Sunshine Act Meetings

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

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).

FEDERAL ELECTION COMMISSION

DATE AND TIME, Wednesday, September 9, 1987, 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C., 437g.
Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.
Matters concerning participation in civil actions or proceedings or arbitration.
International personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE AND TIME: Thursday, September 10, 1987, 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of Dates for Future Meetings.
Correction and Approval of Minutes.
Eligibility Report for Candidates to Receive Presidential Primary Matching Funds.
Draft Advisory Opinion 1987-24—John B. Simon on behalf of Hyatt Corporation.
Draft Advisory Opinion 1987-25—Ricardo A. Otaola.
Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Information Officer, Telephone: 202-376-3155.

Marjorie W. Emmons,
Secretary of the Commission.
[FR Doc. 87-20537 Filed 9-2-87; 8:45 am]
BILLING CODE 6715-01-M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

August 27, 1987.

TIME AND DATE: 10:00 a.m., September 2, 1987.

PLACE: Room 600, 1730 K Street NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: Consideration of the matter below, previously announced in the agenda for September 2, 1987 is canceled.

Consideration will be rescheduled at a future date. Consideration of the other matter previously announced in the agenda for September 2, 1987 remains in effect.

2. *Martha Perando v. Mettiki Coal Corporation,* Docket No. YORK 85-12-D.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, (202) 653-5629.

Jean H. Ellen,
Agenda Clerk.
[FR Doc. 87-20496 Filed 9-2-87; 8:45 am]
BILLING CODE 6735-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, September 9, 1987.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of their routine nature, no substantive discussion of the following items is anticipated. These matters will be voted on without discussion unless a member of the Board requests that an item be moved to the discussion agenda.

1. Proposed extension and revision of the Weekly Report of Assets and Liabilities (FR 2416) and the Weekly Report of Selected Assets (FR 2644).
2. Proposed extensions and revision of the Monthly Survey of Eligible Bankers Acceptances (FR 2006).
3. Proposed revision and extension of Senior Loan Officer Opinion Survey on Bank Lending Practices (FR 2018).
4. Proposed revision and extension of the Domestic Finance Company Reports of Consolidated Assets and Liabilities (FR 2248/2248a).

Discussion Agenda

5. Publication for comment of a proposed amendment to Regulation Z (Truth in Lending) to implement provisions of the Competitive Equality Banking Act of 1987 regarding adjustable rate mortgage caps.
6. 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, DC 20551.

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

James McAfee,
Associate Secretary of the Board.
[FR Doc. 87-20507 Filed 9-2-87; 11:11 am]
BILLING CODE 6219-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: Approximately 10:30 a.m., Wednesday, September 9, 1987, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. 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. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: September 2, 1987.

James McAfee,
Associate Secretary of the Board.
[FR Doc. 87-20508 Filed 9-2-87; 11:11 am]
BILLING CODE 6210-01-M

PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

STATUS: Open.

TIME AND DATE: September 9-10, 1987, 9:00 p.m.

PLACE: City Council Chambers, the Electric Building, 140 South Capital, Idaho Falls, Idaho.

MATTERS TO BE CONSIDERED:

1. Public Hearing on General Model Conservation Standards.
2. Public Hearing on Umatilla Hatchery Amendment.

3. Public Comment on Yakima/Klickitat Outplanting Facility Master Plan Issue Paper.
4. Staff Presentation, Public Comment and Council Deliberation on Comments regarding the Bonneville Power Administration Partnership Program.
5. Public Comment on Heating Cost Comparison Study.
6. Council Decision on the Analysis of Conservation Measures as required by Section 4(k) of the Northwest Power Act.
7. Bonneville Presentation on the Status of the Residential Weatherization Program.
8. Staff Presentation of an Issue Paper on Current Resources in the West for the Western Electricity Study.
9. Staff Presentation of an Issue Paper on the Status of Commercial Model Conservation Standards.
10. Council Decision on Proposed Guidelines on Notice of Meetings.
11. Council Business.
12. Public Comment.

FOR FURTHER INFORMATION CONTACT: Ms. Bess Atkins at (503) 222–5161.

Edward Sheets,

Executive Director.

[FR Doc. 87–20524 Filed 9–2–87; 12:17p.m.]

BILLING CODE 0000–00–M

UNITED STATES INSTITUTE OF PEACE

TIMES AND DATES:

9:00 a.m.–5:00 p.m., Thursday, September 10, 1987
9:00 a.m.–5:00 p.m., Friday, September 11, 1987

PLACE: National Trust for Historic Preservation, 1785 Massachusetts Avenue, NW., Washington, DC 20035.

STATUS: Open (portions may be closed pursuant to subsection (c) of section 552(b) of title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Pub. L. 98–525).

AGENDA (TENTATIVE): Meeting of Board of Directors convened. Chairman's Report. President's Report. Committee Reports. Consideration of minutes of the fifteenth meeting. Report on National Peace Essay Contest. Discussion of Jennings Randolph Program. Presentation on Chairman's Report to Congress and the President. Reports on Housing, TV Project, and Institute Seal. Consideration of grant applications.

CONTACT: Mrs. Olympia Diniak. Telephone: (202) 789–5700.

Dated: September 2, 1987.

Robert F. Turner,

President, United States Institute of Peace.

[FR Doc. 87–20526 Filed 9–2–87; 12:52 PM]

BILLING CODE 3155–01–M

Corrections

Federal Register
Vol. 52, No. 172
Friday, September 4, 1987

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Activities of Self-Regulatory Organization Governing Members Who Possess Material, Nonpublic Information

Correction

In proposed rule document 87-19688 beginning on page 32568 in the issue of Friday, August 28, 1987, make the following corrections on page 32572:

1. In the first column, in the paragraph under **Regulatory Flexibility Act**, in the 20th line, "§ 1.59 (a)(8) and (c)" should read "§ 1.59 (a)(9) and (c)".

2. In the second column, in the **Authority**, in the last line, "rated" should read "noted.".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Western Area Power Administration

Salt Lake City Area Integrated Projects; Rate Order; Utah

Correction

In notice document 87-18432 beginning on page 30245 in the issue of Thursday, August 13, 1987, make the following correction on page 30249:

In the second column, in the first complete paragraph, in the next to the last line, "would be expected" should read "would not be expected".

