotibial polymer/metal/metal constrained prostheses:

1. Identification: A knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device intended to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar resurfacing component may be attached to the resected patella either with a metallic screw or luting agent. All stemmed metallic components within this generic class are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemorotibial polymer/metal/metal constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although a knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, despite the risk of infection, the rate of clinical success associated with implantation of these prostheses surpasses that achieved with more established procedures. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and experience with, the device and a presentation made to the Panel. Dr. Roland Pritchard and Dr. James Fox (Ref. 366) described their experiences with various patellofemoral joint replacing devices including this generic type of device. Dr. Pritchard has implanted patellofemorotibial joint prostheses in at least 100 patients during the past 3 years. Also, Dr. Fox reported that he has achieved good results in over 60 cases since 1974.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surface of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence

of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint patellofemorotibial polymer/metal/metal constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices.

In May 1962, Young (Ref. 368) reported on a series of 16 patients ranging in age from 31 to 70 years who had a Young design prosthesis implanted (two were bilateral implantations). With a followup time between 9 and 61 months (median of 20 months), 7 of these 16 experienced a clinical failure (43.8 percent) with a mean time of about 9 months before prosthesis removal and arthrodesis (joint fusion). In a later report in 1971, Young, (Ref. 373) stratified results by indication: at least 3 of 19 osteoarthrotic knees were failures (15.8 percent incidence); at least 17 of 45 rheumatoid knees failed (37.8 percent incidence); of 4 replacements for giant-cell tumor, 2 failed (50 percent incidence); and at least 6 of 10 traumatic arthritic kees failed (60 percent incidence). Young noted that 9 knees examined sometime after initial implantation demonstrated darkening in tissue adjacent to metallic components. Young believed that the darkening of tissue was caused by tissue contamination from corrosion products. Young also believed that similar tissue darkening was noted by Girzadas, Geens, et al. (Ref. 369). Young believed that the darkening was caused by the bolts used in his design that were made from a cobalt-based alloy, whereas the other components were made from a casting alloy. Young stated that, as a result of his survey of the clinical results of 85 physicians who had implanted the Young-design prosthesis, he was not optimistic about use of the hinged metal/metal knee prostheses and their furture for replacement arthroplasty.

In 1973, Hanslik (Ref. 374), reported results of using the device in 50 patients (two bilaterally implanted), principally for the indication of osteoarthrosis. Minimum followup was not given, while maximum followup was possibly 4 years. The patients ranged in age from 56 to 76 years. At least four failures (8 percent) were associated with restricted gliding of the patellofemoral articulation: one of these was attributed to polymethylmethacrylate-induced bony necrosis. Hanslik used the Young (Ref. 368) design of prosthesis and had made major modifications in implantation technique as recommended by Friedebold and Radloff (Refs. 367 and 370 through 372). Hanslik performed partial resection of the patella rather than total excision and used a polymethylmethacrylate luting agent to grout the medullary stems (presumably in addition to the cancellous bone screws recommended by Young). Friedebold and Radloff (Ref. 372) reported on use of the prosthesis in femorotibial replacement in 11 patients ranging in age from 50 to 80 years, with between 6 months and 5 years of followup. There were three failures (27.3 percent).

Although knee joint patellofemorotibial polymer/metal/metal constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3560: Docket No. 78N–3090; Knee joint patellofemorotibial polymer/metal/ploymer semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses:

1. Identification: A knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device intended to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses be classified into class II because the design, material composition, and mechancial properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls will not provide sufficient control over these characteristics.

Although a knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that, while the risk of infection is greater, the rate of clinical success associated with implantation of this prosthesis surpasses that achieved with more established procedures. The Panel also believes that a performance standard will adequately control the risks associated with the device, such as problems relating to device geometry or mechanical design, and component loosening.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design, or inadequate mechanical

properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. Insall, Ranawat, and coworkers (Refs. 375 through 379) reported on the implantation of the device in 183 patients (220 devices). Complications reported were: general—8 deaths (causes unspecified) reported within 3 years after implantation; remote—none reported; systemic—4 percent from clinical signs and symptoms, 35 percent with "positive" radiographic venograms (which imply blockage of a blood vessel), 11 percent with "positive" radiographic lung scans (direct evidence of clot in pulmonary artery); and local—greater than 23 percent. Of the 220 knees involved, 3 of 139 osteoarthritic knees and 1 of the 81 rheumatoid arthritic knees developed partial femorotibial dislocations.

The complications exhibiting the greatest incidence were: superficial infection (wound drainage) (22.9 percent); developing radiolucency in one or more components (22 percent); tibial component anteroposterior tilt greater than 5 degrees (8 percent); femoral component valgus tilt greater than 5 degrees (5 percent) delayed wound healing (3.8 percent); and pain persisting or originating postoperatively (3.6 percent).

Although knee joint patellofemorotibial polymer/metal/polymer semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accompanying the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3570; Docket No. 78N–3091; Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint femoral (hemi-knee) metallic uncemented prostheses:

1. Identification: A knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint femoral (hemi-knee) metallic uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of limb function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although a knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device.

5. Risks to health: (a) Loss or reduction of joint or limb function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in the loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection. (d) Death: Death may result from lipoembolic sequelae or thromboembolic complications during or immediately following implantation.

FDA disagrees with the Panel recommendation and is proposing that knee joint femoral (hemi-knee) metallic uncemented prostheses be classified into class III. FDA has sought additional data on the safety and effectiveness of the device. FDA is concerned about both the severity of the clinical complications resulting from use of the device and the rate at which these complications occur. The agency used the complication classification scheme developed by Fox (Ref. 380) and grouped complications by time periods following surgical implantation; immediate postoperative complications, within two weeks; short term, within 24 months; and long term, more than 24 months. Platt and Pepler reported in 1969 their clinical results on 55 patients who had this prosthesis implanted with up to 10 years followup

(Ref. 381). Their reported incidence of complications ranged from: (1) General—none reported, and (2) systemic—none reported; to (3) remote—1 late (2 years postoperatively) paranoid schizophrenia (1.8 percent); and (4) local—at least 45 percent. The most frequent complication was immediate postoperative infection with a presumed incidence of 25.5 percent. The reoperation rate for this series of patients was reported as 20 out of 62 knees or 32.4 percent; assuming only one reoperation per patient a 36.4 percent revision rate will result.

Aufranc and Jones, et al. (Refs. 382 through 384), made extensive modifications to M. Smith-Peterson's original "keeled" femoral condylar mold (Ref. 385) and commenced a series of device implantations employing a noncemented stemmed implant in 1952. Clinical results on 64 patients with a minimum of 1-year followup showed that the incidence of complications were, (1) zero for general and remote categories (2) 3.1 percent for systemic (2 thrombophlebitic episodes), and (3) a minimum of 25 percent for cumulated local complications. Matching Platt and Pepler's experience (Ref. 381), the most frequent complication observed was immediate postoperative infection with a presumed incidence of 20.3 percent. This series of patients, as of mid-1969, displayed a reoperation rate of 14 out of 79 knees (17.7 percent), assuming only one reoperation per patient. Considering this result, with their report of 16 clinical results rated at less than "fair," the failure rate is calculated as 38 percent with an average followup time of 87 months. Aufranc and Jones (Ref. 382) note that 6 of their initial 14 implantations were failures (42.9 percent) with a maximum followup of 5 years; apparently 10 more years of surgical experience reduced the overall failure rate by 5 percent, without altering the principal reported failure modes: infection and "poor" clinical result.

Further review of available literature (Refs. 386 through 395), failed to disclose device experience which would significantly alter the trends described above.

FDA finds that knee joint femoral (hemi-knee) metallic uncemented prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing futher loss of functional use of a joint or a limb. FDA believes these uses are of substantial importance in preventing impairment of human health. However, FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the knee joint femoral (hemi-knee) metallic uncemented prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3580; Docket No. 78N–3092; Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses:

1. Identification: A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, intended to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement). The device is intended for use only in treatment of degenerative and posttraumatic patellar (osteo) arthritis.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommended that the indications for use of the device be limited to degenerative and posttraumatic patellar arthritis (Ref. 396). The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that knee joint pateller (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. In 1955, D. C. McKeever (Ref. 397) reported results obtained from implanting this device in 39 patients (4 bilaterally). The reported median

followup time was 54 months. Reported complications were limited to: 2 patients in which too large a prosthesis had been implanted, thus unnecessarily prolonging convalescence; 3 patients with short-term deep infection; 1 patient with a late developing deep infection; and 1 patient with bone necrosis. Four of these complication occurrences necessitated reoperation for removal of the device and 3 knees were arthrodesed as well, producing a cumulative failure rate of 10.3 percent for the series.

DePalma, et al, (Ref. 398), employed the McKeever design in a series of patients, 17 of which were discussed in 1960. With a median followup time of 35 months, they reported only three results that they considered less than good; two fair and one poor. No appearance of complications or reoperations were reported, producing a cumulative failure rate of 5.9 percent. In 1973, Levitt (Ref. 399) reviewed DePalma's series of patients when 68 devices had been implanted (including bilaterals). When a prosthesis was implanted, patients with degenerative joint diseases frequently had had one or more other surgical procedures performed concurrently on the same joint. Levitt noted a readily detectable continuing progression of arthritic degeneration with time as followups were extended. Levitt reexamined 10 out of 20 patients of DePalma's series and determined that 50 percent had unsatisfactory results. He concluded that it was impossible to determine the clinical success of the prosthesis in a joint involved with degenerative disease upon which one or more other surgical procedures had been carried out concurrently with implantation, i.e., a determination of whether the unsatisfactory result(s) was secondary to the continuation of the disease process or to the inefficacy of the prosthesis.

Vermeulen and coworkers in 1973 (Ref. 400) reported results in eight aged female patients with from 3 to 8 years followup. It was not possible to determine from the report the degree of individual clinical improvement.

In reviewing osteoarthrosis of the patellofemoral joint, I. S. Smillie remarked in 1975 that the McKeever prosthesis has not met with success in other surgeons' hands (Ref. 401). This view has been corroborated by a panel member, who noted that the devices did not demonstrate much clinical success and that many of them had to be removed (Ref. 402), and they have seen limited use since the decade of the fifties (Ref. 396).

In 1975, Hanslik (Ref. 403) reported on a series of implantations of the McKeever patellar resurfacing device accompanied by tibial plateau resection and stapling (proximal tibial osteotomy). Seventy-six patients (2 bilaterals) with from 1 to 4.5 years followup were reviewed; however, it was impossible to determine from the report the degree of individual clinical improvement. FDA notes that because the two procedures were done concurrently, it is not possible to attribute any degree of clinical success entirely to the patellar resurfacing device. FDA is unaware of any published data since 1975 showing use of this generic type of device.

Although knee joint patellar (hemi-knee) metallic resurfacing uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3590; Docket No. 78N–3093; Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses:

1. Identification: A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those devices intended for implantation without the use of a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, and Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. the Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properities of the device such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that

knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices.

Stauffer, et al. (Ref. 404), reported their results following implantation of the prosthesis in 28 patients (9 were bilaterally implanted) with a mean followup of 18 months (range: 7 to 34 months). The principal local complications included recurring valgus deformity, patellofemoral pain, and decreased patellar mobility. Seventeen of 37 knees were rated "poor" on the authors' evaluation scale, resulting in a 45.9 percent failure rate. The authors emphasized that the physical condition of a patient's patellofemoral joint before implantation was a major factor in the postoperative functional results. The authors suggested that the condition of a patient's patellofemoral joint be evaluated and reported at the time the prosthesis is implanted, to allow more accurate assessment of the safety and effectiveness of the prosthesis after implantation.

Burrough, et al. (Ref. 405), compared the implantation in the patient's tibia of one tibial condylar resurfacing prosthesis with the implantation of two of the prostheses. Twenty of their 22 patients were rheumatoid arthritics. Equal numbers of patients' knees had one or two tibial condyles resurfaced with the prosthesis, with a mean followup of 10.6 months (range: 2 through 14 months). No complications were reported. Burrough, et al., stated that implantation of two of the prostheses in a patient's tibia provided more improvement in walking and more pain reduction than implantation of one of the devices. However, Henderson and Peterson (Ref. 406) and Clary and Couk (Ref. 407) disagree. FDA reviewed other published reports of clinical studies of tibial resurfacing prostheses (Refs. 408 through 442). Two reports—that of Friedebold and Radloff (Ref. 422) and that of Lowe and coworkers (Ref. 425)—describe the use of a polymethylmethacrylate luting agent to fix the prosthesis into the surgically prepared cavity. The original developers of the prosthesis intended that the device not be cemented (Refs. 409, 410, 418, and 442). The identification of the knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis excludes the use of a polymethylmethacrylate luting agent with this device, because FDA believes that insufficient information exists to establish a performance standard when a luting agent is used with the device.

Although knee joint tibial (hemi-knee) metallic non-constrained resurfacing uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices.

§ 888.3640; Docket No. 78N–3094; Shoulder joint constrained prostheses.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint constrained prostheses:

1. Identification: A shoulder joint constrained prosthesis is an implanted device intended to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommend that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel also recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on their knowledge of the medical literature (Refs. 443 through 446). Two of these references (Refs. 443 and 444) describe a shoulder joint constrained prosthesis (Fenlin and Zippel designs) and report that implantation of the device relieved pain in 16 of 17 patients. In the patient with the painful prosthesis, the authors believed that the device had loosened. The times of implantation were not reported.

Fenlin (Ref. 445) reported that the Fenlin design prosthesis had been implanted in five patients. The results in three of these patients were discussed. One patient was described as being free of pain, and able to use the operated shoulder for all normal activities, except those requiring elevation of the arm above 80°. The length of followup in this patient was 20 months. Complications were reported in the other two patients. In one patient, the device had loosened at 3 months postoperatively, due to abnormal anatomy of the glenoid. The second patient suffered partial nerve palsy due to damage of the axillary nerve during surgery. Linscheid and Cofield (Ref. 446) reported on the implantation of 13 constrained shoulder joint prostheses (6 of the Stanmore design, and 7 of the Bickel design). The average time of followup was reported as 13 months and ranged from 2 to 26 months. There were two cases of dislocations of the Stanmore design

prosthesis and one case of dislocation of the Bickel design prosthesis. There were two additional complications reported with the Bickel design device; one case of fracture of the humeral component and one case of loosening of the glenoid component.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or lossening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the recommendation of the Panel and is proposing that shoulder joint constrained prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of these devices. Cofield (Ref. 447) reported that prosthetic replacement of the shoulder joint is an experimental, investigational procedure. This author noted that basic knowledge about shoulder biomechanics is limited and that current knowledge of shoulder prostheses is not sufficient to establish the requirements of a prosthetic replacement. Buechel, et al. (Ref. 448), noted that complications with current shoulder prostheses have been associated with the designs of the devices: (1) The Bickel design shoulder joint prosthesis was reported to dislocate and loosen due to the limited motion of the prosthesis; (2) the prosthesis design used by Lettin and Scales (presumably the Stanmore design shoulder prosthesis) was reported to significantly limit joint motion, then sublux, and eventually dislocate at the extremes of normal joint motion. Clinical results with several prosthesis designs were reported by Cofield (Ref. 447, 449, and 450). Eleven persons in whom Bickel design prostheses had been implanted were evaluated 18 months to 39 months postoperatively (Ref. 449). Three (27 percent) were experiencing significant pain. The components of the Bickel device had dislocated in two cases. The glenoid component had dislodged from the scapula in two cases and loosened in one. The humeral component had fractured in two other cases. Reoperation was required in four patients and was needed in two or three others. Cofield reported that further clinical and mechanical deterioration in these patients was anticipated due to progressive loosening of the glenoid components and fatigue fracture of the neck of the humeral component, which was not believed to be strong enough. These authors concluded that this type of shoulder joint replacement (i.e., the Bickel design) is not justified. Cofield (Refs. 447 and 450) also reported clinical results in nine patients who had received Stanmore prostheses. After an average postoperative time of 1 year (ranging between 4 and 18 months), six patients had satisfactory relief of pain and three had significant pain. The glenoid component had loosened in two patients. FDA concurs with the Panel that the reported clinical experience with these devices does not establish their long-term safety and effectiveness.

FDA finds that shoulder joint constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or a limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3650; Docket No. 78N–3095; Shoulder joint non-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint non-constrained prostheses:

1. Identification: A shoulder joint non-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint non-constrained prostheses be classified into class III because the devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health. The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel also believes that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the

device and on their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint non-constrained prostheses be classified into class III. FDA has reviewed the Panel recommendation and has sought additional information on the safety and effectiveness of the device. After reviewing the clinical experience with the device, Cofield (Ref. 451) reported that clinical results from implantation of four of these prostheses had been presented. Published clinical reports were available for only one of these implantations. Neer (Ref. 452) reported that the early results were good with the device he implanted. Cofield (Ref. 451) also presented his clinical experience with the device. Cofield discussed 40 of his patients, 33 of whom have had shoulder joint non-constrained prostheses implanted for more than 3 months. He did not report the maximum or average times of implantation. Complications included one infection requiring removal of the device, one postoperative dislocation of the joint which required reoperation, one axillary nerve injury which also required reoperation, one case of heterotopic bone formation, and one retearing of a muscle cuff repair.

FDA finds that shoulder joint non-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint non-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3660; Docket No. 78N–3096; Shoulder joint semi-constrained prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint semi-constrained prostheses:

1. Identification: A shoulder joint semi-constrained prothesis is an implanted device intended to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethyl-methacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint semi-constrained prostheses be classified into class III because the devices are implanted and are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on their knowledge of the medical literature.

5. Risks to health; (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agress with the Panel recommendation and is proposing that shoulder joint semi-constrained prostheses be classified into class III. FDA has sought additional data and information on the safety and effectiveness of the device. Preliminary clinical results with the device were reported by Siegel, et al. (Ref. 453). The authors implanted the St. George design shoulder prosthesis in 28 patients. Postoperative evaluation of 24 patients early in the series revealed that the best results, including pain relief and increased joint range of motion, were obtained on rheumatoid patients.

Complications included infection in one patient and dislocation of the device in two others. The authors stated that longer periods of observation were needed to determine the indications for use of a total shoulder prosthesis of this design.

FDA believes that Siegel, et al.'s, data are insufficient to establish the safety and effectiveness of the prostheses. Additional studies with longer followup times are needed. FDA finds that shoulder joint semi-constrained prostheses are implanted devices that are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of the devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint semi-constrained prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act required that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3680; Docket No. 78N–3058; Shoulder joint glenoid (hemi-shoulder) prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendations regarding the classification of shoulder joint glenoid (hemi-shoulder) prostheses:

1. Identification: A shoulder joint glenoid (hemi-shoulder) prosthesis is an implanted device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, and that is intended to replace a portion of the shoulder joint. This generic type of device is limited to those devices intended for implantation with a ploymethylethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint glenoid (hemi-shoulder) prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Inproper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint glenoid (hemi-shoulder) prostheses be classified into class III. FDA finds that these implanted devices are intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists to fully establish the persons for whose use these devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorable with the likelihood of injury or illness resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of the shoulder joint glenoid (hemi-shoulder) prosthesis presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make this determination. Moreover, FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3690; Docket No. 78N–3097; Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

The orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses:

1. Identification: A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted intramedullary stemmed device made of alloys, such as cobalt-chromium-molybdenum. It is intended to replace the articular surface of the proximal end of the humerus and to be fixed without a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that shoulder joint humeral

(hemi-shoulder) metallic uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls will not provide sufficient control over these characteristics.

Although a shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted device, the Panel believes that premarket approval is not necessary because there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequte biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away of the articulating surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses be classified into class II. FDA has sought additional data and documentation on the safety and effectiveness of this device. Four surgeons reported clinical use of this device (Refs. 454 through 457). In 1955, the Neer device was described (Ref. 454), and clinical results were presented on 12 patients with a time of followup from 2 months to 23 months. Eleven were free from pain, and in the remaining patient, the pain was believed to be caused by improper seating of the device. In 1969, Oster (Ref. 455) reported on four patients who received the Neer prostheses for the treatment of fracture dislocations. The time of followup ranged from 4 months to 18 months, with an average time of 10 months. Two patients had the devices implanted for 1 year or more. The range of motion was reported as limited in two and poor in one. In the fourth patient, the prosthesis had dislocated, reoperation was required, and the prosthesis was removed later due to infection. The author commented that satisfactory results had been obtained in two of the four cases and that the unsatisfactory results in two patients were due to one patient's refusal to cooperate during rehabilitation and the other patient's delay in seeking treatment.

In 1975, Clayton and Ferlic (Ref. 456) reported on the use of the device in eight patients with rheumatoid arthritis. The time of followup ranged from 2 months to 20 months, with an average time of 8 months. All eight patients had pain preoperatively. Postoperative improvements were reported in seven of the eight patients, with four patients having complete relief of pain. Postoperative improvements in range of motion were reported in six patients.

Neer (Ref. 457), the originator of the prosthesis, reported on the long-term results with this device. The devices had been implanted in 21 patients for 5 or more years and the average followup in this series of patients was 6 years, ranging from 8 months to 20 years. Neer reported that excellent results were obtained in 10 of these patients, satisfactory results in 8, and unsatisfactory results in 3. There was no radiologic evidence of loosening of the stem of the prosthesis in the medullary canal and no instance of settling of the prosthesis in the humerus. Neer reported that there were no postoperative complications or significant local complications and only one instance of dislocation, this occurring in a patient with poliomyelitis.