BILLING CODE 1505-01-D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

[OPTS-62053; FRL 3176-1]

Polychlorinated Biphenyls; Exclusions, Exemptions and Use Authorizations

Correction

In proposed rule document 87-15245 beginning on page 25838 in the issue of Wednesday, July 8, 1987, make the following corrections:

1. On page 25838, in the first column, in the **SUMMARY**, in the 23rd line, "elimination" should read "eliminate".

§ 761.20 [Corrected]

2. On page 25860, in the third column, in § 761.20(e)(4)(i), in the sixth line insert "required" after "records".

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Parts 203 and 234

[Docket No. R-87-1317; FR-2266]

Termination of Section 245(b) GPM Program

Correction

In rule document 87-19768 beginning on page 32754 in the issue of Friday, August 28, 1987, make the following correction:

On page 32755, in the third column, in the second complete paragraph, in the fourth line, "justify" should read "disqualify".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 87-AWP-21]

Amendment to Santa Maria, CA, Control Zone

Correction

In rule document 87-19028 beginning on page 31385 in the issue of Thursday, August 20, 1987, make the following correction:

§ 71.171 [Corrected]

On page 31385, in the third column, in § 71.171, in the description for the Santa Maria, CA control zone, in the third line, insert "during" after "effective".

BILLING CODE 1505-01-D

federal register

Friday
September 4, 1987

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 888

Orthopedic Devices; General Provisions and Classifications of 77 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 78N-3028]

Orthopedic Devices; General Provisions and Classifications of 77 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 77 orthopedic devices. In the preamble to this rule, FDA is responding to comments received on the proposed regulations classifying these devices. These actions are being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 5, 1987.

FOR FURTHER INFORMATION CONTACT: Carl Larson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7156.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Background

In the **Federal Register** of July 2, 1982 (47 FR 29052), FDA published a proposed rule containing general provisions applicable to the classification of orthopedic devices, and individual proposed regulations classifying 77 orthopedic devices into one or more of three regulatory classes: Class I (general controls), class II (performance standards), and class III (premarket approval).

FDA is postponing final classification of 2 of the 77 orthopedic devices subject to the proposed rule in order to review additional data on electrical safety. Thus, in this final rule FDA is classifying 75 orthopedic devices based on the proposed rule. Also, in this final rule FDA is codifying the statutory classification into class III of two transitional devices that were not subjects of the proposed classification rule. Accordingly, in this final rule FDA is classifying 77 generic types of orthopedic devices (77 minus 2 plus 2 equals 77). Of these 77 devices, FDA is classifying 15 devices into class I, 37 devices into class II, 24 devices into class III, and 1 device into class II or class III depending upon its intended use.

To reduce printing costs, FDA is publishing in one final rule, the general provisions and the classifications of 77 orthopedic devices. FDA previously published a separate final rule for each device.

Classification of medical devices in commercial distribution is required by section 513 (21 U.S.C. 360c) of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 through 392). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before March 30, 1990, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the proposed regulations described the development of the general provisions and the proposed regulations classifying orthopedic devices and the activities of the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of orthopedic devices. FDA provided a period of 90 days, later extended to 180 days (October 8, 1982; 47 FR 44475), for interested persons to submit written comments on the proposed regulations. The comments received and FDA's responses to the comments are discussed below.

In April 1985, H.R. 2177 (99th Cong. 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) made the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards required by section 514 of the act. If legislation comparable to this bill becomes law, there would be only two categories of devices: Class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because the proposed legislation contains transitional provisions that convert classifications under the current law to classifications under the proposed law, FDA is continuing to issue classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. FDA does not have the resources, however, to establish simultaneously performance standards for all the devices already classified (or being classified) in class II. In the October 23, 1985 notice, FDA announced that it will consider the following factors when setting priorities for establishing performance standards for class II devices:

a. The seriousness of questions concerning the safety or effectiveness of the devices; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device:

b. The recommendations of FDA's advisory committees;

c. The impact of an FDA guideline or recommendation;

d. The effect of a Federal standard or other regulatory controls under an authority other than the act;

e. The impact of voluntary standards;

f. The impact of activities authorized under the general controls provisions of the act;

g. The effect of dissemination of information and educational efforts;

h. The sufficiency of voluntary corrective actions;

i. Valid scientific evidence developed since classification;

j. The existence of a petition for reclassification;

k. The impact of any other factors that affect a devices's safety or effectiveness.

C. Changes in the Name of the Orthopedic Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Orthopedic and Rehabilitation Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to orthopedic devices as did its predecessors, the Orthopedic Device Classification Panel. (1976–1978) and the Surgical and Rehabilitation Devices Panel (1978–1984).

D. Devices Not Being Classified at This Time

FDA is postponing classification of the following two generic types of orthopedic devices in order to review additional data on electrical safety: AC-powered goniometer and AC-powered cast removal instrument.

E. List of Orthopedic Devices

The list below shows, for each orthopedic device, the section of the Code of Federal Regulations at which classification of that device is being codified (or will be codified), the docket number of the corresponding proposed classification regulation (where applicable), the final classification of the device, and an indication (yes or no) of whether public comments were received on the proposed regulation. The list includes the two AC-powered orthopedic devices for which classification is being postponed. For each of these two devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "[1]," and no classification of the device is provided (§§ 888.1500 and 888.5960). The two transitional devices included in this rule are identified with footnote "[2]," (§§ 888.3015 and 888.3027). (See "K. Transitional Devices" near the end of the preamble.)

Section and device	Docket No.	Class	Comments
Subpart B—Diagnostic Devices			
888.1100—Arthroscope	78N-3041	II	Yes.
888.1240—AC-powered dynamometer	78N-3300	II	No.
888.1250—Nonpowered dynamometer	78N-3042	I	No.
(888.1500)—AC-powered goniometer [1]	78N-3043		No.
888.1520—Nonpowered goniometer	78N-3044	I	Yes.
Subpart D—Prosthetic Devices			
888.3000—Bone cap	78N-3046	II	Yes.
888.3010—Bone fixation cerclage	78N-3051	II	Yes.
888.3015—Bone heterograft [2]		III	
888.3020—Intramedullary fixation rod	78N-3056	II	Yes.
888.3025—Passive tendon prosthesis	78N-3098	II	Yes.
888.3027—Polymethylmethacrylate (PMMA) bone cement [2]		III	
888.3030—Single/multiple component metallic bone fixation appliances and accessories	78N-3049	II	Yes.
888.3040—Smooth or threaded metallic bone fixation fastener	78N-3053	II	Yes.
888.3050—Spinal interlaminal fixation orthosis	78N-3047	II	Yes.
888.3060—Spinal intervertebral body fixation orthosis	78N-3048	II	Yes.
888.3100—Ankle joint metal/composite semi-constrained cemented prosthesis	78N-3059	II	Yes.
888.3110—Ankle joint metal/polymer semi-constrained cemented prosthesis	78N-3060	II	Yes.
888.3120—Ankle joint metal/polymer non-constrained cemented prosthesis	78N-3061	III	No.
888.3150—Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	78N-3062	III	Yes.
888.3160—Elbow joint metal/polymer semi-constrained cemented prosthesis	78N-3063	II	Yes.
888.3170—Elbow joint radial (hemi-elbow) polymer prosthesis	78N-3064	II	Yes.
888.3180—Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	78N-3065	III	No.
888.3200—Finger joint metal/metal constrained uncemented prosthesis	78N-3066	III	No.
888.3210—Finger joint metal/metal constrained cemented prosthesis	78N-3301	III	No.
888.3220—Finger joint metal/polymer constrained cemented prosthesis	78N-3067	III	No.
888.3230—Finger joint polymer constrained prosthesis	78N-3068	II	Yes.
888.3300—Hip joint metal constrained cemented or uncemented prosthesis	78N-3070	III	Yes.
888.3310—Hip joint metal/polymer constrained cemented or uncemented prosthesis	78N-3071	III	Yes.
888.3320—Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.	78N-3072	III	No.
888.3330—Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.	78N-3073	III	No.
888.3340—Hip joint metal/composite semi-constrained cemented prosthesis	78N-3074	II	Yes.
888.3350—Hip joint metal/polymer semi-constrained cemented prosthesis	78N-3075	II	Yes.
888.3360—Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis	78N-3077	II	Yes.
888.3370—Hip joint (hemi-hip) acetabular metal cemented prosthesis	78N-3076	III	No.
888.3380—Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	78N-3078	III	No.