FDA reviewed several reports (Refs. 458 through 461) on the use of custom-made humeral prostheses that are not the same generic type of device as that classified herein. The custom-made devices, which were made of polymeric materials rather than metal, were attached to the bone by bone plates rather than through an intramedullary stem and were designed to replace portions of the long bone of the humerus rather than the articular head. Because of these differences, the clinical experience with these custom-made devices cannot be compared to the experience reported for the shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

Although shoulder joint humeral (hemi-shoulder) metallic uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3720; Docket No. 78N–3099; Toe joint constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of toe joint constrained uncemented prostheses:

1. Identification: A toe joint constrained uncemented prosthesis is an implanted device made of silicone elastomer or polyester reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that toe jont constrained

uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that toe joint constrained uncemented prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of the toe joint constrained uncemented prostheses. Several reports described the use of the prostheses in the metatarsophalangeal (MTP) joints of the foot (Refs. 462 through 467).

Although toe joint constrained uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addtion, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA had determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3730; Docket No. 78N–3100; Toe joint phalangeal (hemi-toe) prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of toe joint phalangeal (hemi-toe) prostheses:

1. Identification: A toe joint phalangeal (hemi-toe) prosthesis is an implanted device made of silicone elastomer intended to replace the base of the proximal phalanx of the toe.

2. Recommended classification: Class II. The Panel recommends that establishing a peformance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that toe joint phalangeal (hemi-toe) prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and their knowledge of the medical literature.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and its proposing that toe joint phalangeal (hemi-toe) prostheses be classified into class II. The agency has reviewed the Panel recommendation and has obtained additional data and information describing the use of toe joint phalangeal (hemi-toe) prostheses (Refs. 468 through 472). Swanson, et al. (Refs. 468 and 469), described the development of the prostheses and the surgical technique and reported on 55 patients who received the prostheses. The average range of postoperative joint motion was reported to be 60 degrees in extension and 5 degrees in flexion.

La Porta, et al. (Ref. 470), reported on 536 devices which had been implanted over a 4-year period with excellent postoperative results in 150 out of 536 joints (27.9 percent), good results in 39.1 percent, fair results in 22.9 percent, and poor results in 10.1 percent.

Albin and Weil (Ref. 471) reported that silicone implant arthroplasty had been performed on 1,000 feet at Northlake Community Hospital. Of those 1,000, 150 feet, all of which were operated on by, or under the direct supervision of two surgeons, were selected for evaluation of this procedure. They reported that clinical examinations were made of 50 feet and that radiographic examinations were made of 100 feet with an average followup time of 12.5 months. These

authors reported that the postoperative average active range of joint motion was 43 degrees and that the average passive range of motion was 60 degrees. They reported that there was a recurrence of abduction deviation in 70 percent of the cases and a recurrence of valgus rotation in 48 percent. They reported that while 62 percent of the patients had a good distribution of body weight over the operated joint, this percentage may be improved by a modification of the surgical technique.

Recently, Caneva (Ref. 472) recommended cautious use of this prosthesis in young, extremely active individuals. This author reported that degenerative changes in the bone opposing the prostheses had occurred in four young active male patients about 6 months after surgery. These patients experienced pain, edema, and restricted joint motion.

Although toe joint phalangeal (hemi-toe) prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risk to health associated with the use of these devices. FDA believes that the major risk, bone resorption, is related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3750; Docket No. 78N-3101; Wrist joint carpal lunate prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal lunate prostheses:

1. Identification: A wrist joint carpal lunate prosthesis is a one-piece implanted device made of silicone elastomer. It is intended to replace the carpal lunate bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal lunate prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although carpal lunate prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility or resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal lunate prostheses be classified into class II. FDA has sought additional data and information on the safety and effectiveness of these devices. The agency has reviewed the available medical literature pertaining to silicone wrist joint carpal lunate prostheses. Roca, et al. (Ref. 473), reported clinical results obtained in 10 patients in whom the prosthesis had been implanted for 2 years. The results were rated as satisfactory in seven patients and unsatisfactory in three. The unsatisfactory results were due to disclocation of the device in two cases and medial nerve paresthesia of unexplained origin in the other patient. Lichtman, et al. (Ref. 474), compared the results of implantation of the prosthesis with plaster immobilization of the joint—a nonsurgical alternative treatment in patients with Kienbock's disease (degeneration of the carpal lunate bone)—to establish more clearly the indications for the prosthesis and the timing for the procedure. These investigators concluded that plaster immobilization gave unsatisfactory results, particularly when compared to results obtained from implantation of the device before the carpal lunate bone had collapsed. Twenty devices had been implanted, 14 of which produced satisfactory results when evaluated at 10 through 54 months postoperatively (average was 27 months). The device was noted to have dislocated in 8 patients: in 5 of the 6 patients with unsatisfactory results and in 3 of the 14 patients with satisfactory results. These authors also reported that the original design of the device was modified by deepening the concavities on its surface to provide a more secure articulation between the device and the carpal bones and to reduce the incidence of device dislocation.

Although wrist joint carpal lunate prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device-design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance

standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3760; Docket No. 78N–3102; Wrist joint carpal scaphoid prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal scaphoid prostheses:

1. Identification: A wrist joint carpal scaphoid prosthesis is a one-piece implanted device made of silicone elastomer intended to replace the carpal scaphoid bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal scaphoid prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although these are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of a prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal scaphoid prostheses be classified into class II. The agency obtained additional data and information describing the use of wrist joint carpal scaphoid prostheses. Swanson (Ref. 475) reported that development of the wrist joint carpal scaphoid prosthesis was prompted by the shortcomings of most other current procedures, such as replacement of the carpal scaphoid with a metallic or an acrylic prosthesis. Swanson noted that investigators of these other devices reported problems concerning implant loosening and bone resorption due to the hardness of the implanted material. A recent publication (Ref. 476) cites problems associated with silicone carpal scaphoid prostheses that included fracture of the stem of the prosthesis and implant loosening.

Although wrist joint carpal scaphoid prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3770; Docket No. 78N–3304; Wrist joint carpal trapezium prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint carpal trapezium prostheses:

1. Identification: A wrist joint carpal trapezium prosthesis is a one-piece implanted device made of silicone elastomer or silicone elastomer/polyester material intended to replace the carpal trapezium bone of the wrist.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint carpal trapezium prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint carpal trapezium prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint carpal trapezium prostheses be classified into class II. The agency has sought additional data and information on the safety and effectiveness of these devices. Three types of implant arthroplasty concerning the trapezium are discussed in the medical literature: resurfacing of the

metacarpal surface as described by Kessler and Crawford (Refs. 477 and 478); resurfacing of the trapezial surface as described by Ashworth (Ref. 479); and complete excision and replacement of the trapezium bone with a Swanson-type silicone elastomer or Niebauer-type silicone elastomer/polyester prosthesis (Refs. 480 through 487).

Kessler (Ref. 477) reported that 11 of the 18 patients treated by resurfacing the metacarpal surface with a silicone prosthesis were free from pain 2 years postoperatively. Crawford (Ref. 478) reported that of nine patients receiving this resurfacing prosthesis, improved function was encountered initially, but that within 4 to 8 weeks signs of chronic synovitis were present in all patients. The prosthesis had also subluxated and dislocated in five cases (55 percent). When three of these resurfacing prostheses were removed and replaced with Swanson or Niebauer prostheses, all of the resurfacing prostheses were found to be badly torn. Microsilastic particles were found within the synovium of all joints, with abundant foreign body giant cell reaction. The author concluded that the base of the resurfacing prosthesis was much too weak to allow normal thumb function and that the results obtained with the resurfacing prosthesis did not compare well with the results expected after excision of the trapezium (an alternative treatment), with or without prosthetic replacement of the trapezium.

Ashworth (Ref. 479) reported the results of resurfacing of the trapezium in 42 patients. The trapezium was resurfaced with a silicone prosthesis, using a neurosurgical burr-hole cover that had been adapted by reshaping. The prosthesis was inserted in a hole drilled into the trapezium. Patients were evaluated 1 to 75 months (average 31 months) postoperatively. The results were considered excellent if pain was absent and there had been no decrease in abduction or grip strength. Forty patients were evaluated as having excellent results using these criteria. In the other two patients, the operation was considered to be a failure because the device fractured. The authors believed that, in both cases, the failure was due to error in surgical technique.

A number of authors reported on the use of Swanson (Refs. 480, and 482 through 487) and Niebauer (Refs. 481 and 483) prostheses to replace the entire trapezium. Haffajee (Ref. 480) reported on the implantation of the Swanson prosthesis in 100 hands with a postoperative followup of 1 to 5 years. He found that pain was relieved in all but five hands. While there were no device fractures, there were 19 device dislocations. Swanson (Ref. 486) reported on the implantation of the Swanson prosthesis in 46 patients. The postoperative followup ranged from 6 months to 5½ years, with a followup of 2 or more years in 32 patients. Pain was completely relieved in all 46, but the device had subluxated in 8 patients. Ferlic (Ref. 481) evaluated postoperative results in 11 patients 1 to 3 years after they received Niebauer prostheses. Ferlic found that all patients were satisfied, principally because of relief of pain. There were no device dislocations.

Weilby (Ref. 482) reported that of 100 consecutive patients receiving the Swanson prosthesis, 32 (32 percent) showed implant subluxation with varying degrees of disfunction and complaints. Reoperation for removal of the implant was advised in 16 cases (16 percent). Haffajee (Ref. 480) reported a dislocation rate of 19 percent (9 occurring with the original Swanson design prosthesis and 10 with the newer design). Dislocation of the prosthesis affected the range of thumb abduction, and was noted in 13 of the 15 hands, in the series in which abduction was not improved. Lister (Ref. 484) reported a subluxation rate of 25 percent. Two-thirds of these patients complained of instability and persistent loss of strength and reoperations were necessary for removal of the prosthesis. Sarkin (Ref. 485) reported that of five patients receiving a silicone implant, the prosthesis had subluxated in two (40 percent) and had dislocated in another, requiring surgical removal.

The causes of subluxation and dislocation of the prostheses were considered by several authors. Swanson (Ref. 486) reported that the 8 cases of subluxation which occurred in his series of 46 patients were due to: incomplete removal of the trapezium in 3 patients; uncorrected hyperextension deformity in 4 patients; and inadequate capsular repair around the implant in 1 patient. He reported a mild subluxation in one patient due to a capsular tear unrecognized during surgery. Weilby (Ref. 482) identified several other reasons for dislocation: the use of too large an implant; incomplete removal of osteophytes; damage to the ligaments and joint capsule by previous surgical procedures; and use of an incorrect postoperative dressing. Haffajee (Ref. 480) believed that positioning the base of the implant in the shaft of the bone so that the base/shaft angle was 80° or less might reduce bone implant dislocations. Several authors (Refs. 480, 483, 484, and 485) discussed the effects of a variety of surgical procedures, particularly the use of tendons to stabilize the implant, on the incidence of implant subluxation. Others (Refs. 480 and 484) believed that the design of the Swanson implant encouraged subluxation and one (Ref. 484) recommended that the design be modified.

Although wrist joint carpal trapezium prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3780; Docket No. 78N-3103; Wrist joint polymer constrained uncemented prosthesis.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint polymer constrained uncemented prostheses:

1. Identification: A wrist joint polymer constrained uncemented prosthesis is an implanted device made of polyester-reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint polymer constrained uncemented prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint polymer constrained uncemented prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommenation on the Panel members' personal knowledge of the device; oral presentations made to the Panel on November 14, 1977 (Ref. 488) and March 21, 1978 (Ref. 489); written reports prepared by physicians using the devices (Refs. 490 and 491); and the Panel members' knowledge of the medical literature.

On November 14, 1977, Dr. Alfred Swanson presented clinical results on use of the device in 59 patients (Ref. 488). A total of 76 devices had been implanted. Thirty of these prostheses were made from "conventional" medical grade silicone elastomer and 46 were made from a "high performance" silicone elastomer, a new formulation which was developed to provide increased resistance to tearing and implant fracture. Fifty-six devices had been implanted for over 1 year (range was 12 months to 91 months). Twenty-one devices had been implanted for 1 to 2 years, 17 for 2 to 3 years and 18 for over 3 years. Pain, range of motion, and grasp strength were evaluated pre- and postoperatively. The average range of joint motion had increased from 38 degrees flexion and 6 degrees extension to 41 degrees flexion and 21 degrees extension. Grasp strength had increased from an average of 7 pounds to an average of 12 pounds. The percentage of patients who were pain free increased from 16 percent preoperatively to 89 percent postoperatively. The following complications were reported: four cases of recurrent synovitis, three implant fractures, and one case of severe tendon imbalance.

On March 21, 1978, Mr. Eldon Frisch presented a summary of the postoperative results that had been obtained during clinical testing of the prosthesis (Ref. 489). Postoperative clinical results had been provided by 32 physicians on 101 prostheses made of "conventional" silicone elastomer, and on 200 prostheses made from the "high performance" elastomer. Mr. Frisch reported that good and fair results had been obtained in over 90 percent of the cases with regard to pain relief, joint stability and joint range of motion. The following complications had been reported: seven fractures of implants made of the "conventional" elastomer and one fracture of an implant made of the "high performance" elastomer.

The following additional data on the "high performance" elastomer implants were presented at the March 21, 1978 Panel meeting: two oral presentations and two written reports prepared by physicians who had used the device (Refs. 489 through 491). Drs. John Madden and Edward Nalebuff made oral presentations to the Panel (Ref. 489). Dr. Nalebuff had implanted 37 devices with an average postoperative followup time of 13 months (range 4 through 25 months) and Dr. Madden had implanted 5 devices with an average postoperative followup of 8 months (range 6 months through 1 year). Based on their short-term clinical experience with the device, both surgeons reported that they were satisfied with the results. Dr. Nalebuff reported that the device: (1) Relieved pain in a significant number of patients; (2) provided satisfactory stability; and (3) made it possible to correct joint deformity, maintaining an average of 64 degrees of motion.

Drs. Edward Hay, Alonzo Kornegay, and Spencer Rowland submitted written reports of their short-term clinical results with the device (Refs. 490 and 491). Drs. Hay and Kornegay reported that devices had been implanted in 11 patients with an average postoperative followup of 11½ months (range 3 to 22 months). Pain relief was excellent and wrist joint motion was improved in eight patients. Dr. Rowland reported that 18 devices (15 of the "high performance" elastomer, and 3 of the "conventional" elastomer) had been implanted in 14 patients for at least 1 year (maximum of 30 months). It was reported that all patients had pain-free wrists at the time of evaluation and that none of the patients had lost wrist joint motion.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and the systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint polymer constrained uncemented prostheses be classified into class II. In proposing to classify this device into class II, the agency is relying on the same data discussed by the Panel in support of its recommendation that the device be classified into class II. Although wrist joint polymer constrained uncemented prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health accociated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3790; Docket No. 78N-3305; Wrist joint mental constrained prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of wrist joint metal contrained prostheses:

1. Identification: A wrist joint metal constrained prosthesis is an implanted

device intended to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class III. The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint metal constrained prostheses be classified into class III because the device is implanted and is intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. The Panel believes these uses are of substantial importance in preventing impairment of human health.

The Panel believes that general controls alone will not provide sufficient control over these characteristics. The Panel also believes that it is not possible to establish an adequate performance standard for the device. There is a lack of safety and effectiveness data to demonstrate the satisfactory performance of the device. The Panel has found that insufficient information exists to support the conclusion that general controls or performance standards will be adequate to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device must be subject to premarket approval to assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device and on the available medical literature. Gschwend, et al. (Ref. 492), used this prosthesis in 15 cases from 1971–1975. Fixation was reported to be inadequate and not correlated to loads imposed on the wrist joint. In three cases (20 percent), the distal stem became loose. The stem fractured in two cases (13 percent). On one occasion (6.6 percent) the metacarpal bone broke. In another case, as a result of a disturbance of muscle balance, the investigators observed a fixed ulnar deviation of the wrist joint with a tendency toward radial penetration of the medullary canal of the third metacarpal bone. The investigators also described three cases (20 percent) of a sinking of the prosthesis into the capitate through the third metacarpal.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistence to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint metal constrained prostheses be classified into class III. FDA finds that these implanted devices and intended to be used in relieving disabling pain and in restoring or minimizing further loss of functional use of a joint or limb. FDA believes these uses are of substantial importance in preventing impairment of human health. FDA believes that insufficient clinical experience exists fully establish the persons for use the devices are intended and the proper conditions of use. The agency believes that the probable benefit to health from use of these devices does not compare favorably with the likelihood of illness or injury resulting from their use.

Because of the lack of adequate data to demonstrate the safety and effectiveness of these implanted devices, FDA believes that use of wrist joint metal constrained prostheses presents an unreasonable risk of illness or injury. Because these devices are intended to be implanted in the human body, the Federal Food, Drug, and Cosmetic Act requires that they be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of these devices. On the basis of available information, FDA cannot make that determination. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing that these devices be classified into class III.

§ 888.3800; Docket No. 78N–3104; Wrist Joint Semi-Constrained Prosthesis

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of wrist joint semi-constrained prostheses:

1. Identification: A wrist joint semi-constrained prosthesis is an implanted device intended to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either (a) a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or (b) a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint semi-constrained prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint semi-constrained prostheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel recommends that the labeling for the device include information on the dimensions and kinematics of the device and its strength and wear characteristics.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on several oral presentations made to the Panel. On April 15, 1977, Dr. Robert Volz (Ref. 493) discussed the clinical results obtained following implantation of the AMC-type wrist joint semi-constrained prosthesis. Fifty prostheses had been implanted, 21 by Dr. Volz and 29 by 15 other surgeons participating in the clinical study. The minimum and maximum times the devices had been implanted were reported as 6 months and 33 months, respectively. Dr. Volz noted that the most consistent complication was a tendency of the wrist to drift into an abnormal position (ulnar deviation). At the time of evaluation, about 75 percent of the patients were pain free while 25 percent experienced mild pain. On July 15, 1977, Dr. Robert Beckenbaugh (Ref. 494) made a presentation to the Panel on his clinical experience with the Meuli wrist joint semi-constrained prosthesis. Eighty-four prostheses had been implanted. The average time of implantation was reported as 14 months, with over half of the patients having had the prostheses implanted for 18 months. Dr. Beckenbaugh reported that there had been some problems with positioning of the prosthesis, resulting in a tendency of the wrist to drift into ulnar deviation. These problems required reoperation in 36 percent of the patients receiving the prosthesis in the surgeon's first year of experience with the devices, 20 percent of those implanted received reoperation in his second year of experience with it and 4 percent in his third year. This reduction in the rates of reoperation were related to increased experience with the procedure and the bending and cutting of the intramedullary stems of the metacarpal component of the device. Ninety-three percent of the patients were pain free at the time of the last evaluation. Dr. Frank R. Noyes, a consultant to the Panel, noted that long-term results of the use of wrist joint semi-constrained prostheses were not available and that these results would be required in the future to ascertain whether the Panel's classification recommendation is still appropriate.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength and resistance to wear, may result in a loss or reduction of joint function due to excessive wear, fracture, deformation of the device, or loosening of the device in the surgical cavity. (b) Adverse tissue reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint semi-constrained prostheses be classified into class II. The agency has sought additional information on the use of wrist joint semi-constrained prostheses. The data presented to the Panel by Drs. Beckenbaugh and Volz (Refs. 493 and 494) contained early clinical studies regarding the series of patients involved (Refs. 495 through 498). The only other available published clinical data on wrist joint semi-constrained prostheses are reports from the originator of the Meuli design of the prosthesis (Ref. 499). Meuli reported the clinical results of a series of 21 patients in whom 26 prostheses had been implanted over 5.5 year period. There were nine failures: two infections, one case of device loosening, four cases of ankylosis, and two cases of severe synovitis due to the use of polyester material in an earlier design of the device. On final analysis, however, 18 of the 21 patients were satisfied with the results.

Although wrist joint semi-constrained prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with the use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device. Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.3810; Docket No. 78N–3105; Wrist joint ulnar (hemi-wrist) prosthesis.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of wrist joint ulnar (hemi-wrist) prostheses:

1. Identification: A wrist joint ulnar (hemi-wrist) prosthesis is a mushroom-shaped implanted device that is made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene. It is intended to be inserted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that wrist joint ulnar (hemi-wrist) prostheses be classified into class II because the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, should be controlled to prevent loss or reduction of joint function, adverse tissue reaction, or infection. The Panel believes that general controls alone will not provide sufficient control over these characteristics.

Although wrist joint ulnar (hemi-wrist) postheses are implanted devices, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommends that the labeling of the device describe its dimensions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Loss or reduction of joint function: Improper design or inadequate mechanical properties of the device, such as its lack of strength or resistance to wear, may result in a loss or reduction of joint function due to fracture or deformation of the device, or migration of the device in the surgical cavity. (b) Adverse tissue

reaction: Inadequate biological or mechanical properties of the device, such as its lack of biocompatibility and resistance to wear, may result in an adverse tissue reaction due to dissolution or wearing away from the surfaces of the device and the release of materials from the device to the surrounding tissues and systemic circulation. (c) Infection: The presence of the prosthesis within the body may lead to an increased risk of infection.