[1] Classification postponed.

[2] Not proposed; statutory classification.

Section and device	Docket No.	Class	Comments
888.3390—Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis	78N-3079	II	No.
888.3400—Hip joint femoral (hemi-hip) metallic resurfacing prosthesis	78N-3080	II	Yes.
888.3410—Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis	78N-3081	III	Yes.
888.3480—Knee joint femorotibial metallic constrained cemented prosthesis	78N-3082	III	Yes.
888.3490—Knee joint femorotibial metal/composite non-constrained cemented prosthesis	78N-3083	II	Yes.
888.3500—Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	78N-3302	II	Yes.
888.3510—Knee joint femorotibial metal/polymer constrained cemented prosthesis	78N-3084	II	Yes.
888.3520—Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	78N-3085	II	No.
888.3530—Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	78N-3086	II	Yes.
888.3540—Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	78N-3087	III	Yes.
888.3550—Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	78N-3088	III	Yes.
888.3560—Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.	78N-3090	II	Yes.
888.3570—Knee joint femoral (hemi-knee) metallic uncemented prosthesis	78N-3091	III	No.
888.3580—Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	78N-3092	II, III	Yes.
888.3590—Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	78N-3093	II	No.
888.3640—Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	78N-3094	III	Yes.
888.3650—Shoulder joint metal/polymer non-constrained cemented prosthesis	78N-3095	III	Yes.
888.3660—Shoulder joint metal/polymer semi-constrained cemented prosthesis	78N-3096	III	Yes.
888.3680—Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	78N-3058	III	Yes.
888.3690—Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis	78N-3097	II	Yes.
888.3720—Toe joint polymer constrained prosthesis	78N-3099	II	Yes.
888.3730—Toe joint phalangeal (hemi-toe) polymer prosthesis	78N-3100	II	Yes.
888.3750—Wrist joint carpal lunate polymer prosthesis	78N-3101	II	Yes.
888.3760—Wrist joint carpal scaphoid polymer prosthesis	78N-3102	II	Yes.
888.3770—Wrist joint carpal trapezium polymer prosthesis	78N-3304	II	Yes.
888.3780—Wrist joint polymer constrained prosthesis	78N-3103	II	Yes.
888.3790—Wrist joint metal constrained cemented prosthesis	78N-3305	III	No.
888.3800—Wrist joint metal/polymer semi-constrained cemented prosthesis	78N-3104	II	No.
888.3810—Wrist joint ulnar (hemi-wrist) polymer prosthesis	78N-3105	II	Yes.
Subpart E—Surgical Devices			
888.4150—Calipers for clinical use	78N-3106	I	Yes.
888.4200—Cement dispenser	78N-3107	I	Yes.
888.4210—Cement mixer for clinical use	78N-3108	I	Yes.
888.4200—Cement monomer vapor evacuator	78N-3109	I	No.
888.4230—Cement ventilation tube	78N-3110	I	Yes.
888.4300—Depth gauge for clinical use	78N-3111	I	Yes.
888.4540—Orthopedic manual surgical instrument	78N-3114	I	Yes.
888.4580—Sonic surgical instrument and accessories/attachments	78N-3116	II	No.
888.4600—Protractor for clinical use	78N-3117	I	Yes.
888.4800—Template for clinical use	78N-3118	I	Yes.
888.5850—Nonpowered orthopedic traction apparatus and accessories	78N-3120	I	No.
888.5890—Noninvasive traction component	78N-3122	I	Yes.
888.5940—Cast component	78N-3123	I	No.
(888.5960)—AC-powered cast removal instrument [1]	78N-3124		Yes.
888.5980—Manual cast application and removal instrument	78N-3125	I	No.

[1] Classification postponed.
[2] Not proposed; statutory classification.

F. Changes in Classifications in Final Rule

Based upon consideration of the comments received and on additional information before the agency, FDA has placed the six devices listed below in different classes from those originally proposed:

Section and Device	Proposed class	Final class
888.3100—Ankle joint metal/composite semi-constrained cemented prosthesis	III	II
888.3340—Hip joint metal/composite semi-constrained prosthesis	III	II
888.3480—Knee joint femorotibial metallic constrained prosthesis	II	III
888.3490—Knee joint femorotibial metal/composite non-constrained cemented prosthesis	III	II
888.3500—Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	III	II
888.3550—Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	II	III

FDA's reasons for changing the classifications of these six devices are provided in this preamble under the heading "G. Summary of Comments on Classification and FDA's Responses" in paragraphs 14, 20, 25, 26, 27, and 29.

FDA believes that it is unnecessary to issue a new proposed rule concerning these decisions. The purpose of publishing a proposed regulation and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposed regulation or upon reconsideration, the agency may be persuaded that its proposed classification was incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed regulation on orthopedic devices (see 47 FR 29052). Persons who disagree with the final classification of a device may petition for reclassification of the device under number Subpart C of Part 860 (21 CFR Part 860).

G. Summary of Comments on Classification and FDA's Responses

FDA notes that it is required by section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) to classify a device intended to be implanted into class III, unless the agency determines that such class is unnecessary. After determining that classification of such a device into class III is unnecessary, in determining whether it should classify a device intended to be implanted into class II or class I, FDA believes that it should classify such a device into class II, unless the agency determines such class is unnecessary. Because of the risks to health presented by devices intended to be implanted, such as loss or reduction of limb function, adverse tissue reaction, immediate risk of infection, and long-term potential for increased risk of infection from the presence of a foreign body discussed in the proposed rule (47 FR 29054 at 29055 (Refs. 4 and 5)); FDA believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of any device intended to be implanted. Thus, FDA believes that establishment of a performance standard is necessary for any device intended to be implanted that the agency believes need not be in class III.