FDA agrees with the Panel recommendation and is proposing that wrist joint ulnar (hemi-wrist) prostheses be classified into class II. The agency has sought additional information on the safety and effectiveness of these devices. Two publications (Refs. 500 and 501) presented reports of clinical uses of the devices. Swanson (Ref. 500) presented results on a series of 54 patients. Bilateral implantations were perfrmed in 19 cases providing a total of 73 device implantations. Improvement was reported in the average postoperative values for pronation and supination, extension and flexion, and ulnar and radial deviation. Two types of complications were reported: (1) Migration of the implant in five cases in which the implant was not sutured in place; and (2) significant amounts of bone resorption in the distal centimeter of the ulnar in two other cases. Bone resorption was attributed to the design of the cuff of the device which was reported to have produced an excessively tight fit on the bone. The device and the surgical implantation procedure were reported to have been modified as a result of the adverse effects.

Three years after the initial results were presented by Swanson (Ref. 500), Berg (Ref. 501) reported his clinical results from four patients. The length of postoperative followup ranged from 8 months to 2½ years (average 20 months). Bone resorption was noted to have occurred beneath the cuff of the device in the patient with the longest followup. The author noted that while the followup periods were short, the early results were promising. It was reported that all four patients had relief of pain and that in no case was there a decrease of function, motion, or grip strength after the procedure.

Although wrist joint ulnar (hemi-wrist) prostheses are implanted devices, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of these devices. In addition, FDA has identified and assessed the major risks to health associated with use of these devices. FDA believes that the major risks, i.e., loosening, infection, and adverse tissue reaction, are related to biological responses of the human body to the presence of the device, the device design, and the underlying joint pathology, and not to physical failure(s) of the device.

Clinical experience with these devices has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the devices outweighs any likelihood of injury or illness resulting from their use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with use of these devices. The agency believes that performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by these devices.

§ 888.4150; Docket No. 78N-3106; Calipers for clinical use.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of calipers for clinical use:

1. Identification: A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The panel recommends that calipers for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the GMP regulation in manufacturing the device because this simple device presents no risks to health and all possible defects are readily detectable before use. The Panel noted that this device must be sterilizable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that calipers for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of calipers for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of calipers for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in calipers for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4200; Docket No. 78N-3107; Cement dispenser.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement dispensers:

1. Identification: A cement dispenser is a nonpowered syringe like device intended for use in placing bone cement into surgical sites.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement dispensers be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires

performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: Cement dispensers are routinely used for a variety of surgical procedures, such as fixation of prostheses and repair of bone fractures. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement dispensers be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4210; Docket No. 76N–3108; Cement mixer for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cement mixers for clinical use:

1. Identification: A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recomends that cement mixers for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires performance standards to control the identified risk to health. The Panel also recommends that the material from which the device is fabricated be identified in the device labeling.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement mixers for clinical use be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4220; Docket No. 78N–3109; Cement monomer vapor evacuator.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement monomer vapor evacuators:

1. Identification: A cement monomer vapor evacuator is a device intended for use during surgery for the containment or removal of bone cement monomer vapor or the removal of other undesirable fumes.

2. Recommended clasification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement monomer vapor evacuators be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that cement monomer vapor evacuators be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4230; Docket No. 78N–3110; Cement ventilation tube.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cement ventilation tubes:

1. Identification: A cement ventilation tube is a device, usually made from plastic, that consists of a segment of tubing that is intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cement ventilation tubes be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This is a relatively simple device with few risks associated with its use. The Panel does not believe that this device requires performance standards to control the identified risk to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: The chemically reactive materials present in bone cement may dissolve or leach substances from the device and cause the patient to have an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that cement ventilation tubes be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.4300; Docket No. 78N–3111; Depth gauge for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of depth gauges for clinical use:

1. Identification: A depth gauge for clinical use is a device consisting of an instrument with a graduated scale intended for various uses, such as to determine the proper length of screws for fastening the ends of a fractured bone.

2. Recommended classification: Class I. The Panel recommends that this device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that depth gauges for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the good manufacturing practice regulation because this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that gauges that clinical use be classified

into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of depth gauges for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of depth gauges for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in depth gauges for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4540; Docket No. 78N–3114; Orthopedic manual surgicial instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthopedic manual surgical instruments:

1. Identification: An orthopedic manual surgical instrument is a nonpowered handheld device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

2. Recommended classification: Class I. The Panel recommends that these devices be exempt from premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act, except those requirements pertaining to quality control.

3. Summary of reasons for recommendation: The Panel recommends that orthopedic manual surgical instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Orthopedic manual surgical instruments have been used for many years in a variety of surgical procedures. These are simple, nonpowered devices that present no undue hazards when used for the purposes for which they were designed.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members, personal knowledge of, and clinical experience with, the device.

5. Risks to health: Tissue damage and adverse tissue reaction: Inadequate mechanical properties, such as lack of material strength of the device, may result in device fracture and possible tissue damage and, if fragments of the fractured device remain in the tissue, an adverse tissue reaction may result.

FDA agrees with the Panel recommendation and is proposing that orthopedic manual surgical instruments be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

In response to the Panel's recommendation that manufacturers of orthopedic manual surgical instruments be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of orthopedic manual surgical instruments be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of these devices and thus their safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in orthopedic manual surgical instruments that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4580; Docket No. 78N–3116; Sonic surgical instrument and accessories/ attachments.

The Orthopedic Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of sonic surgical instruments and accessories/ attachments:

1. Identification: A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

2. Recommended classification: Class II. Both Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that the device be classified into class II because certain characteristics of this device, such as its electrical properties, must be controlled by a performance standard. The Panels believe that general controls alone would not provide sufficient safeguards over the dangers associated with use of the device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: Both Panels based their recommendations on the potential hazards associated with the device and on the Panel members' clinical experience with the device. The Panel members believe that the data indicate that the device will cut bone as safely as other techniques without apparent damage to surrounding tissue or bone.

5. Risks to health: (a) Electrical shock: Excessive current leakage from the device may cause electrical shock to the patient or operator. (b) Hard or soft tissue injury: Excessive sonic energy may result in injury to the hard or soft tissue being cut.

FDA agrees with the recommendations of both Panels and is proposing that sonic surgical instruments and accessories or attachments be classified into class II. The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to minimize the risks to health presented by these devices. A performance standard will provide

reasonable assurance of the safety and effectiveness of these devices. The agency also believes that sufficient information exists to establish a performance standard for these devices. FDA has reviewed the recommendations of the Orthopedic Device Classification Panel and of the Neurological Device Classification Panel for sonic surgical instruments and accessories or attachments and has determined that the classification of these devices should be published in the part of the Code of Federal Regulations for orthopedic devices.

§ 888.4600; Docket No. 78N–3117; Protractor for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of protractors for clinical use:

1. Identification: A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on X-rays or in surgery.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that protractors for clinical use be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with premarket notification procedures or with the good manufacturing practice regulation in manufacturing the device because this simple device presents no risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that protractors for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of protractors for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of protractors for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent defects in protractors for clinical use that could harm users. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.4800; Docket No. 78N–3118; Template for clinical use.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of templates for clinical use:

1. Identification: A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that templates for clinical use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with the premarket notification procedures or with the good manufacturing practice regulation because all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Tissue damage and adverse tissue reaction: Fracture of the device could injure surrounding tissue and, if device fragments remain in the tissue, could cause an adverse tissue reaction.

FDA agrees with the Panel recommendation and is proposing that templates for clinical use be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendations that manufacturers of protractors for clinical use be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the Panel's recommendation that manufacturers of templates for clinical use be exempt from the GMP regulation under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to control the risk to health identified by the Panel. Compliance with the GMP regulation will help prevent defects in templates for clinical use that could harm patients. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5850; Docket No. 78N–3120; Nonpowered orthopedic traction apparatus and accessories.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonpowered orthopedic traction apparatus and accessories:

1. Identification: A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the premarket notification procedures under section 510(k) of the act and the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered orthopedic traction apparatus and accessories be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of the device should not be required to comply with the premarket notification procedures or with the good manufacturing practice regulation because these simple devices present no

risks to health and all possible defects are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and experience with, nonpowered orthopedic traction apparatus and accessories.

5. Risks to health: None identified.

FDA agrees with the panel recommendation and is proposing that nonpowered orthopedic traction apparatus and accessories be classified into class I.

In response to the Panel's recommendation that manufacturers of nonpowered orthopedic traction apparatus and accessories be exempt from sections 510(k) and 520(f) of the act, FDA is proposing that these manufacturers be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA is proposing that manufacturers of these devices be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5890; Docket No. 78N–3122; Noninvasive traction component.

The Orthopedic Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of noninvasive traction components:

1. Identification: A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

2. Recommended classification: Class I. The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that noninvasive traction components be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that noninvasive traction components be classified into class I with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

§ 888.5940; Docket No. 78N–3123; Cast component.

The Orthopedic Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cast components:

1. Identification: A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that cast components be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards. The Panel recommends that the manufacturer be exempt from the good manufacturing practice requirements because adherence to the good manufacturing practice regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that cast components be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

In response to the Panel's recommendation that manufacturers of cast components be exempt from section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt from all requirements of the GMP regulation with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

§ 888.5960; Docket No. 78N–3124; AC-powered cast removal instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee made the following recommendation regarding the classficiation of AC-powered cast removal instruments:

1. Identification: An AC-powered cast removal instrument is an AC-powered hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

2. Recommended classification: Class II. The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered cast removal instruments be classified into Class II because the electrical properties of the device must be controlled to prevent electrical injury to the patient or operator. The Panel believes that general controls alone will not provide sufficient safeguards over the dangers associated with use of the device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information exists to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Electrical injury: Excessive current leakage from this device may cause electrical injury to the patient or operator.

FDA agrees with the Panel recommendation and is proposing that AC-powered cast removal instruments be classified into class II. The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to minimize the risks to health presented by these devices. A performance standard will provide reasonable assurance of the safety and effectiveness of these devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

§ 888.5980; Docket No. 78N–3125; Manual cast application and removal instrument.

The Orthopedic Device Classification Panel, an FDA advisory committee,

made the following recommendation regarding the classification of manual cast application and removal instruments:

1. Identification: A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

2. Recommended classification: Class I. The Panel recommends that the device be exempt from the GMP regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panel recommends that manual cast application and removal instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that these devices require performance standards. The Panel recommends that the manufacturer be exempt from the good manufacturing practice requirements because adherence to the good manufacturing practice regulation would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that manual cast application and removal instruments be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

In response to the Panel's recommendation that manufacturers of manual cast application and removal instruments be exempt from section 520(f) of the act, FDA is proposing that a manufacturer of these devices be exempt from all requirements in the GMP regulation, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding maintenance of complaint files. See § 888.1250 *Nonpowered dynamometer* in an earlier section of the preamble and the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

References

The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Transcript of Proceedings: Orthopedic Device Section Meeting, November 19, 1980," Washington, DC.

2. Chao, E. Y. and J. O. Mullen, "Theoretical and Experimental Analysis of the Interface Strength in Geometric Total Knee Replacement," *Closed Loop*, 6(2) :3–16 1976.

3. Rae, T., "A Study on the Effects of Particulate Metals of Orthopedic Interest on Murine Macrophages in Vitro," *Journal of Bone and Joint Surgery*, 57B: 444–453, 1975.

4. Elek, S. D. and P. E. Conen, "The Virulence of S. Pyogenes for Man. A study of the Problems of Wound Infection," *British Journal of Experimental Pathology*, 38:573–586, 1957.

5. Johnson, P. and D. Fromm, "Effects of Bone Wax on Bacterial Clearance," *Surgery*, 89(2):206–209, 1981.

6. Merritt, K., J. W. Shafer, and S. A. Brown, "Implant Site Infection Rates with Porous and Dense Materials," *Journal of Biomedical Materials Research*, 13(1):101–108, January 1979.

7. Swanson, S. A. V., M. A. R. Freeman, and J. C. Heath, "Laboratory Tests on Total Joint Replacement Prostheses," *Journal of Bone and Joint Surgery*, 55B: 759–773, November 1973.

8. Memoli, V. A., J. L. Woodman, R. M. Urban, and J. O. Galante, "Malignant Neoplasms Associated with Orthopedic Implant Materials," *Orthopaedic Research Society (Transactions)*, 7:164, 1982.

9. Berger, S. and S. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273–309, 1974.

10. Walldius, B., "A Comparative Analysis of Different Methods for Arthroplasty of the Knee" *in* "Total Knee Replacement," Chaired by L. G. P. Shiers, Mechancial Engineering Publications, Ltd., London, pp. 34–39, 1975.

11. Hanslik, L., "First Experience on Knee Joint Replacement Using the Young Hinged Prosthesis Combined with a Modification on the McKeever Patella Prosthesis," *Clinical Orthopedics*, 94:115–121, 1973.

12. Volz, R. G. and E. L. Gradillas, "Thermal Deformation of Polyethylene in a Total Knee Prosthesis," *Journal of Bone and Joint Surgery*, 60A:662–663, 1978.

13. Martens, M., P. DeMeester, J. C. Mulier, et al., "Mechanical Failure of Implants in Orthopedic Surgery," *Acta Orthopaedica Belgica*, 39(4):738–751, 1973.

14. Head, W. C., "Wagner Surface Replacement Arthroplasty of the Hip," *Journal of Bone and Joint Surgery*, 63A:420–426, 1981.

15. Rhinelander, F. W., C. L. Nelson, and C. L. and R. D. Stewart, "Experimental Reaming of the Proximal Femur and Acrylic Cement Implantation," *Clinical Orthopedics and Related Research*, 141:74–89, 1979.

16. Mallory, T. H., W. A. Stone, and R. L. St. Pierre, "Potential Hepatotoxic Effects of Methylmethacrylate Monomer," *Clinical Orthopedics*, 93:366–388, 1973.

17. Oppenheimer, B. S., E. T. Oppenheimer, I. Danishefsky, A. P. Stout, and F. R. Eirich, "Further Studies of Polymers as Carcinogenic Agents in Animals," *Cancer Research*, 15:333, 1955.

18. McDougall, A., "Malignant Tumor at Site of Bone Planting," *Journal of Bone and Joint Surgery*, 38B:709, 1956.

19. Oppenheimer, E. T., M. Willhite, I. Danishefsky, and A. P. Stout, "Observations on the Effects of Powdered Polymer and Glass in the Carconogenic Process," *Cancer Research*, 21:132–137, 1961.

20. Bischoff, F. and G. Bryson, "Carcinogenesis Through Solid-State Surfaces," *Progress in Experimental Tumor Research*, 5:85–133, 1964.

21. Carter, R. L. and F. J. C. Roe, "Induction of Sarcomas in Rats by Solid and Fragmented Polyethylene," *British Journal of Cancer*, 23:401, 1969.

22. Freeman, M. A. R., S. A. V. Swanson, and J. C. Heath, "Wear Particles Produced from CoCrMoMn Total Joint Replacement Prostheses," *Annals of the Rheumatic Diseases*, (Supplement) 28:29, 1969.

23. Thompson, J. R. and S. D. Entin, "Primary Extraskeletal Chondrosarcoma," *Cancer*, 23:936–939, April 1969.

24. Ott, G., "Fremdkoerpersarkome," *Experimentelle Medizin Pathologie und Klinik*, 32:1–118, 1970.

25. Heath, J. C., M. A. R. Freeman, and S. A. V. Swanson, "Carcinogenic Properties of Wear Particles from Prostheses Made in CoCr Alloy," *Lancet*, 1(7699):564, 1971.

26. Dowson, D. and S. A. V. Swanson, "Engineering Considerations in Total Knee Replacement," *in* "Total Knee Replacement," Chaired by Shiers, L. G., Mechanical Engineering Publications, Ltd., London, pp. 12–21, 1975.

27. Singh, A. R., W. H. Lawrence, and J. Autian, "Embryonic/Fetal Toxicity and Teratogenic Effects of a Group of Methacrylate Esters in Rats," *Journal of Dental Research*, 51:1632–1638, 1972.

28. Goldstein, A., L. Aronow, and S. M. Kalman, "Chemical Teratogenesis" *in* "Principles of Drug Action: The Basis of Pharmacology," Second edition, Wiley-Interscience, New York, pp. 703–727, 1974.

29. McLaughlin, R. E., S. I. Reger, J. A. Barkalow, M. S. Allen, and C. A. Difazio, "Methylmethacrylate: A Study of Teratogenicity and Fetal Toxicity of the Vapor in the Mouse," *Journal of Bone and Joint Surgery*, 60A:355–358, 1978.

30. Letter dated April 11, 1980 from Dr. Carl A. Larson, Director, Division of Surgical and Rehabilitation Devices to the Amercian Academy of Orthopedic Surgeons.

31. Swanson, A. B., "Silicone-Rubber Implants to Control the Overgrowth Phenomenon in the Juvenile Amputee," *Inter-Clinical Information Bulletin*, 9:5–8, 1972.

32. Lusskin, R., W. A. L. Thompson, A. Pena, and S. Sanwal, "Bone Contouring Under Silicone Polymer Implants," *Clinical Orthopedics and Related Research*, 83:300–317, 1972.

33. Buhler, J., "Percutaneous Cerclage of Tibial Fractures," *Clinical Orthopedics and Related Research*, 105:276–282, 1974.

34. Fenyo, G., "On the Fracture of the Shaft of the Humerus," *Acta Chirurgica Scandinavica*, 137:221–226, 1971.

35. Rhinelander, F. W., "Minimal Internal Fixation of Tibial Fractures," *Clinical Orthopedics and Related Research*, 107:188–220, 1975.

36. Hinki, P. J. and F. W. Rhinelander, "Effective Use of Cerclage in the Treatment of Long Bone Fractures in Dogs," *Journal of the American Veterinary Medical Association*, 166:520–524, 1975.

37. Rhinelander, F. W., "Instruments for Use with Flexible Steel Wire in Bone Surgery," *Journal of Bone and Joint Surgery*, 40A: 365–374, 1958.

38. Bohles, J., "Closed Intramedullary Nailing of the Femur," *Clinical Orthopaedic and Related Research*, No. 60, September–October, 1968.

39. Schneider, H. W., "Use of the 4-Flanged Self Cutting Intramedullary Nail for Fixation of Femoral Fractures," *Clinical Orthopaedic and Related Research*, No. 60, September–October, 1968.

40. Clawson, D. K., R. F. Smith, and T. Hansen, "Closed Intramedullary Nailing of the Femur," *Journal of Bone and Joint Surgery*, 53A (4), June 1971.

41. Cristensen, O., "Kuentscher Intramedullary Reaming and Nail Fixation for Non-Union of Fracture of the Femur and the Tibia," *Journal of Bone and Joint Surgery*, 55B(2), May 1973.

42. Allen, C., K. G. Heiple, and A. H. Burstein, "A Fluted Femoral Intramedullary Rod," *Journal of Bone and Joint Surgery*, 60A(4), June 1978.

43. Hunter, J. M. and R. E. Salisbury, "Use of Gliding Artificial Implants to Produce Tendon Sheaths," *Plastic and Reconstructive Surgery*, 45(6):564, 1970.

44. Hunter, J. M., "Artificial Tendons: Early Development and Application," *American Journal of Surgery*, 109:325, 1965.

45. Weinstein, S. L., B. L. Sprague, and A. E. Flatt, "Evaluation of the Two-Stage Flexor-Tendon Reconstruction in Severely Damaged Digits," *Journal of Bone and Joint Surgery*, 58:786–791, 1976.

46. Hunter, J. M. and R. E. Salisbury, "Flexor-Tendon Reconstruction in Severely Damaged Hands: A Two-Stage Procedure Using a Silicone-Dacron Reinforced Gliding Prosthesis Prior to Tendon Grafting," *Journal of Bone and Joint Surgery*, 53:829–858, July 1971.

47. Hunter, J. M., C. Steindel, R. E. Salisbury, and D. Hughes, "Study of Early Sheath Development Using Static Nongliding Implants," *Journal of Biomedical Materials Research*, 8:155–162, 1974.

48. Elliott, B., "Fractures of the Femoral Condyles," *Southern Medical Journal*, 52:80–85, January 1959.

49. Chiron, S., J. Tremoulet, P. Casey, and M. Muller, "Fractures of the Distal Third of the Femur Treated by Internal Fixation," *Clinical Orthopaedics and Related Research*, No. 100, May 1974.

50. Banks, H., "Nonunion in Fracture of the Femoral Neck," *Orthopedic Clinics of North America*, Vol. 5, No. 4, October 1974.

51. Brown, A. and J. C. D'Arcy, "Internal Fixation for Supracondylar Fractures of the Femur in the Elderly Patient," *Journal of Bone and Joint Surgery*, 53B(3), August 1971.

52. Shelton, M. L., S. A. Grantham, C. S. Neer, and R. Singh, "A New Fixation Device for Supracondylar and Low Femoral Shaft Fractures," *Journal of Truama*, 14(10), October 1974.

53. Burwell, H., "Plate Fixation of Tibial Shaft Fractures," *Journal of Bone and Joint Surgery*, 53B(2), May 1971.

54. Berkin, C. R. and V. D. Marshall, "Three Sided Plate and Femoral Shafts," *Journal of Bone and Joint Surgery*, 45A(5), July 1972.

55. Scales, J. T. and R. Perry, "Screw and Plate Devices in the Fixation of Fractures," *Acta Orthopedic Belgica*, Tome 40, Fasc. 5–6, 1974.

56. Ruedi, T., J. K. Webb, and M. Allgower, "Experience with the Dynamic Compression Plate in 418 Recent Fractures of the Tibial Shaft," *Injury*, 7(4), 1976.

57. Buck, J. E., "Direct Repair of the Defect in Spondylolisthesis, Preliminary Report," *Journal of Bone and Joint Surgery*, 54A:1167–1176, 1972.

58. Dodge, H. S. and G. W. Cady, "Treatment of Fracture of the Radius and Ulna with Compression Plates," *Journal of Bone and Joint Surgery*, 54A:432–437, 1979.

59. Conner, A. N. and M. G. Smith, "Displaced Fractures of the Lateral Humeral Condyle in Children," *Journal of Bone and Joint Surgery*, 54A:460–464, 1979.

60. Artz, T. and J. M. Huffer, "A Major Complication of the Modified Bristow Procedure for Recurrent Dislocation of the Shoulder, A Case Report," *Journal of Bone and Joint Surgery*, 54A:1293, 1972.

61. Perren, S. M., P. Matter, R. Ruedi, and M. Allgower, "Biomechanics of Fractures Healing After Internal Fixation," *Annals of Surgery*, 7:361–390, 1975.

62. Uhthoff, H. K., "Mechanical Factors Influencing the Holding Power of Screws in Compact Bone," *Journal of Bone and Joint Surgery*, 55B:633–639, 1973.

63. Johnson, L. L., J. O. Lottes, and J. P. Arnot, "The Utilization of the Holt Nail for Proximal Femoral Fractures. A Study of One Hundred and Forty-Six Patients," *Journal of Bone and Joint Surgery*, 50A:67–68, 1968.

64. Hughes, A. N. and B. A. Jordan, "Metallurgical Observations on Some Metallic Surgical Implants Which Failed In Vivo," *Journal of Biomedical Materials Research*, 6:33–48, 1972.

65. Burstein, A. H., J. D. Currey, V. H. Frankel, K. G. Heiple, P. Lunseth, and J. C. Vessely, "Bone Strength. The Effect of Screw Holes," *Journal of Bone and Joint Surgery*, 54A:1143–56, 1972.

66. Coleman, S., "Aseptic Necrosis of Bone Due to Trauma," *Orthopedic Clinics of North America*, Vol. 5, No. 4, October 1974.

67. Black, J., "Failure of Implants for Internal Hip Fixation," *Orthopedic Clinics of North America*, Vol. 5, No. 4, October 1974.

68. Holt, . E. P., Jr., "Rigid Fixation by Use of the Holt Nail," *Orthopedic Clinics of North America*, Vol. 5, No. 3, July 1974.

69, Fielding, J., "Pugh Nail Fixation of Displaced Femoral Neck Fixations, a Long Term Follow-up," *Clinical Orthopedics and Related Research*, No. 106, January–February 1975.

70. Ecker, L., J. Joyce, and E. J. Kohl, "The Treatment of Trochanteric Hip Fractures Using a Compression Screw," *Journal of Bone and Joint Surgery* (Am), 60–A, No. 2, pp. 300–306, April 1978.

71. Seinsheimer, F., III, "Subtrochanteric Fractures of the Femur," *Journal of Bone and Joint Surgery* (Am), 60–A, pp. 300–306, April 1978.

72. Friedmann, E., "Early Ambulation After Hip Nailing," *Lackawanna Medicine*, January 1968.

73. Harrington, D. and O. Johnston, "The Management of Comminuted Unstable Intertrochanteric Fractures," *Journal of Bone and Joint Surgery*, 55A(7), October 1973.

74. Jacobs, R. R., H. J. Armstrong, J. H. Whitaker, and J. Pazell, "Treatment of Intertrochanteric Hip Fracture With a Compression Hip Screw and a Nail Plate," *Journal of Trauma*, 16(8), August 1976.

75. Hansen, G. W., and H. S. Tullas, "Subtrochanteric Fractures of the Femur Treated with Nail Plate Devices," *Clinical Orthopedics and Related Research*, 131, March–April 1978.

76. Baker, G. I. and E. F. Barrick, "Deyerle Treatment for Femoral Neck Fractures," *Journal of Bone and Joint Surgery*, 60A(2), March 1978.

77. Massie, W. K., "Fractures of the Hip," *Journal of Bone and Joint Surgery*, 46A(3), April 1964.

78. Cohen, J. and J. Wulff, "Clinical Failure Caused by Corrosion of a Vitallium Plate," *Journal of Bone and Joint Surgery*, 54A(3), April 1972.

79. Rose, R. M., A. Schiller, and E. L. Radin, "Corrosion-Accelerated Mechanical Failure of a Vitallium Nail-Plate," *Journal of Bone and Joint Surgery*, 54A(4), June 1972.

80. Zickel, R. E., "A New Fixation Device for Subtrochanteric Fractures of the Femur," *Clinical Orthopedic and Related Research*, No. 54, October 1967.

81. Mickelson, M. R. and M. Bonfiglio, "Pathological Fractures in the Proximal Part of the Femur Treated by Zickel-Nail Fixation," *Journal of Bone and Joint Surgery*, 58A(8), December 1976.

82. Cuthbert, H. and T. W. Honat, "The Use of the Kuntscher Y Nail in the Treatment of Intertrochanteric and Subtrochanteric Fractures of the Femur," *Injury*, 8(2), November 1976.

83. Fenyo, G., "On Fractures of the Shaft of the Humerus," *Acta Chirurgica Scandinavica*, 137:221–226, 1971.

84. Jones, E. R. L. and M. Esah, "Displaced Fractures of the Neck of the Radius in Children," *Journal of Bone and Joint Surgery*, 53B:429–439, 1971.

85. Green, D. P., "Pins and Plaster Treatment of Comminuted Fractures of the Distal End of the Radius," *Journal of Bone and Joint Surgery*, 57A:304–310, 1975.

86. DaValusco, P. G. and A. C. Monterubio, "Arthrodesis of the Shoulder," *Clinical Orthopedics and Related Research*, 90:178–182, 1973.

87. Flynn, J. C., J. G. Matthews, and R. L. Benoit, "Blind Pinning of Displaced Supracondylar Fractures of the Humerus in Children," *Journal of Bone and Joint Surgery*, 56A:263–272, 1974.

88. Ruedi, R., J. K. Webb, and M. Allgower, "Experience with the Dynamic Compression Plate (DCP) in 418 Recent Fractures of the Tibial Shaft," *Injury*, 7:252–257, 1976.

89. Evans, E. M., M. A. R. Freeman, A. J. Miller and B. Vernon Roberts, "Metal Sensitivity as a Cause of Bone Necrosis and Loosening of the Prosthesis in Total Joint Replacement," *Journal of Bone and Joint Surgery*, 56B:626–642, 1974.

90. Dodge, H. S. and G. W. Cady, "Treatment of Fractures of the Radius and Ulna with Compression Plates," *Journal of Bone and Joint Surgery*, 54A:432–437, 1979.

91. Burwell, H. N., "Plate Fixation of Tibial Shaft Fractures: A Survey of 181 Injuries," *Journal of Bone and Joint Surgery*, 52B:258–271, 1971.

92. Conner, A. N. and M. G. Smith, "Displaced Fractures of the Lateral Humeral Condyle in Children," *Journal of Bone and Joint Surgery*, 54A:460–464, 1970.

93. Artz, T. and J. M. Huffer, "A Major Complication of the Modified Bristow Procedure for Recurrent Dislocation of the Shoulder, A Case Report," *Journal of Bone and Joint Surgery*, 54A:1293, 1972.

94. Scales, J. T. and R. Perry, "Screw and Plate Devices in the Fixation of Fractures," *Acta Orthopedic Belgium*, 40:836–845, 1974.

95. Perren, S. M., P. Matter, R. Ruedi, and M. Allgower, "Biomechanics of Fractures Healing After Internal Fixation," *Annals of Surgery*, 7:361–390, 1975.

96. Skolnick, M. D., M. B. Coventry and D. M. Ilstrup, "Geometric Total Knee Arthroplasty. A Two-year Followup Study," *Journal of Bone and Joint Surgery*, 58A:749–753, 1976.

97. Nachemson, A., "A long Term Followup Study of Non-Treated Scoliosis," *Journal of Bone and Joint Surgery*, 51A:203–208, 1969.

98. Collis, K. K. and I. V. Ponsetti, "Long Term Followup of Patients With Idiopathic Scoliosis Not Treated Surgically," *Journal of Bone and Joint Surgery*, 51A:425–445, April 1969.

99. Harrington, P. R., "Treatment of Scoliosis," *Journal of Bone and Joint Surgery*, 44–A:591–610, June 1962.

100. Harrington, P. R. and J. H. Dickson, "An 11-Year Clinical Investigation of Harrington Instrumentation," *Clinical Orthopedics*, 93:113–130, June 1973.

101. Dickson, J. H. and P. R. Harrington, "The Evolution of the Harrington Instrumentation Technique in Scoliosis," *Journal of Bone and Joint Surgery*, 55A(5):993–1002, 1973.

102. O'Brien, J. P. and A. C. M. C. Yau, "Anterior and Posterior Correction and Fusion for Paralytic Scoliosis," *Clinical Orthopedics*, 86:151–153, 1972.

103. Dawson, E. G., A. Caron, and J. H. Moe, "Surgical Management of Scoliosis in the Adult," *Journal of Bone and Joint Surgery*, 55A(2):437, March 1973.

104. Kostuik, J. P., J. Israel, and J. E. Hall, "Scoliosis Surgery in Adults," *Clinical Orthopedics*, 93:225–234, June 1973.

105. Bonnet, C. and J. C. Brown, "Evolution of Treatment of Paralytic Scoliosis at Rancho Los Amigos Hospital," *Journal of Bone and Joint Surgery*, 57A(2):206–215, 1975.

106. Goldstein, L. A., "Treatment of Idiopathic Scoliosis by Harrington Instrumentation and Fusion with Fresh Autogeneous Iliac Bone Grafts," *Journal of Bone and Joint Surgery*, 51A(2):209–222, 1969.

107. Dolan, J. A. and G. O. MacEwen, "Surgical Treatment of Scoliosis," *Clinical Orthopedics*, 76:125–137, 1971.

108. Dwyer, A. F., N. C. Newton, and A. A. Sherwood, "An Anterior Approach to Scoliosis—A Preliminary Report," *Clinical Orthopedics*, 62:192–202, 1969.

109. Dwyer, A. F., "Experience of Anterior Correction of Scoliosis," *Clinical Orthopedics*, 93:191–206, June 1973.

110. Dwyer, A. F., "Anterior Approach to Scoliosis. The Results of Treatment in 51 Cases," *Journal of Bone and Joint Surgery*, 56B:218–224, 1974.

111. Dwyer, A. F., J. P. O'Brien, et al., "The Late Complications After the Dwyer Anterior Spinal Instrumentation for Scoliosis," *Journal of Bone and Joint Surgery*, 59B:117, 1977.

112. Eisenstein, S. and J. P. O'Brien, "Chylothorax: A Complication of Dwyer's Anterior Instrumentation," *British Journal of Surgery*, 64:339–341, 1977.

113. Hall, J. E., J. Gray, and M. Allen, "Dwyer Instrumentation and Spinal Fusion. A Followup Study," *Journal of Bone and Joint Surgery*, 59B:117, 1977.

114. Schafer, M. F., "Dwyer Instrumentation of the Spine," *Orthopedic Clinics of North America*, 9(1):115–122, January 1978.

115. Silber, I. and W. McMaster, "Retroperitoneal Fibrosis with Hydronephrosis as a Complication of the Dwyer Procedure," *Journal of Pediatric Surgery*, 12(2):255–257, 1977.

116. Simmons, E. H., E. A. Sue-A-Quan, et al., "An Analysis of Dwyer Instrumentation of the Spine with Assessment of Its Place in Spinal Surgery," *Journal of Bone and Joint Surgery*, 59B:117, 1977.

117. Stephen, J. P., K. Wilding, et al., "The Place of Dwyer Anterior Instrumentation in Scoliosis," *Medical Journal of Australia*, 1(7):206–208, February 1977.

118. Winter, R. R., "Combined Dwyer and Harrington Instrumentation and Fusion in the Treatment of Selected Patients with Painful Adult Idiopathic Scoliosis," *Spine*, 3(2):135–141, June 1978.

119. Schafer, M. F., D. Page, and G. Shew, "Mechanical Evaluation of the Dwyer Screw-Cable Attachment," *Spine*, 4(5):398–400, September–October 1979.

120. Summary Minutes of the Twentieth Meeting of the Orthopedic Device Classification Panel, March 21, 1978.

121. Summary Minutes of the Twenty-First Meeting of the Orthopedic Device Classification Panel, July 13, 1978.

122. Summary Minutes of the Eighteenth Meeting of the Orthopedic Device Classification Panel, July 1977.

123. Summary Minutes of the Twenty-Fourth Meeting of the Orthopedic Section of the Surgical and Rehabilitation Devices Panel, November 1980.

124. Kempson, G. E., M.A. R. Freeman, and M. A. Tuke, "Engineeering Considerations in the Design of an Ankle Joint," *Biomedical Engineering*, 10(5):1138, 1975.

125. Pappas, M., F. F. Buechel, and A. F. DePalma, "Cylindrical Total Ankel Joint Replacement," *Clinical Orthopedics and Related Research*, 118:82–92, 1976.

126. Stauffer, R. N., "Total Ankle Joint Replacement as an Alternative to Arthrodesis," *Geriatrics*, 31(3):79–82, 85, 1976.

127. Stauffer, R. N., "The Prosthetic Ankle Joint," in DHEW/RSA "Workshop on Internal Joint Replacement," Edited by C. L. Compere and J. L. Lewis, RSA, Chicago, pp. 76–83, 1977.

128. Evanski, P. M. and T. R. Waugh, "Management of Arthritis of the Ankle," *Clinical Orthopedics and Related Research*, 122:110–115, 1977.

129. Scholz, K. C., "Total Ankle Replacement Arthroplasty," *in* "Foot Science," edited by Batemen, J. E., Philadelphia, pp. 106–35, 1976.

130. Freeman, M. A. R., "Current State of Joint Replacement," *British Medical Journal*, 2(6047):1301–1304, 1976.

131. Newton, S. E., from Proceedings of the Annual Meeting of the American Academy of Orthopedic Surgeons, February 1978, Dallas.

132. Summary Minutes of the Seventeenth Meeting of the Orthopedic Device Classification Panel, April 1977.

133. Dee, R., "Five Years Experience with Total Replacement of the Elbow in Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications, 1977–5," Mechanical Engineering Publications Ltd. Great Britain, pp. 89–92, 1977.

134. Souter, W. A., "Total Replacement Arthroplasty of the Elbow," ibid, pp. 99–106.

135. Devas, M. B. and V. Shah, "Arthroplasty of the Upper Limb. Link Arthroplasty of the Elbow. Link Arthroplasty of the Metacarpophalangeal Joints—A Progress Report," ibid, pp. 33–40.

136. Gshwend, N., H. Scheier, and A. Bahler, "GSB Elbow, Wrist-MP and PIP-Joints," ibid, pp. 107–116.

137. Ewald, F. C., "Total Elbow Replacement," *Orthopedic Clinics of North America*, 6:685–696, 1975.

138. Engelbrecht, E., H. W. Buchholoz, J. Rottger, and A. Siegel, "Total Elbow Replacement with a Hinge and Non-Blocked System," op. cit., pp. 83–88.

139. Pritchard, R. N., "Flexible Elbow Joint Replacement," ibid, pp 63–68.

140. Schlein, A. P., "Semiconstrained Total Elbow Arthroplasty," *Clinical Orthopedics and Related Research*, 121:222–229, November–December 1976.

141. Nicol, A. C., N. Berne, and J. P. Paul, "A Biomechanical Analysis of Elbow Joint Function," op cit., pp. 45–52.

142. Lee, A. J. C. and R. S. M. Ling, "The Optimized Use of PMMA Bone Cement and Some Limitations of its Use in the Fixation of Upper Limb Prostheses," ibid, pp. 41–44.

143. Bryan, R. S., "Total Elbow Arthroplasty," DHEW/RSA Workshop on Internal Joint Replacement, Edited by C. L. Compere and J. L. Lewis, Chicago, IL., pp. 30–32, 1977.

144. Cavendish, M. E. and M. A. Elloy, "A Simple Method of Total Elbow Replacement," op cit., pp. 21–26.

145. Dobyns, J. H., R. S. Bryan, R. L. Linscheid, and L. F. A. Peterson, "Special Problems of Total Elbow Arthroplasty," *Geriatrics*, 31(4):57–61, 1976.

146. Parsons, D. W. J., "[Discussion of Papers by N. C. Roles and Scales, Roantree and Towers]." *Proceedings of the Royal Society of Medicine*, 64:639–640, 1971.

147. Ewald, F. C., W. H. Thomas, C. B. Sledge, R. D. Scott, and R. Poss, "Non-Constrained Metal to Plastic Total Elbow Arthroplasty in Rheumatoid Arthritis," ibid. pp. 77–82, 1977.

148. Hall, A. J., "Report of a Case of Late Infection About a Total Knee Prosthesis Secondary to Urinary Tract Infection," *Journal of Bone and Joint Surgery*, 56B:144–147, 1974.

149. Brand, R. A., "Late Hematogenous Infection in Total Joint Replacement." *Journal of the Iowa Medical Society*, 65(9): 388–390, 1975.

150. Engelbrecht, E., H. W. Buchholz, J. Rottger, and A. Siegel, "Total Elbow Replacement with a Hinge and a Non-blocked System in Joint Replacement in the Upper Limb," op. cit., pp. 83–88, 1977.

151. Dee, R., "Five Years Experience with Total Replacement of the Elbow in Joint Replacement in the Upper Limb," ibid., pp. 89–92, 1977.

152. Ewald, F. C., "Total Elbow Replacement," *Orthopedic Clinics of North America*, 6:685–696, 1975.

153. Nicol, A. C., N. Berme, and J. P. Paul, "A Biomechanical Analysis of Elbow Joint Function in Joint Replacement in the Upper Limb," op. cit., pp. 45–52, 1977.

154. Swanson, A. B., "Flexible Implant Resection Arthroplasty in the Hand and Extremities," C. V. Mosby Co., St. Louis, pp. 265–275, 1973.

155. Stevens, P. S., "Distal Humeral Prosthesis for the Elbow," *in* "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications 1977–5," Mechanical Engineering Publications Ltd., Great Britain, pp. 69–76, 1977.

156. Street, D. M., T. Stevens, and P. S. Stevens, "A Humeral Replacement Prosthesis for the Elbow," *The Journal of Bone and Joint Surgery*, 56A:1147–1158, 1974.

157. Flatt, A. E., "Restoration of Rheumatoid Finger-Joint Function," *Journal of Bone and Joint Surgery*, 43A:753–774, 1961.

158. Flatt, A. E., "Restoration of Rheumatoid Finger-Joint Function, II" *Journal of Bone and Joint Surgery*, 45A:1101–1103, 1963.

159. Flatt, A. E., "Prosthetic Substitution for Rheumatoid Finger Joints," *Plastic and Reconstructive Surgery*, 40:565–570, 1967.

160. Flatt, A. E. and G. W. Fischer, "Biomechanical Factors in the Replacement of Rheumatoid Finger Joints," *Annuals of Rheumatic diseases*, 28:36–41, 1969.

161. Flatt, A. E. and M. R. Ellison, "Restoration of Rheumatoid Finger-Joint Function, III," *Journal of Bone and Joint Surgery*, 54:1317–1333, 1972.

162. Flatt, A. E., "Studies in Finger Joint Replacement: A Review of the Present Position," *Archives of Surgery*, 107:437–443, 1973.

163. Girzados, D. V. and M. L. Clayton, "Limitations of the Use of Metallic Prosthesis in the Rheumatoid Hand," *Clinical Orthopedics and Related Research*, 67:127–132, 1969.

164. Calenoff, L. and W. B. Stromberg, "Silocone Rubber Arthroplasties of the Hand," *Radiology*, 107:29–34, 1973.

165. Millender, L. H. and E. A. Nalebuff, "Metacarpophalangeal Joint Arthroplasty Utilizing the Silicone Rubber Prosthesis," *Orthopedic Clinics of North America*, 4(2):349–371, 1973.

166. McFarland, G. B., Jr., "Early Experience with the Silicone Rubber Prosthesis (Swanson) in the Reconstruction Surgery of the Rheumatoid Hand," *Southern Medical Journal*, 65:1113–1117, 1972.

167. Walker, P. S. and L. R. Straub, "Development and Evaluation of a Mechanical Finger Prosthesis," *in* "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications, 1977–5," Mechnical Engineering Publications Ltd., Great Britain, pp. 168–173, 1977.

168. Goldner, J. L. and J. R. Urbaniak, "The Clinical Experience with Silicone-Dacron ™ Metacarpophalangeal and Interphalangeal Joint Prosthesis," *Journal of Biomedical Materials Research*, 4:137–163, 1973.

169. Nicolle, F. V. and J. S. Calnan, London, "A New Design of Finger Joint Prosthesis for the Rheumatoid Hand," *The Hand*, 4(2):135–146, 1972.

170. Smith, R. J. and A. S. Broudy, "Advances in Surgery of the Rheumatoid Hand," *Current Practices in Orthopedic Surgery*, 7:1–35, 1977.