1. One comment asked that FDA explain its rationale for proposing to classify into class II a number of orthopedic implants with failure rates in excess of 20 percent, while proposing to classify into class III other such devices for which insufficient data are available to estimate their failure rates and, consequently, whose failure rates may be less than 20 percent.

FDA agrees that further explanation is needed. In accordance with section 513 of the act (21 U.S.C. 360c), FDA is classifying into class II orthopedic devices intended to be implanted for which sufficient evidence is available to (a) identify and assess the risks to health presented by the devices, (b) weigh the probable benefits to health from use of the devices against the probable risks from such use, (c) establish performance standards to provide reasonable assurance of the safety and effectiveness of the devices, and (d) determine that the general controls of class I alone are insufficient to provide such assurance. Implants for which such evidence is unavailable are being placed in class III, as required by section 513 of the act. Accordingly, consistent with the statutory standard, FDA proposed to classify into class III many orthopedic devices intended to be implanted because important information concerning their safety and effectiveness is not currently available.

To provide reasonable assurance of the safety and effectiveness of devices intended to be implanted, clinical studies of the devices should include periodic followup examinations of patients over a number of years. These periodic examinations should include taking X-rays of the implant to help determine whether the device is biocompatible. If long-term followup of patients receiving an implant has not been documented in the results of the clinical studies, or if such data are unavailable, FDA believes that the safety and effectiveness of the device have not been established. Thus, when the failure rate of a device intended to be implanted is unknown because of lack of followup data, FDA is classifying the device into class III. When such data become available, and if the data establish that the device has an acceptable failure rate, the device may be reclassified.

2. Comments argued that, for several reasons, FDA should classify into class I many of the devices intended to be implanted that it proposed be in class II or class III. FDA's responses to each of these arguments follow.

2a. Comments recommended that many devices intended to be implanted be classified into class I because, for those devices, the existence of a performance standard or the requirement of premarket approval would not improve the outcome for a patient who develops an infection following implantation of a device.

FDA agrees that the existence of a performance standard or the requirement of premarket approval would not change the result for a patient who develops an infection following implantation of the device, but disagrees that that is a valid reason for classifying the device into class I. Although performance standard requirements and premarket approval requirements will not eliminate all possibility of infection, these requirements will reduce the risk of infection and, therefore, FDA believes that these requirements are necessary to provide reasonable assurance of the safety and effectiveness of these devices.

2b. Comments recommended that FDA classify many devices intended to be implanted into class I in order to ensure their continued commercial availability.

FDA disagrees with the comments. The continued commercial availability of a device is not the major criterion to be considered by FDA when classifying devices. Classification decisions are based on the degree of regulatory control necessary to ensure the safety and effectiveness of the device. In any event, classification of a preamendments device into class II or class III has no immediate impact on the commercial availability of the device. For each device classified into class II or class III, FDA must publish an additional proposed and final regulation allowing further public comment before the agency may establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact."

2c. Comments requested that many devices intended to be implanted be classified into class I instead of class II as proposed, arguing that the Panel recommended that standards be established, not for the finished devices themselves, but rather for the materials intended for use in such devices.

FDA disagrees with the comments. As stated in the "Summary of the Reasons for Recommendations" for each of the regulations proposing that devices intended to be implanted be classified into class II, the Panel recommended and FDA proposed that performance standards be established that would apply both to the materials intended for use in the devices and to the finished devices themselves.

2d. Comments requested that many orthopedic devices intended to be implanted be classified into class I, arguing that the literature cited in the proposed rule did not support classification of these devices into class II or class III.

FDA disagrees with the comments. FDA based its proposed classification of each device primarily on the Panel's recommendation. Section 513(c)(2)(A) of the act requires that a Panel summarize the data upon which its recommendation is based. The legislative history of the amendments provides that the term "data" as used in that section has a special meaning. As used in section 513(c)(2)(A), "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or the judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94–853, 94th Cong., 2d Sess. 40 (1976)). FDA's proposed classifications, therefore, are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited medical literature. Furthermore, FDA believes that a lack of data in the literature regarding a device intended to be implanted, or a lack of clinical experience with the device, supports classifying the device into class II or class III, rather than class I. Moreover, the little literature available shows that such devices present risks to health that can be controlled only by requiring performance standards or premarket approval.

2e. Several comments argued that many orthopedic devices intended to be implanted should be classified into class I because no major health problems have been identified in FDA's device experience network or in manufacturers' complaint files for either the devices or the materials used in them.

FDA disagrees with the comments. FDA believes that the data in complaint files of manufacturers or the voluntarily submitted adverse experience reports in FDA's device experience network are not necessarily an accurate reflection of the number of adverse experiences with devices. Although FDA has published in the**Federal Registe**r final rule requiring manufacturers and importers to report to FDA adverse experiences with devices (49 FR 36326; September 14, 1984), the rule does not apply to physicians who implant orthopedic devices. Consequently, FDA may not be informed of all adverse experiences with these devices. Further, FDA has identified risks to health presented by orthopedic devices intended to be implanted that support classifying the devices into class II or class III. As stated earlier, a lack of information about, or a lack of clinical experience with, a device intended to be implanted also supports classification of the device into class II or class III.

2f. Comments argued that FDA should classify many joint prostheses intended to be implanted into class I because little data exist showing a correlation between in vitro wear and strength measurements of the devices or the materials intended for use in them, and performance of the devices after they are implanted.

FDA agrees that little data are available showing a correlation between in vitro measurements of wear or strength of devices intended to be implanted, or materials used in them, and in vivo performance of such devices. FDA is not classifying any device intended to be implanted solely on the basis of the amount of in vitro wear and strength data available. However, as shown by the available data summarized in the proposed rule (Ref. 7; 47 FR 29052 at 29055), when wear debris produced by an orthopedic implant was injected into rats, tumorigenesis was observed among a significant proportion of the rats. Further, the fact that little data exists supports the concept that the increased level of control provided by classification into class II or class III is necessary. The fact that little in vitro wear and strength data exists certainly does not support classifying devices intended to be implanted into class I. Thus, FDA believes that it is necessary to classify joint prostheses into class II or class III in order to ensure that the level of wear debris produced by an orthopedic joint prosthesis is kept to a minimum by requiring in vitro wear and strength measurements of the devices before they are implanted. FDA believes that sufficient information exists for manufacturers to develop standard methods for in vitro measurements of wear or strength of joint prostheses and of materials intended for use in these devices. Further, FDA believes that the results of such comparative measurements of wear or measurements of other critical device attributes using standard test methods should be included in the labeling of the devices to assist the physician in selecting an appropriate device for a patient.

2g. Comments noted that FDA did not include in the proposed regulations the acceptance criteria for materials intended for use in components of devices intended to be implanted and did not identify which of the materials used in such devices the agency believed resulted in a lack of biocompatibility. For these reasons, comments suggested that many devices intended to be implanted be classified into class I.