171. Devas, M. and V. Shah, "Link Arthroplasty of the Metacarpophalangeal Joints," *Journal of Bone and Joint Surgery*, 57:72–77, 1975.

172. Devas, M. and V. Shah, "Arthroplasty of the Upper Limb. Link Arthroplasty of the Elbow. Link Arthroplasty of the Metacarpophalangeal Joints—A Progress Report," *in* "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers, 1977–5," Mechanical Engineering Publications Ltd., Great Britain, pp. 154–161, 1977.

173. Hirsch, D., D. Page, D. Miller, J. H. Dumbleton, and E. H. Miller, "A Biomechanical Analysis of the Metacarpophalangeal Joint of the Thumb," *Journal of Biomechanics*, 7:343–348, 1973.

174. Page, D., J. H. Dumbleton, and E. H. Miller, "A Study of the Wear Resistance of a Prosthesis for the Metacarpophalangeal Joint of the Thumb," *Clinical Orthopedics and Related Research*, 100:301–308, 1974.

175. Walker, P. S., L. R. Straub, W. Davidson, and M. S. Moneim, "Development and Evaluation of a Mechanical Finger Prosthesis," *in*, "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications, 1977–5," Mechanical Engineering Publications Ltd., Great Britain, pp. 127–132, 1977.

176. Walker P. S. and M. J. Erkman, "Laboratory Evaluation of a Metal-Plastic Type of Metacarpophalangeal Joint Prosthesis," *Clinical Orthopedics and Related Research*, 112:349–356, 1975.

177. Smith, R. J. and A. S. Broudy, "Advances in Surgery of the Rheumatoid Hand," *Current Practices in Orthopedic Surgery*, 7:1–35, 1977.

178. Walker, P. S., "Human Joints and their Artificial Replacements," *C. C. Thomas, Springfield, IL, pp. 270–272, 337–351, 1977.*,

179. Nicolle, F., "Modified Design of Encapsulated Metarcarpophalangeal Joint Prosthesis for the Rheumatoid Hand," *in*, "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications, 1977–5," Mechanical Engineering Publications Ltd., Great Britain, pp. 133–135, 1977.

180. Schetrumpf, J., "A New Metacarpophalangeal Joint Prosthesis," *The Hand*, 7(1):75–77, 1975.

181. Nicolle, F. V. and J. S. Calnan, London, "A New Design of Finger Joint Prosthesis for the Rheumatoid Hand," *The Hand*, 4(2): 135–146, 1972.

182. Griffiths, R. W. and F. V. Nicolle, London, "Three Years' Experience of Metacarpophalangeal Joint Replacement in the Rheumatoid Hand," *The Hand*, 7(3):275–283, 1975.

183. Burton, D. S. and D. J. Schurman, "Hematogenous Infection in Bilateral Total Hip Arthroplasty," *Journal of Bone and Joint Surgery*, 57A:1004–1005, 1975.

184. Beckenbaugh, R. D., J. H. Dobyns, R. L. Linscheid, and R. S. Bryan, "Review and Analysis of Silicone-Rubber Metacarpophalangeal Implants," *Journal of Bone and Joint Surgery*, 58(A):483–7, 1976.

185. Goldner, J. L., J. S. Gould, J. R. Urbaniak, and D. E. McCollum, "Metacarpophalangeal Joint Arthroplasty with Silicone-Dacron Prostheses (Niebauer type): Six and a Half Years' Experience," *Journal of Hand Surgery*, 2:200–211, 1977.

186. Goldner, J. L. and J. R. Urbaniak, "The Clincial Experience with Silicone-Dacron Metacarpophalangeal and Interphalangeal Joint Prostheses," *Journal of Biomedical Materials* 4:137–163, 1973.

187. Hagert, C. G., "Metacarpophalangeal Joint Implants II: Roentgenographic Study of the Niebauer-Cutter Metacarpophalangeal Joint Prosthesis," *Scandinavian Journal of Plastic and Reconstructive Surgery*, 9:158–164, 1975.

188. J. J. Niebauer and R. M. Landry, "Dacron-Silicone Prosthesis for the Metacarpophalangeal and Interphalangeal Joints," *The Hand*, 3:55–61, 1971.

189. Swanson, A. B., "Flexible Implant Arthroplasty for Arthritic Finger Joints: Rationale, Technique and Results of Treatment," *Journal of Bone and Joint Surgery*, 54–A: 435–455, 1972.

190. Swanson, A. B., "Flexible Implant Arthroplasty in the Hand," *Clinical and Plastic Surgery*, 3:141–157, 1976.

191. Hagert, C. G., O. Eiken, N. M. Ohlsson, W. Aschan, and A. Movin, "Metacarpophalangeal Joint Implants," *Scandinavian Journal of Plastic and Reconstructive Surgery*, 19:147–157, 1975.

192. Mannerfelt, L. and K. Anderson, "Silastic Arthroplasty of the Metacarpophalangeal Joints in Rheumatoid Arthritis," *Journal of Bone and Joint Surgery*, 57A:484–489, 1975.

193. Ferlic, D. C., M. L. Clayton, and M. Holloway, "Complications of Silicone Implant Surgery in the Metacarpophalangeal Joint," *Journal of Bone and Joint Surgery*, 57A:991–994, 1975.

194. Aptekar, R. G., J. M. Davie, and H. S. Cattell, "Foreign Body Reaction to Silicone Rubber, Complication of a Finger Joint Implant," *Clinical Orthopaedics and Related Research*, 231–232.

195. Hagert, C. G., "Metacarpophalangeal Joint Implants," *Scandinavian Journal of*

Plastic and Reconstructive Surgery, 9:216–226, 1975.

196. Weightman, S. S., R. Rose, I. Paul, and E. Radin, "Environmental Fatigue Testing of Silastic Joint Proshteses," *Journal of Biomedical Materials Research*, Symposium, 3:15–24, 1972.

197. Swanson, A. B. and J. H. Herndon, "Flexible (Silicone) Implant Arthroplasty of the Metacarpophalangeal Joint of the Thumb," *Journal of Bone and Joint Surgery*, 59A:362–368, 1977.

198. Swanson, A. B., "Implant Resection Arthroplasty of the Proximal Interphalangeal Joint," *Orthopedic Clinics of North America*, 4(4):1007–1209, 1973.

199. Braun, R. M. and J. Chandler, "Quantitative Results Following Implant Arthroplasty of the Proximal Finger Joints in the Arthritic Hand," *Clinical Orthopaedics and Related Research*, 83:135–143, 1972.

200. Sivash, K. M., "The Development of a Total Metal Prosthesis for The Hip Joint from a Partial Joint Replacement," *Reconstructive Surgery and Traumatics*, 11:53–62, 1969.

201. Wilson, P. D., Jr., H. C. Amstutz, A. Dzerniecki, E. A. Salvati, and D. G. Mendes, "Total Hip Replacement with Fixation by Acrylic Cement," *Journal of Bone and Joint Surgery*, 54(A):207–236, 1972.

202. Bentley, G. and R. B. Duthie, "A Comparative Review of the McKee-Farrar and Charnley Total Hip Prostheses," *Clinical Orthopedics and Related Research*, 95:127–142, 1973.

203. Mendes, D. G., "Roentgenographic Evolution in Total Hip Replacement," *Clinical Orthopedics and Related Research*, 95:104–110, 1973.

204. Ring, P. A., "Total Replacement of the Hip Joint, A Review of a Thousand Operations," *Journal of Bone and Joint Surgery*, 56B(1):44–58, 1974.

205. Lindholm, R. V. and J. Puranen, "Ring Total Hip Replacement in Osteoarthrosis," *Acta Orthopaedica Scandinavica*, 47:311–316, June 1976.

206. Summary of Minutes of the Twentieth Meeting of the Orthopedic Device Classification Panel, March 21, 1978.

207. Summary of Minutes of the Twenty-First Meeting of the Orthopedic Device Classification Panel, July 13, 1978.

208. Hirsch, C., "Clinical Symposium Problems in Total Hip Replacements," *Journal of Biomedical Materials Research*, No. 5 (Part 2), pp. 227–244, 1974.

209. Dietschi, C., A. Huggler, and Y. Suezawa, "Problems of Loosening" *in* "Total Hip Prosthesis," Edited by N. Gschwend and H. U. Debrunner, Hans Huber Publishers, Vienna, pp. 144–152, 1976.

210. Anderson, G. B. J., M. A. R. Freeman, and S. A. V. Swanson, "Loosening of the Cemented Acetabular Cup in Total Hip Replacement," *Journal of Bone and Joint Surgery*, 54B:590–599, 1972.

211. Stuhmer, G., "A Supplementary Evaluation of 46 Cases of Loosening Which Occurred Late" *in* "Total Hip Prosthesis," Edited by N. Gschwend and H. U. Debrunner, Hans Huber Publishers, Vienna, pp. 132–143, 1976.

212. Swanson, S. A. V., "The State of the Art in Joint Replacement—Part 3: Results, Problems and Trends," *Journal of Medical Engineering and Technology*, 2(1):16–20, January 1978.

213. Wilson, P. D., Jr., E. A. Salati, P. W. Hughes, H. J. Robinson, and D. M. Dines, "Total Prosthetic Replacement of the Hip—1977," Proceedings of the Workshop on Internal Joint Replacement, pp. 38–61, March 3–5, 1977.

214. Blacker, G. J. and J. Charnley, "Changes in the Upper Femur After Low-Friction Arthroplasty," *Clinical Orthopedics and Related Research*, 137:15–23, 1978.

215. Desmet, A. A., D. Kramer, and W. Martel, "The Metal-Cement Interface in Total Hip Prostheses," *American Journal of Roentgenology*, 129:279–282, 1977.

216. Dussault, R. G., A. B. Goldman, and B. Ghelman, "Radiologic Diagnosis of Loosening and Infection in Hip Prostheses," *Journal of the Canadian Association of Radiologists*, 28:119–123, 1977.

217. Reckling, F. W., M. A. Asher, and W. L. Dillon, "A Longitudinal Study of the Radiolucent Line at the Bone-Cement Interface Following Total Joint Replacement Procedures," *Journal of Bone and Joint Surgery*, 59A:355–358, 1977.

218. Marmor, L., "Femoral Loosening in Total Hip Replacement," *Clinical Orthopedics and Related Research*, 121:116–119, 1976.

219. Shine, J. J. and D. A. O'Neill, "A Method of Measurement of Progressive Radiolucent Lines in Total Hip Arthroplasty," *Clinical Orthopedics and Related Research*, 137:118–119, 1978.

220. Bocco, F., P. Langan, and J. Charnley, "Changes in the Calcar Femoris in Relation to Cement Technology in Total Hip Replacement," *Clinical Orthopedics and Related Research*, 128:287–295, 1977.

221. Volz, R. G. and R. J. Wilson, "Factors Affecting the Mechanical Stability of the Cemented Acetabular Component in Total Hip Replacement," *Journal of Bone and Joint Surgery*, 59A:501–504, 1977.

222. Oh, I. and W. H. Harris, "Proximal Strain Distribution in the Loaded Femur. An *in vitro* Comparison of the Distributions in the Intact Femur and After Insertion of Different Hip-Replacement Femoral Components," *Journal of Bone and Joint Surgery*, 60(1):75–85, 1978.

223. Simon, S. R., I. L. Paul, R. M. Rose, and E. L. Radin, "Stiction-Friction of Total Hip Prostheses and Its Relationship to Loosening," *Journal of Bone and Joint Surgery*, 57A:226–230, 1975.

224. Heilmann, K., P. B. Diezel, J. A. Rossner, and K. A. Brinkmann, "Morphological Studies in Tissues Surrounding Alloarthroplastic Joints," *Virchows Archives A. Pathology Anatomy and Histology*, 366:93–106, 1975.

225. Revell, P. A., B. Weightman, M. A. R. Freeman, and B. Vernon-Roberts, "The Production and Biology of Polyethylene Wear Debris," *Archives of Orthopedic and Traumatic Surgery*, 91:167–181, 1978.

226. Andriacchi, T. P., J. O. Galante, T. B. Belytschko, and S. Hampton, "A Stress Analysis of the Femoral Stem in Total Hip Prostheses," *Journal of Bone and Joint Surgery*, 58A:618–624, 1976.

227. Eftekhar, N., "Principles of Total Hip Arthroplasty," C. V. Mosby Co., St. Louis, pp. 58–124, 535–551, 1978.

228. Harris, W. H., A. L. Schiller, J. M. Scholler, R. A. Freiber, and R. Scott, "Extensive Localized Bone Resorption in the Femur Following Total Hip Replacement," *Journal of Bone and Joint Surgery*, 58A(5):612–616, 1976.

229. Nicholson, O. R., "Total Hip Replacement: An Evaluation of the Results and Technics," *Clinical Orthopedics and Related Research*, 95:217–223, 1973.

230. Charnley, J. and Z. Cupic, "The Nine and Ten Year Results of the Low-Friction Arthroplasty of the Hip," *Clinical Orthopedics and Related Research*, 95:9–25, 1973.

231. Ducheyne, P., P. DeMeester, and E. Aernoudt, "Fatigue Fracture of the Femoral Component of Charnley and Charnley-Muller Type Total Hip Prosthesis," *Journal of Biomedical Materials Research Symposium*, 6:199–219, 1975.

232. Devine, T. M. and J. Wulff, "Cast vs. Wrought Cobalt-Chromium Surgical Implant Alloys," *Journal of Biomedical Materials research*, 9:151–167, 1975.

233. Martens, M., E. Aernoudt, P. deMeester, P. Ducheyne, J. C. Mulier, R. deLangh, and P. Kestelijn, "Factors in the Mechanical Failure of the Femoral Component in Total Hip Prosthesis," *Acta Orthopaedica Scandinavica*, 45(5):693–710, 1974.

234. Collis, K. K., "Femoral Stem Failure in Total Hip Replacement," *Journal of Bone and Joint Surgery*, 59A(98):1033–1041, 1977.

235. Galante, J. O., W. Rostoker, and J.M. Doyle, "Failed Femoral Stems in Total Hip Prostheses," *Journal of Bone and Joint Surgery*, 57A(2):230.

236. Markolf, K. L. and H. C. Amstutz, "A Comparative Experimental Study of Stresses in Femoral Total Hip Replacement Components: The Effects of Prostheses Orientation and Acrylic Fixation," *Journal of Biomechanics*, 9:73–79, 1976.

237. Charnley, J., "Fracture of Femoral Prostheses in Total Hip Replacement," *Clinical Orthopedics and Related Reserach*, 111:105–120, 1975.

238. Bechtol, C. O., "Failure of Femoral Implant Components in Total Hip Replacement Operations," *Orthopedic Review*, 4(11):23–29, 1975.

239. Wheeler, K. R. and L. A. James, "Fatigue Behavior of Type 316 Stainless Steel Under Simulated Body Conditions," *Journal of Biomedical Materials Research*, 5:267–281, 1971.

240. Dowling, J. M., J. R. Atkinson, D. Dowson, and J. Charnley, "The Characteristics of Acetabular Cups Worn in the Human Body," *Journal of Bone and Joint Surgery*, 60B:375–382, 1978.

241. Rostoker, W. and J. O. Galante, "Some New Studies of the Wear Behavior of Ultrahigh Molecular Weight Polyethylene," *Journal of Biomedical Materials Research*, 10:303–310, 1976.

242. Walker, P. S. and P. G. Bullough, "The Effects of Friction and Wear in Artificial Joints," *Orthopedic Clinics of North America*, 4(2):275–293, 1973.

243. Gold B. L. and P. S. Walker, "Variables Affecting the Friction and Wear of Metal-on-Plastic Total Hip Joints," *Clinical*

Orthopedics and Related Research, 100:270–278, 1974.

244. Clarke, I. C., K. Black, C Rennie, and H. C. Amstutz, "Can Wear in Total Hip Arthoplasties Be Assessed from Radiographs? *Clinical Orthopedics and Related Research*, 121:126–142, 1976.

245. Charnley, J. and D. K. Halley, "Rate of Wear in Total Hip Replacement," *Clinical Orthopedics and Related Research*, 112:170–179, 1975.

246. Cullen, J. C., B. R. Tietjens, J. Poon, and J. B. Gavin, "A Scanning Electron Microscopic Study of Wear in the Plastic Components of Prosthetic Knee and Hip Joints," *Australian and New Zealand Journal of Surgery*, 47(2):189–192, 1977.

247. Winter, G. D., "Prostheses and Tissue: The Interface Problem," *Biomedical Engineering*, 8:390–394, September 1973.

248. Bullough, P. G., "Some Considerations of Chronic Hip Disease and Its Treatment," *Journal of the Irish Colleges of Physicians and Surgeons*, 8(2):43–53, 1978.

249. Torgerson, W. R., "Three Years of Experience with Total Hip Replacement," *Clinical Orthopedics and Related Research*, 95:151–147, 1973.

250. Murray, W. R., "Results in Patients with Total Hip Replacement Arthroplasty," *Clinical Orthopedics and Related Research*, 95:80–90, 1973.

251. Mallory, T. H., T. L. Meyer, Jr., and J. D. Bombach, "Six Hundred Ninety Total Hip Replacements: A Comparative Study," *Ohio State Medical Journal*, 74(1):23–27, 1978.

252. Leinbach, T. S. and F. A. Barlow, "Seven Hundred Total Hip Replacements," *Clinical Orthopedics and Related Research*, 95:174–192, 1973.

253. Evarts, C. M., K. E. DeHaven, C. L. Nelson, H. R. Collins, and A. H. Wilde, "Interim Results of Charnley-Muller Total Hip Arthroplasty," *Clinical Orthopedics and Related Research*, 95:193–200, 1973.

254. Harris, W. H., "Clinical Results Using the Muller-Charnley Total Hip Prosthesis," *Clinical Orthopedics and Related Research*, 86:95–101, 1972.

255. Harris, W. H., "Preliminary Report of Results of Harris Total Hip Replacement," *Clinical Orthopedics and Related Research*, 95:168–173, 1973.

256. Harris, W. H., "A 'Second Generation' Total Hip Replacement," *Orthopedic Clinics of North America*, 4:513–522, 1973.

257. DeHaven, K. E., C. M. Evarts, A. H. Wilde, H. R. Collins, C. Nelson, and C. D. Razzano, "Early Results of Charnley-Muller Total Hip Reconstruction," *Orthopedic Clinics of North America*, 4(2):465–472, 1973.

258. Lubinus, H. S., "Total Hip Replacement Using the Brunswick-System," *Clinical Orthopedics and Related Research*, 95:211–212, 1973.

259. Moczynski, G., E. Abraham, R. Barmada, and R. D. Ray, "Evaluation of Total Hip Replacement Arthroplasties," *Clinical Orthopedics and Related Research*, 95:213–216, 1973.

260. Lagrange, J. and E. Letournel, "The 'L.L.' Total Hip Prosthesis," *International Surgery*, 60(1):21–24, 1975.

261. Buchholz, H. W. and G. Noack, "Results of the Total Hip Prosthesis Design 'St. George,'" *Clinical Orthopedics and Related Research*, 95:201–210, 1973.

262. Evanski, P. M., T. R. Waugh, and C. F. Orofino, "Total Hip Replacement with the Charnley Prosthesis," *Clinical Orthopedics and Related Research*, 95:69–72, 1973.

263. Eftekhar, N. S. and F. E. Stinchfield, "Experience with Low-Friction Arthroplasty," *Clinical Orthopedics and Related Research*, 95:60–68, 1973.

264. Eftekhar, N. W., and F. E. Stinchfield, "Total Replacement of the Hip Joint by Low Friction Arthroplasty," Symposium on Interposition and Implant Arthroplasty.

265. Bentley, G. and R. B. Duthie, "A Comparative Review of the McKee-Farrar and Charnley Total Hip Prostheses," *Clinical Orthopedics and Related Research*, 95:127–142, 1973.

266. Collis, D. K. and R. C. Johnston, "Comparative Evaluation of the Results of Cup Arthoplasty and Total Hip Replacement," *Clinical Orthopedics and Related Research*, 86:102–114, 1972.

267. Johnston, R. C., "Clinical Follow-Up of Total Hip Replacement," *Clinical Orthopedics and Related Research*, 95:118–126, 1973.

268. Singsen, B. H., A. S. Isaacson, B. H. Bernstein, M. J. Patzakis, H. K. Kornreich, K. K. King, and V. Hanson, "Total Hip Replacement in Children with Arthritis," *Arthritis and Rheumatism*, 21(4):401–406, 1978.

269. Martens, M., P. deMeester, J. C. Mulier, L. Desmet, and G. Hessels, "Mechanical Failure of Implants in Orthopedic Surgery," *Acta Orthopaedica Belgica*, 39(4):738–751, 1973.

270. Carlsson, A. S., C. F. Gentz, and J. Stenport, "Fracture of the Femoral Prosthesis in Total Hip Replacement According to Charnley," *Acta Orthopaedica Scandinavica*, 48:650–655, 1977.

271. Bisla, R. S., A. E. Inglis, and C. S. Ranawat, "Joint Replacement Surgery in Patients Under Thirty," *Journal of Bone and Joint Surgery*, 58A(8):1098–1104, 1976.

272. Eftekhar, N., "Charnley 'Low-Friction Torque' Arthroplasty," *Clinical Orthopedics and Related Research*, 81:93–104, 1971.

273. Halley, D. K. and J. Charnley, "Results of Low Friction Arthroplasty in Patients Thirty Years of Age or Younger," *Clinical Orthopedics and Related Research*, 112:180–191, 1975.

274. Griffith, M. J., M. K. Seidenstein, D. Williams, and J. Charnley, "Eight Year Results of Charnley Arthroplasties of the Hip with Special Reference to the Behavior of Cement," *Clinical Orthopedics and Related Research*, 137:24–36, 1978.

275. Beckenbaugh, R. D., H. S. Tressler, and E. W. Johnson, "Results after Hemiarthroplasty of the Hip Using a Cemented Femoral Prosthesis. A Review of 109 Cases with an Average Followup of 36 Months," *Mayo Clinic Proceedings*, 52:349–353, 1977.

276. Jensen, J. S. and P. Holstein, "A Long-Term Followup of Moore Arthroplasty in Femoral Neck Fractures," *Acta Orthopaedica Scandinavica*, 46:764–774, 1975.

277. Andersson, G. and J. M. Nielsen, "Results After Arthroplasty of the Hip With Moore's Prosthesis," *Acta Orthopaedica Scandinavica*, 43:397–410, 1972.

278. Slooff, T. J. J. H., "The Unstable Endoprosthesis of the Hip," *Archivum Chirurgicum Neerlandicum*, 23:205–216, 1971.

279. Homsy, C. A., H. A. Tullos, M. S. Anderson, N. M. Diferrante, and J. W. King, "Some Physiological Aspects of Prosthesis Stabilization With Acrylic Polymer," *Clinical Orthopedics and Related Research*, 83:317–328, 1972.

280. Rhinelander, F. W., C. L. Nelson, and R. O. and C. L. Stewart, "Experimental Reaming of the Proximal Femur and Acrylic Cement Implantation," *Clinical Orthopedics and Related Research*, 141:74–89, 1979.

281. Dobbs, H. S., "The Incidence of Fracture in Total Hip Replacement Femoral Components," *Engineering in Medicine*, 7(2):107–110.

282. Johnson, J. T. H. and O. Crothers, "Nailing vs. Prosthesis for Femoral-Neck Fractures," *Journal of Bone and Joint Surgery*, 57A:686–692, 1975.

283. Salvati, E. A., T. Artz, P. Aglietti, and S. E. Asnis, "Endoprosthesis in the Treatment of Femoral Neck Fractures," *Orthopedic Clinics of North America*, 5:757–777, 1974.

284. Scales, J. T., K. W. J. Wright, H. Dobbs, G. D. Winter, and H. Kemp, "Risks of Total Hip Replacement," *British Medical Journal*, 2:612, June 1975.

285. Summary Minutes of the Eighteenth Meeting of the Orthopedic Device Classification Panel, July 1977.

286. McKellop, H. A., W. Phillips, I. C. Clarke, and H. C. Amstutz, "Wear Properties of Sialon Ceramics and Delrin" 150 Homopolymer Under Physiological Conditions," Transaction of the 4th Annual Meeting of the Society for Biomaterials, April 29–May 2, 1978.

287. Dumbleton, J. H., "The Friction and Wear of Delrin" and the Performance of the Christiansen Total Hip Prosthesis," J. H. Dumbleton, Ph.D., Dissertation, Department of Materials Science and Metallurgical Engineering, University of Cincinnati, Cincinnati.

288. Summary Minutes of the Twenty-Second meeting of the Orthopedic Device Classification Panel, January 19, 1979.

289. Anderson, P. R. and J. W. Milgram, "Dislocation and Component Separation of the Bateman Hip Endoprosthesis," *Journal of the American Medical Association*, 240:2079–2080, November 3, 1978.

290. Barmada, R. and I. M. Siegel, "Postoperative Separation of the Femoral and Acetabular Components of a Single-Assembly Total Hip (Bateman) Replacement," *Journal of Bone and Joint Surgery*, 61–A:777–78, July 1979.

291. Drinker, H. and W. R. Murray, "The Universal Proximal Femoral Endoprosthesis," *Journal of Bone and Joint Surgery*, 61–A:1167–1174, December 1979.

292. Langan, P., "The Giliberty Bipolar Prosthesis," *Clinical Orthopedics and Related Research*, 141:169–175, June 1979.

293. Aufranc, O. E. and E. B. Sweet, "Study of Patients with Hip Arthroplasty at Massachusetts General Hospital," *Journal of the American Medical Association*, 170(5): 67–75, 1959.

294. Johnson, R. C. and C. B. Larson, "Results of Treatment of Hip Disorders with

Cup Arthroplasty," *Journal of Bone and Joint Surgery*, 51(8):1461–1479, 1969.

295. Freeman, M. A. R., "Total Surface Replacement Hip Arthroplasty," *Clinical Orthopedics and Related Research*, 134:2–4, July–August 1978.

296. Gerard, Y., "Hip Arthroplasty By Matching Cups," *Clinical Orthopedics and Related Research*, 134:25–35, July–August 1978.

297. Trentani, C. and E. Vaccarino, "The Paltrinieri-Trentani Hip Joint Resurface Arthroplasty," *Clinical Orthopedics and Related Research*, 134:36–40, July–August 1978.

298. Furuya, K., M. Tsuchiya, and S. Kawachi, "Socket-Cup Arthroplasty," *Clinical Orthopedics and Related Research*, 134:4–44, July–August 1978.

299. Freeman, M. A. R., H. U. Cameron, and G. C. Brown, "Cemented Double Cup Arthroplasty of the Hip: A 5-year Experience with the ICLH Prosthesis," *Clinical Orthopedics and Related Research*, 134:45–52, July–August 1978.

300. Capello, W. N., P. H. Ireland, T. R. Trammell, and P. Eicher, "Conservative Total Hip Arthroplasty: A Procedure to Conserve Bone Stock," *Clinical Orthopedics and Related Research*, 134:59–74, July–August 1978.

301. Wagner, H., "Surface Replacement Arthroplasty of the Hip," *Clinical Orthopedics and Related Research*, 134:102–130, July–August 1978.

302. Tanaka, S., "Surface Replacement of the Hip Joint," *Clinical Orthopedics and Related Research*, 134:75–79, July–August 1978.

303. Amstutz, H. C., A. Graff-Radford, T. A. Gruen, and I. C. Clarke, "Tharies, Surface Replacement: A Review of the First 100 Cases," *Clinical Orthopedics and Related Research*, 134:87–101, July–August 1978.

304. Insall, J. N., C. S. Ranawat, P. Aglietti, and J. Shine, "A Comparison of 4 Models of Total Knee Replacement Prostheses," *Journal of Bone and Joint Surgery*, 58A:754–765, September 1976.

305. Deburge, A., "GUEPAR Hinge Prosthesis," *Clinical Orthopedics*, 120:47–53, October 1976.

306. Engelbrecht, E., A. Siegel, J. Roettger, and H. W. Buchholz, "Statistics of Total Knee Replacement," *Clinical Orthopedics*, 120:54–64, October 1976.

307. Freeman, P. A., "Walldius Arthroplasty," *Clinical Orthopedics*, 94:85–91, July–August 1973.

308. Phillips, H. and J. G. Taylor, "The Walldius Hinge Arthroplasty," *Journal of Bone and Joint Surgery*, 57B:51–62, 1975.

309. Habermann, E. T., S. D. Deutsch, and G. D. Rovere, "Knee Arthroplasty with the Use of the Walldius Total Knee Prosthesis," *Clinical Orthopedics*, 94:72–84, July–August 1973.

310. Wilson, F. C. and G. L. Venters, "Results of Knee Replacement with the Walldius Prosthesis," *Clinical Orthopedics*, 120:33–46, October 1976.

311. Blundell-Jones, G., "Total Knee Replacement-The Walldius Hinge," *Clinical Orthopedics*, 94:50–57, July–August 1973.

312. Bain, A. M., "Replacement of the Knee Joint with the Walldius Prosthesis Using Cement Fixation," *Clinical Orthopedics*, 94:65–71, July–August 1973.

313. Brady, T. A. and J. N. Garber, "Knee Joint Replacement Using Shiers Knee Hinge," *Journal of Bone and Joint Surgery*, 56A:1610–1614, December 1974.

314. Watson, J. R., H. Wood, and R. C. J. Hill, "The Shiers Arthroplasty of the Knee," *Journal of Bone and Joint Surgery*, 58B:300–304, August 1976.

315. Kettelkamp, D. B., "Knee Implants," Proceeding of Total Joint Replacement Workshop, Northwestern University, Chicago, March 3, 1977.

316. Chand, K., "The Knee Joint in Rheumatoid Arthritis III. Treatment by Hinged Total Knee Prosthetic Replacement," *International Surgery*, 59:600–607, November–December 1974.

317. Deburge, A., J. H. Aubriot, and J. P. Genet, "Current Status of a Hinge Prosthesis (GUEPAR)," *Clinical Orthopedics and Related Research*, 145:91–93, November–December 1979.

318. Arden, G. P. and B. A. Kamdar, "Complications of Arthroplasty of the Knee," *in* "Total Knee Replacement," chaired by L. G. P. Shiers, Mechanical Engineering Publications, Ltd., London, pp. 118–122, 1975.

319. Kaushal, S. P., J. O. Galante, R. McKenna, and F. Bachman, "Complications Following Total Knee Replacements," *Clinical Orthopedics and Related Research*, 121:181–187, November–December 1976.

320. Van Camp, D. H., H. W. Croon, and J. Lindwer, "Influence of Cyclic Loading on Mechanical Loosening of Hinged Knee Prostheses," *Engineering in Medicine*, 4:235–239, 1978.

321. Walker, P. S., "Human Joints and Their Artificial Replacements," Charles C. Thomas, Publisher, Springfield, IL, p. 321, 1977.

322. Wagner, J. and R. Bourgois, "Biomedical Study of the Hinged Knee Prosthesis," *Clinical Orthopedics and Related Research*, 102:188–193, July–August 1974.

323. Swanson, S. A. V., M. A. R. Freeman, and J. C. Heath, "Laboratory Tests on Total Joint Replacement Prostheses," *Journal of Bone and Joint Surgery*, 55B:759–773, November 1973.

324. Brodersen, M. P., R. H. Fitzgerald, L. F. A. Peterson, M. B. Coventry, and R. S. Bryan, "Arthrodesis of the Knee Following Failed Total Knee Arthroplasty," *Journal of Bone and Joint Surgery*, 61A:181–185, March 1979.

325. Summary Minutes of the Twentieth Meeting of the Orthopedic Device Classification Panel, March 21, 1978.

326. Summary Minutes of the Twenty-First Meeting of the Orthopedic Section of the Surgical and Rehabilitation Devices Panel, July 13, 1978.

327. Matthews, L. S., H. Kaufer, and D. A. Sonstegard, "The Spherocentric Knee," Draft of unpublished paper presented at the American Academy of Orthopedic Surgeons meeting, February 1, 1976.

328. Matthews, L. S., D. A. Sonstegard, and H. Kaufer, "The Spherocentric Knee," *Clinical Orthopedics and Related Research*, 94:234–241, 1973.

329. Sonstegard, D. A., H. Kaufer, and L. S. Matthews, "The Spherocentric Knee," *Journal of Bone and Joint Surgery*, 59A:602–616, 1977.

330. Marmor, L., "The Modular Knee," *Clinical Orthopedics*, 94:242–248, 1973.

331. Marmor, L., "The Modular Knee System," *Journal of Bone and Joint Surgery*, 56B:388–389, 1974.

332. Chand, K., "The Knee Joint in Rheumatoid Arthritis. Treatment by Nonhinged Total Knee Prosthetic Replacement," *International Surgery*, 60:11–18, 1975.

333. Cloutier, J. M., F. Gauthier, and R. Rizkallah, "Arthroplasty of the Knee Using the Marmor Prosthesis," *Journal of Bone and Joint Surgery*, 58B:142, 1976.

334. Laskin, R. S., "Modular Total Knee Replacement Arthroplasty," *Journal of Bone and Joint Surgery*, 58A:766–772, 1976.

335. Laurenson, G. R., "Total Knee Replacement," *Journal of Bone and Joint Surgery*, 58B:265, 1976.

336. Sneppen, O., N. Fredensborg, A. Karle, and U. Klaumann, "Lateral Dislocation of the Patella Following Marmor and GUEPAR Arthroplasty of the Knee," *Acta Orthopedica Scandinavica, 49:291–294, 1978.*

337. Van Vuren, J. B., Knee Joint Replacement Arthroplasty: The Choice of Prosthesis and Results," *Journal of Bone and Joint Surgery*, 60B:292, 1978.

338. Carlova, J., "He Risked His Career to Save His Good Name," *Medical Economics*, pp. 109–126, November 1978.

339. Marmor, L., "The Modular Knee. Case Report With a Minimum Followup of Two Years," *Clinical Orthopedics*, 120:86–94, 1976.

340. Cracchiolo, A., III, M. Benson, G. A. M. Finerman, K. Horacek, and H. C. Amstutz, "A Prospective Comparative Clinical Analysis of the First-Generation Knee Replacements," *Clinical Orthopedics*, 145:37–46, November-December 1979.

341. Marra, J. M., H. C. Amstutz, M.. Matos, and R. Gold, "The Pathology of the Joint Tissues and its Clinical Relevance in Prosthesis Failure," *Clinical Orthopedics*, 117:221–240, 1976.

342. Ducheyne, P., A. Kagan, II, and J. A. Lacey, "Failure of Total Knee Arthroplast Due to Loosening and Deformation of the Tibial Component," *Journal of Bone and Joint Surgery*, 60A:384–391, 1978.

343. Marmor, L., "Single Compartment Replacement With the Marmor Modular Knee," *Orthopaedic Review*, 6:81–84.

344. Kettelkamp, D. B. and E. Y. S. Chao, "A Method for Quantitative Analysis of Medial and Lateral Compression Forces at the Knee During Standing," *Clinical Orthopedics*, 83:202–13, 1972.

345. Freeman, M. A. R., S. A. V. Swanson, and J. C. Heath, "Study of the Wear Particles Produced From CoCrMoMn Total Joint Replacement Prostheses," *Annals of the Rheumatic Diseases* (Supplement), 28:29, 1969.

346. Heath, J. C., M. A. R. Freeman, and S. A. V. Swanson, "Carcinogenic Properties of Wear Particles From Prostheses Made in CoCr Alloy," *Lancet*, 1(7699):564, 1971.

347. Coleman R. F., J. Herrington, and J. T. Scales, "Concentration of Wear Products in Hair, Blood, and Urine After Total Hip Replacement," *British Medical Journal*, 1:527–529, 1973.

348. Seedhom B. B., D. Dowson, and V. Wright, "Wear of Solid Phase Formed High-Density Polyethylene in Relation to the Life of Artificial Hips, Knees," *Wear*, 24(1):35–51, 1973.

349. Swanson, S. A. V., M. A. R. Freeman, and J. C. Heath, "Laboratory Tests on Total Joint Replacement Prostheses," *Journal of Bone and Joint Surgery*, 55B:759–773, 1973.

350. Mendes, D. G., F. Figarola, P. G. Bullough, and P. Loudis, "HDPE Prosthetic Femoral Head Replacement in the Dog," *Clinical Orthopedics*, 111:274–283, 1975.

351. Reckling, F. W., M. A. Asher, F. A. Mantz, and D. O. Jelton, "Performance Analysis of an ex vivo Geometric Total Knee Prosthesis," *Journal of Bone and Joint Surgery*, 57A:108–114, 1975.

352. Dumbleton, J. A. and C. Shen, "The Wear Behavior of Ultra-High Molecular Weight Polyethylene," *Wear*, 37:279–289, 1976.

353. Trent, P. S. and P. S. Walker, "Wear and Conformity in Total Knee Replacement," *Wear*, 36:175–187, 1976.

354. Cullen, J. C., B. R. Tietjens, and J. B. Gavin, "A Scanning Electron Miscroscopic Study of Wear in the Plastic Components of Prosthetic Knee and Hip Joints," *Australian/New Zealand Journal of Surgery*, 47(2):189–192, 1977.

355. Rose, R. M., "Behavior of Polyethylene in Total Joint Prosthesis," *Bulletin of the Hospital for Joint Diseases*. 38(1):45–46, 1977.

356. Walker, P. S., "A Biomechanical Rationale for a Graduated Knee Prosthesis System," *Bulletin of the Hospital for Joint Diseases*, 38:20, 1977.

357. Revell, P. A., M. A. R. Freeman, and B. W. Weightman, "The Response of Articular Tissues to Polyethylene Wear Debris From Prosthetic Joints," *Journal of Bone and Joint Surgery*, 60B:282, 1978.

358. Revell. P. A., B. W. Weightman, M. A. R. Freeman, and B. Vernon-Roberts, "The Production and Biology of Polyethylene Wear Debris," *Archiv fuer Orthopaedische und Unfall-Chirurgie*, 91:167–181, 1978.

359. Rostoker, W., E. Y. S. Chao, and J. O. Galante, "The Appearances of Wear on Polyethylene—A Comparison of in vivo and in vitro Wear Surfaces," *Journal of Biomedical Materials Research*, 12:317–335, 1978.

360. Holman, P. K. and H. D. D. Tyer, "Early Results of Geometric Total Knee Arthroplasty," *Journal of Bone and Joint Surgery*, 57B:249, 1975.

361. Insall, J. N., C. S. Ranawat, P. Aglietti, and J. Shine, "A Comparison of Four Models of Total Knee Replacement Prostheses," *Journal of Bone and Joint Surgery*, 58A:754–765, 1976.

362. Fox, K. W., "Geometric Total Knee Arthroplasty: Local Complications," *Texas Medicine*, 72:92–97. 1976.

363. Riley, L. H. and D. S. Hungerford, "Geometric Total Knee Replacement for Treatment of the Rheumatoid Knee," *Journal of Bone and Joint Surgery*, 60A:523–527, 1978.

364. Cracchiolo, A., III, M. Benson, G. A. M. Finerman, K. Horacek, and H. C. Amstutz, "A Prospective Comparative Clinical Analysis of the First-Generation Knee Replacements," *Clinical Orthopedics*, 145:37–46, November-December 1979.

365. Larsson, S. E. and O. Ahlgren, "Reconstruction with Endoprosthesis in Gonarthrosis," *Clinical Orthopedics*, 145:126–135, 1979.

366. "Transcript of Proceedings: Orthopedic Device Classification Panel Meeting, April 14, 1977," New Orleans, 1977.

367. Hanslik, L., "Das patellofemorale Gleitlagerbeim total kniegelenkersatz. Vorlaeufige Mitteilung ueber die implanation einer modifizierten McKeever-Endoprothese in Kombination mit der Alloarthroplastik nach Young," *Zeitschrift fuer Orthopaedie und Ihre Gremzgebicte*, 109:435–440, 1971.

368. Young, H. H., "Use of a Hinged Vitallium Prosthesis for Arthroplasty of the Knee. A Preliminary Report," *Journal of Bone and Joint Surgery*, 45A:1627–1641, 1963.

369. Girzadas, D. V., S. Geens, M. L. Clayton, and J. D. Leidholt, "Performance of a Hinged Metal Knee Prosthesis: A Case Report With a Follow-Up of 3.5 Years and Histological and Metallurgical Data," *Journal of Bone and Joint Surgery*, 50A:355–364, 1968.

370. Friedebold, G., "First Experiences With the Young Knee in Synovectomy and Arthroplasty in Rheumatoid Arthritis," Edited by Chapchal, G., G. Thieme Verlag, Stuttgart, 1967.

371. Friedebold, G., "Arthrolysen und Arthroplastiken des Kniegelenkes," *Chirurgiae Plasticae Reconstructiae*, 7:50–58, 1970.

372. Friedebold, G. and H. Radloff, "Alloarthroplasties of the Knee Joint. Indications and Results," *Reconstructive Surgery and Traumatology*, 12:181–196, 1971.

373. Young, H. H., "Reconstruction of Knee Joint With Young-Type Hinged Vitallium Prosthesis," *Reconstructive Surgery and Traumatology*, 12:176–180, 1971.

374. Hanslik, L., "First Experience on Knee Joint Replacement Using the Young Hinged Prosthesis Combined with a Modification on the McKeever Patella Prosthesis," *Clinical Orthopedics*, 94:115–121, 1973.

375. Insall, J. N., C. S. Ranawat, W. N. Scott, and P. S. Walker, "Total Condylar Knee Replacement, Preliminary Report," *Clinical Orthopedics*, 120:149–154, 1976.

376. Aglietti, P., J. N. Insall, P. S. Walker, and P. Trent, "A New Patella Prosthesis, Design and Application," *Clinical Orthopedics*, 107:176–187, 1975.

377. Kettelkamp, D. B., "Excision of the Cruciate Ligaments in Total Knee Replacement," *Clinical Orthopedics*, 131:308, 1978.

378. Insall, J. N., W. N. Scott, and C. S. Ranawat, "The Total Condylar Knee Prosthesis," *Journal of Bone and Joint Surgery*, 61A:173–180, 1979.

379. Insall, J. N., "Reply to Excision of the Cruciate Ligaments in Total Knee Replacement," *Clinical Orthopedics*, 131:308–309, 1978.

380. Fox, K. W., "Geometric Total Knee Arthroplasty: Local Complications," *Texas Medicine*, 72:92–97, 1976.

381. Platt, G. and C. Pepler, "Mold Arthroplasty of the Knee. A Ten-Year Followup Study," *Journal of Bone and Joint Surgery*, 51B:76–87, 1969.