FDA disagrees with the comments. FDA believes that it was unnecessary to include in the proposed classification regulations specific criteria for acceptance of materials intended for use in devices intended to be implanted or to identify specific materials used in such devices thar may not be biocompatible. The appropriate time to identify the materials to be used in these devices and to establish acceptance criteria for these materials is when FDA establishes performance standards for the devices or when manufacturers prepare applications for premarket approval of the devices. Certainly, the absence of this information does not support classifying these devices into class I, as these devices are intended to be implanted to fix living bone or replace a joint, uses which are of substantial importance in preventing impairment of human health. Moreover, section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) requires that FDA classify all implants into class III unless the agency determines that, for a particular implant, premarket approval is unnecessary to provide reasonable assurance of its safety and effectiveness. FDA believes that orthopedic devices intended to be implanted have not been implanted in a sufficient number of patients by a sufficient number of medical practitioners to provide adequate evidence on the long-term biocompatibility of these devices to permit these devices to be classified into class I. Consequently, FDA believes that insufficient evidence of safety and effectiveness is available at this time to support classifying any orthopedic device intended to be implanted into class I. The considerations discussed in this paragraph are also relevant to the comments described below in paragraphs 10, 14, 16, 17, 20, 22, 23, 26, 27, 29, 32, 35, 36, 37, 38, and 39.

3. One comment complained that public involvement in the classification of orthopedic devices was limited and that, as a result, FDA proposed to classify too many orthopedic devices in class II or class III.

FDA disagrees with the comment. During its classification deliberations, the Panel held public meetings and provided the public numerous opportunities to make presentations and submit data. Additionally, when FDA published its proposed rule classifying orthopedic devices, the agency provided 180 days for interested persons to comment on the proposed rule and included in the proposed rule a list of

500 references supporting its proposed classifications.

4. Comments said that mandatory performance standards are unnecessary for the orthopedic devices that FDA proposed to classify into class II that are subject to voluntary standards, arguing that the voluntary standards are adequate to control the documented risks.

FDA disagrees with the comments. Section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)) requires that performance standards be established under section 514 of the act (21 U.S.C. 360d) for each device classified into class II. In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a final policy statement regarding class II devices in which it identified the factors the agency will take into account in setting priorities for initiating proceedings to establish performance standards under section 514 of the act. See "B. FDA's Priorities for Establishing Performance Standards" at the beginning of this preamble. Among the factors FDA will consider is the existence of an adequate, adhered to voluntary standard. In the notice of October 23, 1985 (50 FR 43065) FDA stated "[u]nder the final policy, FDA will not conclude that an adequate, adhered to voluntary standard makes a performance standard under section 514 of the act unnecessary for a class II device. FDA does not believe nor does the legislative history suggest, however, that Congress intended that FDA could not consider the existence of adequate adhered to, voluntary standards in setting priorities for the initiation of proceedings under section 514 of the act."

5. Comments recommended that the labeling for joint prostheses devices intended to be implanted should be improved by including in the package insert the kinematic description of the device. The comments also recommended that a kinematic description of the device be included in the codified identification of the device.

FDA agrees that the labeling of a joint prosthesis device intended to be implanted should contain the kinematic description of the device. FDA also agrees that the classification regulation for each such device should be clarified by including a general kinematic description of the device. In the preamble to the proposed rule, FDA defined several terms used in the proposed names or identifications of joint prostheses devices intended to be implanted. To clarify further the names of such devices and their identifications, FDA is codifying certain definitions, § 888.5 *Resurfacing technique*, and § 888.6 *Degree of constraint*. One of the terms defined, i.e., degree of constraint, is a general kinematic description of the device.

6. Comments noted that the proposed names of many, but not all, prosthetic devices included information regarding: (a) The general kinds of materials used in the construction of the device (e.g., "metallic" or "polymer"), and (b) whether or not bone cement (§ 888.3027) is to be used during implantation of the device (e.g., use in the name and identification of the device of the term "cemented" or "uncemented"). The comments suggested that, for the sake of consistency, the names of all prosthetic devices should include this information.

FDA agrees with the comments that the names of the devices should be clarified. For the sake of consistency, therefore, in the final rule FDA is including in the name of each prosthetic device intended to be implanted information regarding the general kinds of materials used in the construction of the device and, where appropriate, whether or not bone cement (§ 888.3027) is intended to be used to implant the device.

7. One comment said that where the only risk to health cited by the Panel concerning a device was electrical shock or leakage current, FDA should classify the device into class I.

FDA tentatively agrees with the comment. FDA believes that two electrically powered orthopedic devices present only the risk of electrical shock or leakage current: AC-powered goniometer (§ 888.1500) and AC-powered cast removal instrument (§ 888.5960). Accordingly, FDA is postponing classification of these two devices pending review of additional data regarding electrical safety of devices. See the discussion under "D. Devices Not Being Classified at This Time" located earlier in this preamble.

8. Section 888.1100; Arthroscope; proposed class II.

a. Comments on the proposed regulation classifying this device argued that the device should be classified into class I instead of class II as proposed, because performance standards are not necessary to control the risks of electrical shock or leakage current presented by this device.

The agency tentatively agrees that AC-powered devices that present only the risk of electrical shock or leakage current should be considered for classification into class I. However, the arthroscope presents risks to health in addition to the risks of electrical shock and leakage current, i.e., the risks of infection and tissue trauma. The agency believes that establishment of a performance standard for this device is necessary to control these risks.

b. One comment on the proposed regulation classifying the arthroscope argued that the device should be classified into class I because it has a record of safe use. The comment submitted published reports (Studies 1 through 18) showing results of clinical experience with the device.

FDA concludes that the studies provided by the comments contain insufficient data on long-term followup for FDA to evaluate fully the safety and effectiveness of the arthroscope. As noted above, the device presents risks to health of infection and tissue trauma, risks which general controls alone would be insufficient to control. A performance standard would control the design, optical characteristics, size, shape, rigidity/flexibility, surface finish, materials used, and construction of the device to assure that it is capable of being sterilized properly and that it has sufficient strength to prevent tissue trauma from breakage of the device when it is inserted into a patient's joint. Accordingly, the agency believes that establishment of a performance standard for this device is necessary.

c. One comment urging the agency to classify this device into class I said that the labeling requirements of class I are sufficient to ensure proper use of the device by surgeons.

FDA agrees that adequate directions for use in the labeling of the device would generally ensure that the device is used properly by surgeons. However, the device is required to comply with the labeling requirements of class I, whether the device is classified into class I, class II, or class III. (See discussion at "N. Economic Impact.") FDA disagrees that adequate labeling would ensure that the device performs properly. Therefore, for the reasons provided in paragraph 8b above, FDA believes that establishment of a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device, and that sufficient information is available to establish such a standard. Accordingly, in this final rule FDA is adopting the proposed regulation classifying the arthroscope into class II with minor clarifying changes.

9. Comments on the proposed regulations classifying the devices listed below argued that these devices should be classified into class I instead of class II or class III as proposed because the risks to health cited in the proposed regulations either were not identified by the Panel or are not supported by the cited literature.

Section and Device

888.1100—Arthroscope
888.3010—Bone fixation cerclage
888.3020—Intramedullary fixation rod
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
888.3530—Knee joint femorotibial metal/polymer semi-constrained prosthesis
888.3540—Knee joint patellofemoral polymer/metal semi-constrained prosthesis
888.3560—Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis

FDA disagrees with the comments. FDA has re-reviewed the supplemental data sheets on which the Panel recorded information concerning the classification of the devices named above and the transcript of the Panel meeting during which classification of these devices was discussed. The risks to health that were listed in the proposed regulations accurately reflect the risks to health identified by the Panel for these devices. In addition, as stated in the proposed regulations, clinical experience and judgment also qualify as valid scientific evidence to support classification of a device. Thus, while many of the risks to health identified in the proposed regulations are, in fact, supported by the cited literature, it is unnecessary that every risk to health cited by the Panel be supported by the medical literature. Accordingly, FDA is adopting the proposed regulations classifying the devices listed above into class II or class III as proposed because performance standards or requirements of premarket approval are necessary to control the risks to health presented by these devices that were identified in the proposed regulations.

10. Section 888.3000; Bone cap; proposed class II.

Comments requested that this device be classified into class I instead of class II as proposed. The comments cited three published reports of preclinical and clinical experience with the device to support their requests (Studies 19, 20, and 21).

FDA disagrees with the comments. One of the studies (Study 19) reports on the use of the device in surgical procedures involving dogs. The other two studies (Studies 20 and 21) describe experimental use of the device and surgical technique for its implantation at one clinic. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the bone cap. FDA still believes that the device should be classified into class II because a performance standard is necessary to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish, in order to prevent loss or reduction of limb function, adverse tissue reaction, or infection. FDA believes that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such a standard. Accordingly, FDA is adopting the proposed regulation classifying the bone cap into class II with minor clarifying changes.

11. Section 888.3050; Spinal interlaminal fixation orthosis; proposed class II.

a. Comments requested that this device be classified into class I instead of class II as proposed. In support of the request, the comments cited one published study that they claimed showed a low incidence of infections following implantation of the device (Study 22), and two published studies that they claimed showed a low incidence of adverse tissue reactions or fracture of a component of the device (Studies 23 and 24). The comments argued that all of the complications resulting from use of the device are related to surgical technique, and not to the safety and effectiveness of the device itself.

FDA disagrees with the comments. FDA disagrees that the studies cited by the comments support classifying this device in class I. One of the studies involved implantation of a different type of device in a part of the body other than the spine. In another study, the rate of adverse results could not be determined because the total numbers of patients and implanted devices were unknown. In the remaining study, the authors determined that the device components that fractured showed characteristics of fatigue fracture. FDA believes that performance standards are necessary to control the risks to health listed in the proposed regulation, i.e., adverse tissue reaction, infection, and paralysis. As with all surgically implanted devices, the surgical risks attendant upon implantation of the device must be considered along with the risks presented by the device itself in determining the total risks to health from the intended uses of the device.

b. One comment on the proposed regulation classifying the spinal interlaminal fixation orthosis into class II objected that the proposed regulation did not identify what specific material in the device might cause an adverse tissue reaction or infection, two of the risks to health identified by the Panel.

FDA agrees that it did not identify a specific material used in the device that may cause an adverse tissue reaction or infection. However, the proposed regulations do contain information on the risks of adverse tissue reaction or infection that may be caused by orthopedic implants in general (47 FR 29054).

Therefore, for the reasons stated in the preamble to the proposed rule, FDA believes that the spinal interlaminal fixation orthosis should be classified into class II and that sufficient information exists to establish performance standards for the device, including the telemetered data on stress forces placed on the device (Study 25) and studies concerning stress analysis of the rod component of the device (Study 26). FDA believes that establishing performance standards for the device will provide reasonable assurance of its safety and effectiveness. Accordingly, FDA is adopting the proposed regulation classifying the spinal interlaminal fixation orthosis into class II with minor clarifying changes.

12. Section 888.3060; Spinal intervertebral body fixation orthosis; proposed class II.

a. One comment urged FDA to classify this device into class I instead of class II as proposed, citing a published study that the comment claimed showed a low incidence of infections following implantation of the device (Study 22).

FDA disagrees with the comment. The data in Study 22 cannot be used to evaluate the safety and effectiveness of the spinal intervertebral body fixation orthosis. The spinal intervertebral body fixation orthosis is implanted as treatment for "sway back," scoliosis (lateral curvature of the spine), or other conditions. Study 22 describes clinical treatment of deep wound infections following total hip arthroplasty. Study 22, therefore, involves implantation of a different device in a part of the body other than the spine.

b. One comment indicated that the major risk to health from use of this device is failed fusion of the vertebrae following implantation of the device. The comment argued that, because this problem is caused by improper surgical technique, establishing performance standards for the device would not reduce the incidence of failed fusion and, therefore, that the device should be classified into class I instead of class II as proposed.

FDA disagrees with the comment. Although performance standards may not reduce the risk of failed fusion, they would reduce the risks of adverse tissue reaction, infection, and paralysis by controlling the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in the final rule FDA is adopting the proposed regulation classifying the spinal intervertebral body fixation orthosis into class II with minor clarifying changes.

13. FDA received comments suggesting that, to simplify the regulations, the three devices listed below should be combined into one generic type of device, identified as the single/multiple component metallic bone fixation appliances and accessories: Bone fixation cerclage (§ 888.3010), intramedullary fixation rod (§ 888.3020), and smooth or threaded bone fixation fastener (§ 888.3040).

FDA disagrees with the comments. Each of the devices listed above has different indications for use, has different functions, or presents different risks to health. Accordingly, FDA is adopting the proposed regulations on the devices listed above, with minor clarifying changes.

14. Section 888.3100; Ankle joint metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 27 through 33) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3110) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the ankle joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined 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. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device. However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the ankle joint metal/composite semi-constrained prosthesis. In addition, FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the ankle joint metal/composite semi-constrained prosthesis into class II, with minor clarifying changes.

15. Section 888.3150; Elbow joint constrained prosthesis; proposed class III.

a. A comment agreed that class III is appropriate for the elbow joint constrained prosthesis because the device has an unacceptably high failure rate due to the interaction between the two implanted metallic parts.

FDA agrees with the comment and is classifying the elbow joint constrained prosthesis into class III as proposed.

b. A comment noted that the identification of this device excluded the ultra-high molecular weight polyethylene (UHMWPE) component often used as a bushing or liner between the metallic humeral and ulnar components of the device.