382. Aufranc, O. E. and W. N. Jones, "Mold Arthoplasty of the Knee," *Journal of Bone and Joint Surgery*, 40A:1431, 1958.

383. Jones, W. N., O. E. Aufranc, and W. L. Kermond, "Mold Arthroplasty of the Knee," *Journal of Bone and Joint Surgery*, 40A:1431, 1958.

384. Jones, W. N., "Mold Arthroplasty of the Knee Joint," *Clinical Orthopedics*, 66:82–89, 1969.

385. Riley, L. H., Jr., "The Evolution of Total Knee Arthroplasty," *Clinical Orthopedics*, 120:7–10, 1976.

386. Kitridou, R. C., H. R. Schumacher, J. L. Sbarbaro, Jr., and J. L. Hollander, "Recurrent Hemarthrosis After Prosthetic Knee Arthroplasty," *Arthritis and Rheumatism*, 12(5):520–528, 1969.

387. Turner, R. H. and O. E. Aufranc, "Femoral Stem Replacement Arthroplasty of the Knee," *Surgical Clinics of North America*, 49(4):917–927, 1969.

388. Friedebold, G. and H. Radloff, "Alloarthroplasties of the Knee Joint. Indications and Results," *Reconstructive Surgery and Traumatology*, 12:181–196, 1971.

389. Yeoman, P. M., "Arthroplasty of the Knee: A Comparative Study of Platt's Mould and McKee Arthroplasties," *Journal of Bone and Joint Surgery*, 53B(1):150, 1971.

390. Turner, R. A., E. M. Brown, J. L. Sbarbaro, Jr., and J. L. Hollander, "Arthroplasty of the Knee With Tibial and/or Femoral Metallic Implants in Rheumatoid Arthritis," *Arthritis and Rheumatism*, 15:1–15, 1972.

391. Groeneveld, H. B., "Combined Femorotibial-Patellar Endoprosthesis of the Knee Joint Preserving the Ligaments," *Acta Orthopaedica Belgica*, 39:210–215, 1973.

392. Kettelkamp, D. B., "Functional Analysis of the Knee," *in* "Workshop on Fundamental Studies for Internal Structural Prostheses," chaired by F. W. Clippinger, Jr., National Academy of Sciences, Washington, DC pp. 19–23, 1973.

393. Sbarbaro, J. L., Jr., "Femoral Condylar Mold Arthroplasty in 150 Rheumatoid Knees," *Acta Orthopaedica Belgica*, 39:138–147, 1973.

394. Wilde, A. H., H. R. Collins, C. M. Evarts, C. L. Nelson, K. E. DeHaven, and J. A. Bergfeld, "Current Use of Geometric Knee Replacement Arthroplasty," *Orthopedic Review*, 3(3):25–31, 1974.

395. Arden, G. P. and B. A. Kamdar, "Complications of Arthroplasty of the Knee," *in* "Total Knee Replacement," chaired by L. G. Shiers, Mechanical Engineering Publications Ltd., London, pp. 118–122, 1975.

396. "Transcript of Proceedings: Orthopedic Device Classification Panel, January 28, 1977," Washington, DC, 1977.

397. McKeever, D. C., "Patellar Prosthesis," *Journal of Bone and Joint Surgery*, 37A:1074–1084, 1955.

398. DePalma, A. F., B. Sawyer, and D. J. Hoffman, "Reconsideration of Lesions Affecting the Patellofemoral Joint," *Clinical Orthopedics*, 18:63–85, 1960.

399. Levitt, R. L., "A Long-Term Evaluation of Patellar Prostheses," *Clinical Orthopedics*, 97:153–157, 1973.

400. Vermeulen, H., E. DeDoncker, and M. Watillon, "Les Prostheses Rotuliennes de Mac Keever dans l'Arthrose Femoropatellaire," *Acta Orthopedica Belgica*, 39:79–90, 1973.

401. Smillie, I. S. M., "The Biomechanical Basis of Osteoarthrosis of the Knee," *in* "Total Knee Replacement," chaired by L. G. P. Shiers, Mechanical Engineering Publications Ltd., London, pp. 8–11, 1975.

402. "Transcript of Proceedings: Orthopedic Device Classification Panel, July 15, 1977," New Orleans, 1977.

403. Hanslik, L., "Erfahrungen mit der Kniegelenks Endoprothetik und der Alloplastik des Patellofemoralen Gleitlagers," *Zeitschrift fuer Orthopaedie und Ihre Grenzgebiete,* 113:516–519, 1975.

404. Stauffer, R., D. B. Kettelkamp, C. Thompson, D. Wenger, "MacIntosh Prosthesis. Prospective Clinical Trial and Gait Evaluation," *Archives of Surgery,* 110:717–720, 1975.

405. Burrough, S. J., M. J. Clarke, A. G. Hill, and A. R. Taylor, "A Prospective Study of the MacIntosh Arthroplasty," *in* "The Knee Joint," Edited by Ingwersen, O. S., B. Van Linge, T. J. Van Rens, G. E. Rosingh, B. E. Veraart, and D. LeVay, *Excerpta Medica Foundation,* Amsterdam, pp. 316–323, 1974.

406. Henderson, E. D. and C. A. Peterson, "Experience with the Use of the MacIntosh Prosthesis in Knees of Patients with Rheumatoid Arthritis," *Southern Medical Journal,* 62:1311–1315, 1969.

407. Clary, B. B. and D. E. Couk, "Experience with the MacIntosh Knee Prosthesis," *Southern Medical Journal,* 65:265–272, 1972.

408. Arden, G. P. and B. A. Kamdar, "Complications of Arthroplasty of the Knee," *in* "Total Knee Replacement," chaired by L. G. P. shiers, Mechanical Engineering Publications Ltd., London, pp. 118–122, 1975.

409. MacIntosh, D. L., "Hemiarthroplasty of the Knee Using a Space Occupying Prosthesis for Painful Varus and Valgus Deformities," *Journal of Bone and Joint Surgery,* 40A:1431, 1958.

410. Elliott, R. B. and D. C. McKeever, "Tibial Plateau Prosthesis," *Clinical Orthopedics,* 18:86–95, 1960.

411. MacIntosh, D. L., "(Untitled under) The Little Orthopaedic Club," *Journal of Bone and Joint Surgery,* 44A:205, 1962.

412. Crellin, R. Q., "MacIntosh Prosthesis for Tibial Plateau Fractures," *Journal of Bone and Joint Surgery,* 47B:196, 1965.

413. MacIntosh, D. L. "Arthroplasty of the Knee in Rheumatoid Arthritis," *Journal of Bone and Joint Surgery,* 43B:179, 1966.

414. MacIntosh, D. L., "Arthroplasty of the Knee in Rheumatoid Arthritis Using the Hemiarthroplasty Prosthesis," *in* "Synovectomy and Arthroplasty in Rheumatoid Arthritis," Edited by Chapchal, G., and G. Thieme, Verlag, Stuttgart, p. 131, 1967.

415. Mooney, M. G., D. G. Leavitt J. F. LeCocq, and H. L. Leavitt, "McKeever's Vitallium Implants for Tibial Articular Reconstruction," *Pacific Medicine and Surgery,* 75:11–21, January-February 1967.

416. Murray, W. R., "Arthroplasty of the Knee in Rheumatoid Arthritis," *Journal of Bone and Joint Surgery,* 49A:1022, 1967.

417. Dewar, F. P., "MacIntosh Prosthesis in Rheumatoid Arthritis," *Journal of Bone and Joint Surgery,* 50B:677, 1968.

418. Kates, A., A. G. L. Kay, J. Wajtulewski, T. Riley, and E. N. Coomes, "Experiences of Arthroplasty of the Rheumatoid Knee Using MacIntosh Prosthesis," *Annals of the Rheumatic Diseases,* 28:328, 1969.

419. Kitridou, R. C., H. R. Schumacher, J. L. Sbarbaro, Jr., and J. L. Hollander, "Recurrent Hemarthrosis After Prosthetic Knee Arthroplasty," *Arthritis and Rheumatism,* 12:520–528, 1969.

420. Potter, T. A., "Arthroplasty of the Knee with Tibia Metallic Implants of the McKeever and MacIntosh Design," *Surgical Clinics of North America,* 49:903–915, 1969.

421. McCollum, D. E., J. Goldner, and S. N. Lang, "Tibial Plateau Prosthesis in Arthroplasty of the Knee," *Journal of Bone and Joint Surgery,* 52A:827–828, 1970.

422. Friedebold, G. and H. Radloff, "Alloarthroplasties of the Knee Joint. Indications and Results," *Reconstructive Surgery and Traumatology,* 12:181–196, 1971.

423. Jessop, J. D. and C. J. Moore, "Followup of the MacIntosh Arthroplasty of the Knee Joint," *Rheumatology and Physical Medicine,* 11:217–224, 1972.

424. Kay, N. R. M. and H. D. Martins, "The MacIntosh Tibial Plateau Hemiprosthesis for the Rheumatoid Knee," *Journal of Bone and Joint Surgery,* 54B:256–262, 1972.

425. Lowe, L. W., A. Kates, and A. G. L. Kay, "MacIntosh Arthroplasty in the Rheumatoid Knee," *Journal of Bone and Joint Surgery,* 54B:170, 1972.

426. MacIntosh, D. L. and G. A. Hunter, "The Use of the Hemiarthroplasty Prosthesis for Advanced Osteoarthritis and Rheumatoid Arthritis of the Knee," *Journal of Bone and Joint Surgery,* 54B:244–255, 1972.

427. Potter, T. A., M. S. Weinfeld, and W. H. Thomas, "Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis," *Journal of Bone and Joint Surgery,* 54A:1–24, 1972.

428. Turner, R. A., E. M. Brown, J. L. Sbarbaro, Jr., and J. L. Hollander, "Arthroplasty of the Knee with Tibial and/or Femoral Metallic Implants in Rheumatoid Arthritis," *Arthritis and Rheumatism,* 15:1–15, 1972.

429. Bryan, R. S., "Management of Arthritis of the Knee Joint," *in* "Current Practice in Orthopedic Surgery," Edited by Ahstrom, J. P., Jr., C. V. Mosby Co., St. Louis, pp. 118–133, 1973.

430. Conaty, J. P., "Surgery of the Hip and Knee in Patients with Rheumatoid Arthritis," *Journal of Bone and Joint Surgery,* 55A:301–314, 1973.

431. Hastings, D. E. and W. A. Hewitson, "Double Hemiarthroplasty of the Knee in Rheumatoid Arthritis," *Journal of Bone and Joint Surgery,* 55B:112–118, 1973.

432. Naves, J., "Vingt cas d'arthroplastie du genou par implants partiels de MacKeever et MacIntosh," *Acta Orthopedica Belgica,* 39:113, 1973.

433. Ranawat, C. S., L. Jordan, and L. R. Straub, "MacIntosh Hemiarthroplasty in Rheumatoid Knee," *Acta Orthopedica Belgica,* 39:102–112, 1973.

434. Sbarbaro, J. L., Jr., "Hemi-tibial Plateau Prosthesis," *Acta Orthopedica Belgica,* 39:91–101, 1973.

435. Swanson, A. B., "Low Modulus Force-Dampening Materials for Knee Joint Prostheses," *Acta Orthopedica Belgica,* 39:116–137, 1973.

436. Kettelkamp, D. B., "Tibial Arthroplasty in Reconstruction of the Arthritic Knee," *Clincial Orthopedics,* 101:74–81, 1974.

437. Sbarbaro, J. L., Jr., "Press Fit Implant Arthroplasty of the Hip and Knee," *Biomedical Materials Research Symposium,* 2:285–288, 1974.

438. Wilde, A. H., H. R. Collins, C. M. Evarts, C. L. Nelson, K. E. deHaven, and J. A. Bergfeld, "Current Use of Geometric Knee-Replacement Arthorplasty," *Orthopedic Review,* 3:25–31, 1974.

439. Ewald, F. C., R. D. Scott, W. H. Thomas, and C. B. Sledge, "The Importance of Intercondylar Stability in Knee Arthroplasty," *Journal of Bone and Joint Surgery,* 57A:1033, 1975.

440. Clayton, M. L., "Current Concepts regarding the Rheumatoid Knee and Including Total Knee Arthroplasty," *in* "Current Practice in Orthopedic Surgery," Edited by Ahstrom, J. P., Jr., C. V. Mosby Co., St. Louis, pp. 196–202, 1977.

441. Van Vuren, J. B., "Knee Joint Replacement Arthroplasty: The Choice of Prosthesis and Results," *Journal of Bone and Joint Surgery,* 60B:292, 1978.

442. Townley, C. O., "Articular Plate Replacement Arthroplasty for the Knee Joint," *Clinical Orthopedics,* 36:77–85, 1964.

443. Romero, R. L. and E. M. Burgess, "Total Shoulder Replacement," *Journal of Bone and Joint Surgery* 57A:1033, 1975.

444. Fenlin, J. M., Jr., "Total Shoulder Prosthesis," *Journal of Bone and Joint Surgery,* 58A:735, 1976.

445. Fenlin, J. M., Jr., "Total Glenohumeral Joint Replacement," *Orthopedic Clinic of North America,* 6:565–583, 1975.

446. Linscheid, R. L. and R. H. Cofield, "Total Shoulder Arthroplasty: Experimental but Promising," Geriatrics, 64–69, April 1976.

447. Cofield, R. H., "Status of Total Shoulder Arthroplasty," *Archives of Surgery,* 12:1088–1091, 1971.

448. Buechel, F. F., M. J. Pappas, and A. F. DePalma, " 'Floating Socket' Total Shoulder Replacement: Anatomical, Biomechanical and Surgical Rationale," *Journal of Biomedical Materials Research,* 12:89–144, 1978.

449. Cofield, R. H. and R. N. Stauffer, "The Bickel Glenohumeral Arthroplasty," *in* "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers, 1977–5," Mechanical Engineering Publications Ltd., Great Britain, pp. 15–20, 1977.

450. Cofield, R. H., "Total Shoulder Arthroplasty: The Current State of Development," *in* "DHEW/RSA Workshop on Internal Joint Replacement," Edited by C. L. Compere and J. L. Lewis, Chicago, pp. 33–37, 1977.

451. Cofield, R. H., "Total Shoulder Arthroplasty: The Current State of Development," *in* "DHEW/RSA Workshop on Internal Joint Replacement," Edited by C. L. Compere and J. L. Lewis, Chicago, pp. 33–37, 1977.

452. Neer, C. S., "Replacement Arthroplasty for Glenohumeral Osteoarthritis," *Journal of Bone and Joint Surgery,* 56A:1–13, 1974.

453. Siegel, A., H. W. Bucholz, E. Engelbrecht, and J. Rottger, "The Non-Blocked Shoulder Endoprosthesis" *in* "Joint

Replacement in the Upper Limb," Institution of Mechanical Engineers Conference Publication, 1977–5, Mechanical Engineering Publications Ltd., Great Britain, pp. 21–26, 1977.

454. Neer, C. S.,"Articular Replacement for Humeral Head," *Journal of Bone and Joint Surgery*, 37A:215–228, 1955.

455. Oster, A., "Fracture Dislocations of the Shoulder Joint. Four Cases Treated with Vitallium Prosthesis," *Acta Chirurgica Scandinavica*, 135:499–504, 1969.

456. Clayton, M. L. and D. C. Ferlic, "Surgery of the Shoulder in Rheumatoid Arthritis" *Clinical Orthopedics and Related Research*, 106:166–174, 1975.

457. Neer, C. S., "Replacement Arthroplasty for Glenohumeral Osteoarthritis," *Journal of Bone and Joint Surgery*, 56A: 1–13, 1974.

458. Burrows, H. J., J. N. Wilson, and J. T. Scales, "Excision of Turmors of Humerus and Femur with Restoration by Internal Prostheses," *Journal of Bone and Joint Surgery*, 57B:148–159, 1975.

459. Lynn, T. A., P. G. Alexakis, and C. O. Bechtol, "Stem Prosthesis to Replace Lost Proximal Humerus," *Clinical Orthopedics and Related Research*, 43:245–246. 1965.

460. Packard, A. G., "Prosthetic Replacement of the Proximal Half of the Humerus," *Clinical Orthopedics and Related Research*, 93:250–252. 1973.

461. Poirier, H., "Massive Osteolysis of the Humerus Treated by Resection and Prosthetic Replacement," *Journal of Bone and Joint Surgery*, 50B:158–160.

462. Aeby, C. H. and P. D. Leon, "Utilization of Calnan-Nicolle Implant," *Journal of the American Podiatry Association*, 68:167–171, 1978.

463. Carey, B. D., "Reduction of Severe Hallux Valgus and Hallux Limitus: Dow Corning Silastic TM Finger Joint Prosthesis," *Journal of Foot Surgery*, 10:1–4, 1971.

464. Kaplan, B. R. and S. J. Cohen, "The Use of the Calnan-Nicolle Prosthesis for Metatarsophalangeal Joint Replacement," *Journal of the American Podiatry Association*, 66:165–172, 1976.

465. McGlamry, E. D. and J. A. Ruch, "Status of Implant Arthroplasty of the Lesser Metatarsophalangeal Joints," *Journal of the American Podiatry Association*, 66:155–164, 1976.

466. Wenger, R. J. J. and R. C. Whalley, "Total Replacement of the First Metatarsophalangeal Joint," *Journal of Bone and Joint Surgery*, 60(B):88–92, 1978.

467. Reinherz, R. and M. Kent, "Total Reconstruction of the First Metatarsophalangeal Joint by Utilizing the Cutter Hinged Prosthesis: A Case Study," *Jounal of Foot Surgery*, 16:121–125, 1977.

468. Swanson, A. B., S. L. Biddulph, and C. G. Hagert, "A Silicone Rubber Implant to Supplement the Keller Toe Arthroplasty," *Inter-Clinic Information Bulletin*, Prosthetics and Orthotics, N.Y. University, Post-Graduate Medical School, Vol. 10, No. 6:7–14, 1971.

469. Swanson, A. B., "Implant Arthroplasty for the Great Toe," *Clinical Orthopedics*, 85:75–81, 1972.

470. LaPorta, G. A., P. Pilla, and K. P. Richter, "A Report of 536 Procedures Using a Silastic Intramedullary Stemmed Implant," *Journal of the American Podiatry Association*, 66(3):126–147, 1976.

471. Albin, R. L. and L. S. Weil, "Flexible Implant Arthroplasty of the Great Toe: An Evaluation," *Journal of the American Podiatry Association*, 64(12):967–975, 1974.

472. Caneva, R. E., "Postoperative Degeneration Changes in the Metacarpal Head Following Use of the Swanson Implant: Four Case Reports," *The Journal of Foot Surgery*, 16(1):34–37, 1977.

473. Roca, J., J. E. Beltran, M. F. Fairen, and A. Alvarex, "Treatment of Kienbock's Disease Using a Silicone Rubber Implant," *Journal of Bone and Joint Surgery*, 58A(3):373–376, 1976.

474. Lichtman, D. L., G. R. Mack, R. I. MacDonald, S. F. Gunther, and J. N. Wilson, "Kienbock's Disease: The Role of Silicone Replacement Arthroplasty," *Journal of Bone and Joint Surgery*, 59A(7):899–907, 1977.

475. Swanson, A. B., "Silicone Rubber Implants for the Replacement of the Carpal Scaphoid and Lunate Bones," *Clinical Orthopedics of North America*, 1(2):299–309, 1970.

476. Eiken O. and K. G. Holmqvist, "Replacement of Carpal Bones with Exact Fitting Silicone Rubber Implants," *Scandinavian Journal of Plastic and Reconstructive Surgery*, 11:189–193, 1977.

477. Kessler, I., "Silicone Arthroplasty of the Trapezio-Metacarpal Joint," *Journal of Bone and Joint Surgery, 55B(2): 285–291, 1973.*

478. Crawford, G. P., "Interposition Arthroplasty of the Carpo-Metacarpal Joint of the Thumb," *The Hand*, 9(2):130–134, 1977.

479. Ashworth, C. R., G. Blatt, R. G. Chuinard, and H. H. Stark, "Silicone Rubber Interposition Arthroplasty of the Carpometacarpal Joint of the Thumb," *Journal of Hand Surgery*, 2(5):345:357, 1977.

480. Haffajee, D., "Endoprosthetic Replacement of the Trapezium for Arthrosis in the Carpometacarpal Joint of the Thumb," *Journal of Hand Surgery*, 2(2):141–148, 1977.

481. Ferlic, D. C., G. A. Busbee, and M. L. Clayton, "Degenerative Arthritis of the Carpometacarpal Joint of the Thumb: A Clinical Follow-up of Eleven Niebauer Prostheses," *Journal of Hand Surgery*, 2(3):212–215, 1977.

482. Weilby, A. and J. Sondorf, "Results Following Removal of Silicone Trapezium Metacarpal Implants," *Journal of Hand Surgery*, 3(2):154–156, 1978.

483. Jackson, I. T. and R. A. St. Onge, "The Use of Palmaris Longus Tendon to Stabilize Trapezium Implants," *The Hand*, 9(1):42–44, 1977.

484. Lister, G. D., H. E. Kleinert, J. E. Kutz, and E. Atasoy, "Arthritis of the Trapezial Articulations Treated by Prosthetic Replacement," *The Hand*, 9(2):117–129, 1977.