FDA agrees with the comment. FDA's proposed identification of the device inadvertently failed to include the UHMWPE bushing that often is used in the elbow joint constrained prosthesis. FDA is modifying the identification of the device in the final rule to include this component.

c. A comment noted that, while the original versions of the elbow joint constrained metallic rigid hinge device had unacceptably high failure rates, many of the original devices either are no longer marketed or have been modified to provide less rigid restraint, thereby reducing the incidence of device loosening. These later, modified versions of the device consist of constrained, loose hinge, elbow joint prostheses with an UHMWPE bushing. The comment submitted six published studies (Studies 34 through 39) that it claimed show that five more recent, modified versions of the device (Volz, Tri-Axial, Mayo, Pritchard-Walker, and Coonrad) are safe and effective and should be classified into class II instead of class III as proposed.

FDA has reviewed the studies supplied by the comment and has concluded that they do not show that the more recent loose hinge versions of the elbow joint constrained prosthesis with or without a UHMWPE bushing have a significantly reduced overall rate of loosening compared to the earlier rigid hinge versions of this device. Also, as stated in the proposed regulation, the biomechanics of the elbow joint are not well understood (Refs. 144 and 145) and the amount of varus-valgus laxity in elbow joint constrained devices necessary to reduce the rate of loosening is currently unknown. FDA believes that premarket approval is necessary to ensure the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the elbow joint constrained prosthesis into class III with minor clarifying changes.

16. Section 888.3170; Elbow joint radial (hemi-elbow) prosthesis; proposed class II.

Comments on the elbow joint radial (hemi-elbow) prosthesis requested that the device be in class I rather than class II as proposed. To support the request, the comments submitted three studies (Studies 40, 51, and 52). In these studies, the practitioners implanting the device reported that the results were predictable and satisfactory, that the risks to health identified in the proposed regulation (loss or reduction of joint function, adverse tissue reaction, and infection) were essentially nonexistent, or occurred at low frequency rates, and thus these risks were not unreasonable risks requiring controls of regulatory performance standards.

FDA disagrees with the comments. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the elbow joint radial (hemi-elbow) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed

to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the elbow joint radial (hemi-elbow) prosthesis into class II with minor clarifying changes.

17. Section 888.3230; Finger joint polymer constrained prosthesis; proposed class II.

a. Comments suggested that this proposed generic type of device be split into three generic types: (1) Finger joint plastic/elastomer constrained uncemented prosthesis, (2) finger joint elastomer/polyester fiber composite constrained porous ingrowth prosthesis, and (3) finger joint elastomer constrained uncemented prosthesis. The comments said that FDA had proposed to group dissimilar devices into one generic type of device.

FDA disagrees with the comments. FDA recognizes that this proposed generic type of device includes devices of various designs, materials, and fixation techniques. Despite these variations, however, the devices encompassed within the proposed generic type of device do not differ significantly in purpose, design, materials, or function, or any other feature relating to safety or effectiveness (see the definition of generic type of device in 21 CFR 860.3(i)). FDA believes that the same regulatory controls are required to provide reasonable assurance of the safety and effectiveness of all the devices encompassed within this proposed generic type of device.

b. Some comments requested that the finger joint polymer constrained prosthesis be classified into class II instead of class II as proposed. These comments submitted eight published studies (Studies 42 through 49) and a letter from a medical practitioner to support their requests.

FDA disagrees with the comments. FDA's review of the additional data submitted by the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the finger joint polymer constrained prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish.

c. One comment suggested that the device be classified in class III instead of class II as proposed, claiming that a high percentage of complications occur from use of the device. No additional data on complication rates were provided by the comment.

FDA disagrees with the comment. FDA has no knowledge of a high complication rate from use of the device. Although the finger joint polymer constrained prosthesis is an implanted device, FDA has determined that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. In addition, FDA had identified and assessed the major risks to health associated with the use of this device. 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 the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA further believes that informative labeling and compliance with general controls may greatly reduce the risks to health associated with the use of this device. The agency believes that a performance standard is necessary because general controls alone are insufficient to minimize the risks to health presented by the device. Accordingly, FDA is adopting the proposed regulation classifying the finger joint polymer constrained prosthesis into class II with minor clarifying changes.

18. Section 888.3300; Hip joint metal constrained prosthesis; proposed class III.

A comment stated that the proposed name of this device and its proposed identification are inconsistent with respect to the materials used in the device.

FDA agrees with the comment. Accordingly, fn the final rule, FDA has revised the identification of the device to remove reference to a polyethylene component.

19. Section 888.3310; Hip joint metal/polymer constrained prosthesis; proposed class III.

A comment argued that this device should not be classified because it is no longer commercially distributed.

FDA agrees that the device is not currently commercially distributed. This device was commercially distributed before the enactment date of the amendments. Accordingly, in the final rule FDA is adopting the proposed regulation classifying the hip joint metal/polymer constrained prosthesis into class III with minor clarifying changes.

20. Section 888.3340; Hip joint metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 33 and 53 through 57) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3350) that FDA proposed to classify in class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the hip joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined 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. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA also believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint metal/

composite semi-constrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the hip joint metal/composite semi-constrained prosthesis into class II with minor clarifying changes.

21. Section 888.3360; Hip joint femoral (hemi-hip) metallic prosthesis; proposed class II—Section 888.3400; Hip joint femoral (hemi-hip) resurfacing prosthesis; proposed class II.

Comments requested that these devices be classified into class I instead of class II as proposed. The comments argued that the mechanical properties of the devices, such as their strength and the resistance to wear of the materials used in them, should not be used as a basis for classifying the devices into class II.

FDA disagrees with the comments. FDA believes that the mechanical properties of the materials intended for use in implanted joint prostheses are important criteria to be considered in determining whether performance standards are necessary to ensure the safety and effectiveness of the devices. For example, if a material used to construct a joint prosthesis lacked strength or resistance to wear, particles of the material could break or wear off of the contact surfaces of the joint prosthesis within the patient's joint and cause pain and inflammation. Further, as shown by the data summarized in the proposal (Ref. 7; 47 FR 29052 at 29055), when wear debris produced by an orthopedic implant was injected into rats, tumorigenesis was observed among a significant proportion of the rats. FDA believes that sufficient information exists to develop standard methods for measuring strength and resistance to wear of joint prostheses and the materials intended for use in such devices. FDA believes that results of comparative, standardized in vitro measurements of wear or other critical device parameters should be included in the labeling of joint prostheses to assist the user in selecting an appropriate device for a patient. See also paragraphs 2f and 2g earlier in this preamble. FDA believes that the general controls of class I are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) metallic prosthesis and the hip joint femoral (hemi-hip) resurfacing prosthesis. FDA believes that performance standards are necessary to control the risks to health presented by these two devices and that sufficient information is available to develop performance standards that would provide reasonable assurance of their safety and effectiveness. Accordingly, FDA is adopting the proposed regulations classifying the two devices above into class II with minor clarifying changes.