485. Sarkin, T. L., "Osteoarthritis of the Trapeziometacarpal Joint," *South African Medical Journal*, 49:392–394, 1975.

486. Swanson, A. B., "Disabling Arthritis at the Base of the Thumb. Treatment by Resection of the Trapezium and Flexible (Silicone) Implant Arthroplasty," *Journal of Bone and Joint Surgery*, 54–A(3):456–471, 1972.

487. Eiken, O., "Prosthetic Replacement of the Trapezium," *Scandinavian Journal of Plastic and Reconstructive Surgery, 5:131–135, 1971.*

488. Summary Minutes of the Nineteenth Meeting of the Orthopedic Device Classification Panel, November 1977.

489. Summary Minutes of the Twentieth Meeting of the Orthopedic Device Classification Panel, March 1978.

490. Hay E. L. and A. D. Kornegay, "A Preliminary Report of Experience With Swanson Implant Wrist Arthroplasty," published data submitted to the Orthopedic Device Classification Panel, March 1978.

491. Rowland, S. A., "Clinical Experience with Swanson Implant Wrist Arthroplasties in the Rheumatoid Patient," unpublished data submitted to the Orthopedic Device Classification Panel, March 1978.

492. Gschwend, N., H. Scheier, and A. Bahler, "GSB Elbow, Wrist, MP and PIP Joints," *in* "Proceedings of Joint Replacement in the Upper Limb Conference," sponsored by the Institute of Mechanical Engineering, April 18–20, 1977.

493. Summary Minutes of the Seventeenth Meeting of the Orthopedic Device Classification Panel, April 1977.

494. Summary Minutes of the Eighteenth Meeting of the Orthopedic Device Classification Panel, July 1977.

495. Volz, R. G., "Clinical Experiences with a New Total Wrist Prosthesis," *Archives fuer Orthopaedische und Unfall-Chirurgie*, 85:205–209, 1976.

496. Beckenbaugh, R. D. and R. L. Linscheid, "Total Wrist Arthroplasty: A Preliminary Report," *Journal of Hand Surgery*, 2:337–344, 1977.

497. Volz, R. G., "The Development of a Total Wrist Arthroplasty," *Clinical Orthopedics*, 116:209–214, 1976.

498. Linscheid, R. L. and R. D. Bechenbaugh, "Total Arthroplasty of the Wrist to Relieve Pain and Increase Motion," *Geriatrics*, pp. 48–52, 1976.

499. "Joint Replacement in the Upper Limb: Institution of Mechanical Engineers Conference Publications 1977–5," Mechanical Publications Ltd., Great Britain, pp. 117–122, 1977.

500. Swanson, A. B., "Implant Arthroplasty for Disabilities of the Distal Radioulnar Joint: Use of a Silicone Rubber Capping Implant Following Resection of the Ulnar Head," *Orthopedic Clinics of North America*, 4(2):373–382, April 1973.

501. Berg, E., "Indications for Results with the Swanson Distal Ulnar Prosthesis," *Southern Medical Journal*, 69(7):858–861, July 1976.

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 888

Medical devices, Orthopedic devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 888, to read as follows:

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.
888.1 Scope.

Subpart B—Orthopedic Diagnostic Devices

888.1100 Arthoscope.
888.1240 AC-powered dynamometer.
888.1250 Nonpowered dynamometer.
888.1500 AC-powered goniometer.
888.1520 Nonpowered goniometer.

Subpart D—Orthopedic Prosthetic Devices

888.3000 Bone cap.
888.3010 Bone fixation cerclage.
888.3020 Intramedullary fixation rod.
888.3025 Passive tendon prosthesis.
888.3030 Single/multiple component metallic bone fixation appliances and accessories.
888.3040 Smooth or threaded metallic bone fixation fastener.
888.3050 Spinal interlaminal fixation orthosis.
888.3060 Spinal intervertebral body fixation orthosis.
888.3100 Ankle joint metal/composite semi-constrained prosthesis.
888.3110 Ankle joint metal/polymer semi-constrained prosthesis.
888.3120 Ankle joint metal/polymer non-constrained prosthesis.
888.3150 Elbow joint constrained prosthesis.
888.3160 Elbow joint semi-constrained prosthesis.
888.3170 Elbow joint radial (hemi-elbow) prosthesis.
888.3180 Elbow joint humeral (hemi-elbow) uncemented prosthesis.
888.3200 Finger joint metal/metal constrained uncemented prosthesis.
888.3210 Finger joint metal/metal contrained prosthesis.
888.3220 Finger joint metal/polymer constrained prosthesis.
888.3230 Finger joint polymer constrained prosthesis.
888.3300 Hip joint metal constrained prosthesis.
888.3310 Hip joint metal/polymer constrained prosthesis.
888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.
888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
888.3340 Hip joint metal/composite semi-constrained prosthesis.
888.3350 Hip joint metal/polymer semi-constrained prosthesis.
888.3360 Hip joint femoral (hemi-hip) metallic prosthesis.
888.3370 Hip joint (hemi-hip) acetabular metal prosthesis.
888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.
888.3390 Hip joint femoral (hemi-hip) metal/polymer prosthesis.
888.3400 Hip joint femoral (hemi-hip) resurfacing prosthesis
888.3410 Hip joint metal/polymer semi-constrained resurfacing prosthesis
888.3480 Knee joint femorotibial metallic constrained prosthesis.
888.3490 Knee joint femorotibial metal/composite non-constrained prosthesis.
888.3500 Knee joint femorotibial metal/composite semi-constrained prosthesis.
888.3510 Knee joint femorotibial metal/polymer constrained prosthesis.
888.3520 Knee joint femorotibial metal/polymer non-constrained prosthesis.
888.3530 Knee joint femorotibial metal/polymer semi-constrained prosthesis.
888.3540 Knee joint patellofemoral polymer/metal semi-constrained prosthesis.
888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.
888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.
888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.
888.3640 Shoulder joint constrained prosthesis.
888.3650 Shoulder joint non-constrained prosthesis.
888.3660 Shoulder joint semi-constrained prosthesis.
888.3680 Shoulder joint glenoid (hemi-shoulder) prosthesis.
888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
888.3720 Toe joint constrained uncemented prosthesis.
888.3730 Toe joint phalangeal (hemi-toe) prosthesis.
888.3750 Wrist joint carpal lunate prosthesis.
888.3760 Wrist joint carpal scaphoid prosthesis.
888.3770 Wrist joint trapezium prosthesis.
888.3780 Wrist joint polymer constrained uncemented prosthesis.
888.3790 Wrist joint metal constrained prosthesis.
888.3800 Wrist joint semi-constrained prosthesis.
888.3810 Wrist joint ulnar (hemi-wrist) prosthesis.
888.4150 Calipers for clinical use.
888.4200 Cement dispenser.
888.4210 Cement mixer for clinical use.
888.4220 Cement monomer vapor evacuator.
888.4230 Cement ventilation tube.
888.4300 Depth gauge for clinical use.
888.4540 Orthopedic manual surgical instrument.
888.4580 Sonic surgical instrument and accessories/attachments.
888.4600 Protractor for clinical use.
888.4800 Template for clinical use.
888.5850 Nonpowered orthopedic traction apparatus and accessories.
888.5890 Noninvasive traction components.
888.5940 Cast components.
888.5960 AC-powered cast removal instruments.
888.5980 Manual cast application/removal instruments.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgery device) is listed on one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Orthopedic Diagnostic Devices

§ 888.1100 Arthroscope.

(a) *Identification.* An arthroscope is a type of electrically powered endoscope that is intended to make visible the interior of a joint. The arthroscope may be combined with accessories to permit surgery in selected anatomic locations.

(b) *Classification.* Class II (performance standards).

§ 888.1240 AC-powered dynamometer.

(a) *Identification.* An AC-powered dynamometer is an electrically powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

(b) *Classification.* Class II (performance standards).

§ 888.1250 Nonpowered dynamometer.

(a) *Identification.* A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.1500 AC-powered goniometer.

(a) *Identification.* An AC-powered goniometer is an AC-powered measuring and recording device intended to evaluate joint function by measuring ranges of motion, acceleration, or forces exerted by a joint.

(b) *Classification.* Class II (performance standards).

§ 888.1520 Nonpowered goniometer.

(a) *Identification.* A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Subpart D—Orthopedic Prosthetic Devices

§ 888.3000 Bone cap.

(a) *Identification.* A bone cap is a mushroom-shaped implanted device made of either silicone elastomer or ultra-high molecular weight polyethylene. It is intended to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) *Classification.* Class II (performance standards).

§ 888.3010 Bone fixation cerclage.

(a) *Identification.* A bone fixation cerclage is an implanted device that is made of alloys such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. When implanted, the device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

(b) *Classification.* Class II (performance standards).

§ 888.3020 Intramedullary fixation rod.

(a) *Identification.* An intramedullary fixation rod is an implanted device that consists of a rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

(b) *Classification.* Class II (performance standards).

§ 888.3025 Passive tendon prosthesis.

(a) *Identification.* A passive tendon prosthesis is an implanted device made of silicone elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

(b) *Classification.* Class II (performance standards).

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/mutliple component metallic bone fixation appliances and accessories are implanted devices, consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that is made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that is intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are intended to be used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The device is intended to be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletel system.

(b) *Classification.* Class II (performance standard).

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is an implanted device that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed or have a formed, slotted head on the end. It is intended to be used for fixation of bone fractures, bone reconstructions, as a guide pin for insertion of other implants, or to be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II (performance standards).

§ 888.3050 Spinal interlaminal fixation orthosis.

(a) *Identification.* A spinal interlaminal fixation orthosis is an implanted device made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also has been used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) *Classification.* Class II (performance standards).

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification.* A spinal intervertebral body fixation orthosis is an implanted device made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is intended to apply force to a series of vertebrae to correct "sway back", scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification.* Class II (performance standards).

§ 888.3100 Ankle joint metal/composite semi-constrained prosthesis.

(a) *Identification.* An ankle joint metal/composite semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-

chromium-molybdenum, and a tibial resurfacing component fabricated from a carbon fiber reinforced ultra-high molecular weight polyethylene composite, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3110 Ankle joint metal/polymer semi-constrained prosthesis.

(a) *Identification.* An ankle joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3120 Anke joint metal/polymer non-constrained prostheses.

(a) *Identification.* An ankle joint metal/polymer non-constrained prosthesis is an implanted device intended to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3150 Elbow joint constrained prosthesis.

(a) *Identification.* An elbow joint constrained prosthesis is an implanted device made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys and ultra-high molecular weight polyethylene, that is intended to replace an elbow joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together (or affined). The generic type of device is limited to those prostheses intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3160 Elbow joint semiconstrained prosthesis.

(a) *Identification.* An elbow joint semi-constrained prosthesis is an implanted device intended to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing compoonent made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class II (performance standards).

§ 888.3170 Elbow joint radial (hemi-elbow) prosthesis.

(a) *Identification.*An elbow joint radial (hemi-elbow) prosthesis is an implanted device made of medical grade silicone elastomer intended to replace the proximal end of the radius. The device is intended for implantation without a polymethylmethacryate luting agent (bone cement).

(b) Classification. Class II (performance standards).

§ 888.3180 Elbow joint humeral (hemi-elbow) uncemented prosthesis.

(a) *Identification.*An elbow joint humeral (hemi-elbow) uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The device is intended for implantation without a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or prostheses made from alloys and ultrahigh molecular weight polyethylene. This generic type of device is limited to prostheses intended to be implanted without a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3210 Finger joint metal/metal constrained prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is an implanted device intended to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, and is limited to those to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) Classification. Class III (premarket approval).

§ 888.3220 Finger joint metal/metal constrained prosthesis.

(a) *Identification.* A finger joint metal/polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, an ultra-high molecular weight polyethylene, and is limited to those devices that are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3230 Finger joint polymer constrained prosthesis.

(a) *Identification.* A finger joint polymer constrained prosthesis is an implanted device intended to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination of polypropylene and polyester material. The flexibile across-the-joint component may be covered with a silicone rubber sleeve. These prostheses are intended to be implanted

without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3300 Hip joint metal constrained prosthesis.

(a) *Identification.* A hip joint metal constrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of an alloy with an ultra-high molecular weight polyethylene insert, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3310 Hip joint metal/polymer constrained prosthesis.

(a) *Identification.* A hip joint metal/polymer contrained prosthesis is an implanted device intended to replace a hip joint. The device prevents dislocation in more than oen anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended to be used without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3340 Hip joint metal/composite semi-constrained prosthesis.

(a) *Identification.* A hip joint metal/composite semi-constrained prosthesis is an implanted two-part device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys such as cobalt-chromium-molybdenum, and an acetabular component made of carbon fiber reinforced ultra-high molecular weight polyethylene. Both components are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3350 Hip joint metal/polymer semi-constrained prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained prosthesis is an implanted device intended to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3360 Hip joint femoral (hemi-hip) metallic prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be fixed to the bone with a polymethylmethacrylate luting agent (bone cement), as well as designs which have large window-like holes in the stem of the device and which are intended to be used without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) *Classification.* Class II (performance standards).

§ 888.3370 Hip joint (hemi-hip) acetabular metal prosthesis.

(a) *Identification.* A hip joint (hemi-hip) acetabular metal prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis stem is intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3390 Hip joint femoral hemi-hip metal/polymer prosthesis.

(a) *Identification.* A hip joint femoral hemi-hip metal/polymer prosthesis is an implanted two-part device intended to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with a polymethylmethacrylate luting agent (bone cement) or implanted by impaction.

(b) *Classification.* Class II (performance standards).

§ 888.3400 Hip joint femoral (hemi-hip) resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) resurfacing prosthesis is an implanted device intended to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

(b) *Classification.* Class II (performance standards).

§ 888.3410 Hip joint metal/polymer semi-constrained resurfacing prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained resurfacing prosthesis is an implanted two-part device intended to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral cap component made of alloy, such as cobalt-chromium-molybdenum, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3480 Knee joint femorotibial metallic constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metallic constrained prosthesis is an implanted device intended partially to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, and internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3490 Knee joint femorotibial metal/composite non-constrained prosthesis.

(a) Identification. A knee joint femorotibial metal/composite non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon-fibers composite and are intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3500 Knee joint femorotibial metal/composite semi-constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint. The device limits translation and rotation in one or more plans via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3510 Knee joint femorotibial metal/polymer constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chronium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3520 Knee joint femorotibial metal/polymer nonconstrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene, and are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained prosthesis is an implanted device intended partially to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consists of a femoral component made of alloys, such as cobalt-chronium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene, and is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3540. Knee joint patellofemoral polymer/metal semi-constrained prosthesis.

(a) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained prosthesis is an implanted two-part device intended partially to replace a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspects of the distal demur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement). The patellar component is designed to be implanted only with its femoral component.

(b) *Classification.* Class III (premarket approval).

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained prosthesis is an implanted device intended to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar resurfacing component may be attached to the resected patella either with a metallic acrew or luting agent. All stemmed metallic components within this generic class are intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis is an implanted device intended to replace a knee joint. The device limits translation and rotation in one or more plans via the geometry of its articulating surfaces. It has no linkage across-the-joint.

This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended to be implanted with polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) *Indentification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, that is intended to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device made of alloys, such as cobalt-chromium-molybdenum, intended to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those devices intended for implantation without use of polymethylmethacrylate luting agent (bone cement). The device is intended for use only in treatment of degenerative and posttraumatic patellar (osteo) arthritis.

(b) *Classification.* Class II (performance standards).

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prostheses.

(a) *Identification.* A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is an implanted device intended partially to replace a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those devices intended for implantation without the use of a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3640 Shoulder joint constrained prosthesis.

(a) *Identification.* A shoulder joint constrained prosthesis is an implanted device intended to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3650 Shoulder joint non-constrained prosthesis.

(a) *Identification.* A shoulder joint non-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3660 Shoulder joint semi-constrained prosthesis.

(a) *Identification.* A shoulder joint semi-constrained prosthesis is an implanted device intended to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) prosthesis.

(a) *Identification* . A shoulder joint glenoid (hemi-shoulder) prosthesis is an implanted device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, and that is intended to replace a portion of the shoulder joint. This generic type of device is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class III (premarket approval).

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is an implanted intramedullary stemmed device made of alloys, such as cobalt-chromium-molybdenum.

It is intended to replace the articular surface of the proximal end of the humerus and to be fixed without a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3720 Toe joint constrained uncemented prosthesis.

(a) *Identification.* A toe joint constrained uncemented prosthesis is an implanted device made of silicone elastomer or polyester reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II (performance standards).

§ 888.3730 Toe joint phalangeal (hemi-toe) prosthesis.

(a) *Identification.* A toe joint phalangeal (hemi-toe) prosthesis is an implanted device made of silicone elastomer intended to replace the base of the proximal phalanx of the toe.

(b) *Classification.* Class II (performance standards).

§ 888.3750 Wrist joint carpal lunate prosthesis.

(a) *Identification.* A wrist joint carpal lunate prosthesis is a one-piece implanted device made of silicone elastomer. It is intended to replace the carpal lunate bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3760 Wrist joint carpal scaphoid prosthesis.

(a) *Identification.* A wrist joint carpal scaphoid prosthesis is a one-piece implanted device made of silicone elastomer or silicone elastomer intended to replace the carpal scaphoid bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3770 Wrist joint carpal trapezium prosthesis.

(a) *Identification.* A wrist joint carpal trapezium prosthesis is a one-piece implanted device made of silicone elastomer/polyester material intended to replace the carpal trapezium bone of the wrist.

(b) *Classification.* Class II (performance standards).

§ 888.3780 Wrist joint polymer constrained uncemented prosthesis.

(a) *Identification.* A wrist joint polymer constrained uncemented prosthesis is an implanted device made of polyester-reinforced silicone elastomer. It is intended to be used without a polymethylmethacrylate luting agent (bone cement) to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II (performance standards).

§ 888.3790 Wrist joint metal constrained prosthesis.

(a) *Identification.* A wrist joint metal constrained prosthesis is an implanted device intended to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those devices intended for implantation with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (premarket approval).

§ 888.3800 Wrist joint semi-constrained prosthesis.

(a) *Identification.* A wrist joint semi-constrained prosthesis is an implanted device intended to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prosthesis that have either (1) a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or (2) a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those devices intended to be implanted with a polymethylmethacrylate luting agent (bone cement).

(b) *Classification.* Class II (performance standards).

§ 888.3810 Wrist joint ulnar (hemi-wrist) prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) prosthesis is a mushroom-shaped implanted device that is made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene. It is intended to be inserted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification.* Class II (performance standards).

Subpart E—Orthopedic Surgery Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification.* A caliper for clinical use is a compass-like device intended for use in measuing the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4200 Cement dispenser.

(a) *Identification.* A cement dispenser is a nonpowered syringe like device intended for use in placing bone cement into surgical sites.

(b) *Classification.* Class I (general controls).

§ 888.4210 Cement mixer for clinical use.

(a) *Identification.* A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement.

(b) *Classification.* Class I (general controls).

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery for the containment or removal of bone cement monomer vapor or the removal of other undesirable fumes.

(b) *Classification.* Class I (general controls).

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a device usually made of plastic, that consists of a segment of tubing that is intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement.

(b) *Classification.* Class I (general controls).

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a device consisting of an instrument with a graduated scale intended for various uses, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4540 Orthopedic manual surgical instrument.

(a) *Identification.* An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4580 Sonic surgical instrument and accessories/attachments.

(a) *Identification.* A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

(b) *Classification.* Class II (performance standards).

§ 888.4600 Protractor for clinical use.

(a) *Identification.* A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on x-rays or in a surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.4800 Template for clinical use.

(a) *Identification.* A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

(a) *Identification.* A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practices regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5890 Noninvasive traction component.

(a) *Identification.* A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

(b) *Classification.* Class I (general controls).

§ 888.5940 Cast component.

(a) *Identification.* A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, top cap, cast support, and walking iron.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5960 AC-powered cast removal instrument.

(a) *Identification.* An AC-powered cast removal instrument is an AC-powered hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification.* Class II (performance standards).

§ 888.5980 Manual cast aplication and removal instrument.

(a) *Identification.* A manual cast application and removal instrument is a nonpowered hand-held device intended

to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Because FDA believes that more time is needed for interested persons to submit comments on the classification of the numerous devices in this proposed regulation and the need to stagger the comment periods to allow an orderly review of all of the outstanding proposed classification regulations, FDA is providing a period through October 1, 1982 for interested persons to comment on this proposal. FDA finds in accordance with section 520(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(d)(2)) that good cause exists to extend the comment period beyond 90 days. Similar extensions of comment periods were granted for good cause for other proposed classification regulations. (See the **Federal Register** of March 19, 1982 (47 FR 11879).)

Interested persons may, on or before October 1, 1982 submit to the Dockets Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments regarding the general provisions are to be identified with the docket number found in brackets in the heading of this document. Comments regarding a particular device are to be identified with the docket number for that device found in the "Panel Recommendations and FDA's Proposed Classifications" sections. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has carefuly analyzed the economic effects of this proposed rule and certifies that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that this proposal does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules proposing classification of devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and, under the proposed rules, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket aproval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

Dated: June 7, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-17576 Filed 7-1-82; 8:45 am]

BILLING CODE 4160-01-M