22. Section 888.3360; Hip joint femoral (hemi-hip) metallic prosthesis; proposed class II.

A comment argued that the literature cited in the proposed rule contained no evidence that the design of the device contributed to its failure and, therefore, suggested that the device be in class I.

FDA disagrees with the comment. As discussed in paragraph 2d above, FDA's proposed classifications are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited literature. It is unnecessary, therefore, that all risks to health presented by a device be described in the medical literature. Moreover, Ref. 236, cited in the proposed rule, contains data showing that faulty design of the stem of the device did, indeed, contribute to its failure. Also, a comparative study of various designs of the device showed that different stem designs resulted in variations in yield strength (Study 58). FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) metallic prosthesis.

FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the hip joint femoral (hemi-hip) metallic prosthesis into class II with minor clarifying changes.

23. Section 888.3400; Hip joint femoral (hemi-hip) resurfacing prosthesis; proposed class II.

A comment argued that this device should be classified into class I because there is no evidence showing that failure of the device due to lack of strength is related to improper design of the device.

FDA disagrees with the comment. As discussed in paragraph 2d above, FDA's proposed classifications are based as much on the Panel members' personal knowledge of, and clinical experience with, the devices as on the data in the cited literature. It is unnecessary, therefore, that every reason why a device may fail be documented in the medical literature. FDA believes that the device presents the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the hip joint femoral (hemi-hip) resurfacing prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the hip joint femoral (hemi-hip) resurfacing prosthesis into class II with minor clarifying changes.

24. Section 888.3410; Hip joint metal/polymer semi-constrained resurfacing prosthesis; proposed class III.

Comments recommended that FDA classify this device into class II instead of class III as proposed, arguing that one of the risks to health identified in the proposed regulation, adverse tissue reaction, is only a hypothetical risk that has not been documented. The comments submitted additional data to support the request (Studies 59 through 61).

FDA disagrees with the comments. The references cited in the proposed rule (Refs. 9, 89, 241, 242, 243, 299, 341, 342, and 345 through 359) do, in fact, discuss adverse tissue reactions resulting from implantation of this device. In addition, the data supplied in the comments. show that the device continues to present the other risks to health described in the proposed regulation, i.e., loss or reduction of joint function and infection. FDA believes that there is insufficient information from which to conclude that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of this device. FDA believes that premarket approval is necessary to provide such assurance. Accordingly, FDA is adopting the proposed regulation classifying the hip joint metal/polymer semi-constrained resurfacing prosthesis

into class III with minor clarifying changes.

25. Section 888.3480; Knee joint femorotibial metallic constrained prosthesis; proposed class II—Section 888.3550; Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis; proposed class II.

Comments suggested that these devices be classified into class III instead of class II as proposed, because the literature FDA cited in the proposed regulation shows that a large volume of metallic particles are generated within the joint after implantation due to metal-to-metal contact between articulating components of the devices. The comments said that these metallic particles cause adverse effects in patients. Some of the comments noted that FDA proposed to classify into class III several other prostheses that had similar metal-to-metal articulation.

FDA agrees with the comments. Because of their design, these devices present a potential unreasonable risk of illness or injury. In addition, the devices are purported or represented to be for a use (implantation to replace a major joint) that is of substantial importance in preventing impairment of human health. Furthermore, the agency has determined that premarket approval is necessary for the devices because general controls and performance standards are insufficient to provide reasonable assurance of their safety and effectiveness. FDA also believes that there is insufficient information to establish a standard to provide such assurance. Accordingly, in this final rule, FDA is classifying both the knee joint femorotibial metallic constrained prosthesis and the knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis into class III with minor clarifying changes.

26. Section 888.3490; Knee joint femorotibial metal/composite non-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed, and submitted published and unpublished additional data (Studies 33, 53, and 62 through 65) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees that the device should be classified into class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3520) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the knee joint metal/composite non-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of its safety and effectiveness. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint femorotibial metal/composite nonconstrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, in this final rule FDA is classifying the knee joint femorotibial metal/composite nonconstrained prosthesis into class II, with minor clarifying changes in the regulation.

27. Section 888.3500; Knee joint femorotibial metal/composite semi-constrained prosthesis; proposed class III.

Comments recommended that this device be classified into class I instead of class III as proposed and submitted published and unpublished additional data (Studies 53, 62, 63, 66, and 67) to support their recommendations. The polymer component of this device consists of ultra high molecular weight polyethylene (UHMWPE) with carbon fibers composite.

FDA disagrees with the recommendations of the comments that the device be classified in class I. However, FDA no longer believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Based on the evidence now available, FDA believes that the clinical performance and mechanical properties of the device are comparable to a similar device (§ 888.3530) that FDA proposed to classify into class II in which the polymer component consists of UHMWPE without the carbon fibers composite. Although the knee joint metal/composite semi-constrained prosthesis is intended to be implanted, FDA has determined that premarket approval is not necessary because sufficient information exists to establish performance standards that will provide reasonable assurance of its safety and effectiveness. Clinical experience with the device has established the persons for whose use the device is intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of the device outweighs any likelihood of injury or illness resulting from its use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the device.

However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint femorotibial metal/composite semi-constrained prosthesis. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is classifying the knee joint femorotibial metal/composite semi-constrained prosthesis into class II, with minor clarifying changes in the regulation.

28. Section 888.3540; Knee joint patellofemoral polymer/metal semi-constrained prosthesis; proposed class III.

Comments requested that this device be classified into class I instead of class III as proposed, arguing that the risks to health identified in the proposed rule classifying this device, i.e., loss or reduction of joint function, adverse tissue reaction, and infection, occur very infrequently. The comments submitted a published study supporting their request (Study 68).

FDA disagrees with the comments. FDA believes that the data provided by the comments (Study 68), particularly the failure rate of the device as reflected by the number of revisions performed, show that insufficient information exists to determine that the general controls of class I or the establishment of performance standards would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the knee joint patellofemoral

polymer/metal semi-constrained prosthesis into class III with minor clarifying changes.

29. Section 888.3560; Knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis; proposed class II.

Comments requested that this device be classified into class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation classifying this device, i.e., loss or reduction of joint or limb function, adverse tissue reaction, and infection, occur very infrequently. The comments submitted six studies in support of their requests (Studies 63 and 69 through 73).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the knee joint patellofemorotibial polymer/metal/polymer semi-constrained prosthesis into class II with minor clarifying changes.

30. Section 888.3580; Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis; proposed class II.

a. One comment recommended that this device be classified into class III instead of class II as proposed, arguing that the device has metal to metal articulation which generates harmful metallic particles within the joint after implantation.

FDA disagrees with the comment. The device does not have metal to metal articulation, but rather is intended to articulate with intact hyaline cartilage within the femoral sulcus (groove). It is unlikely, therefore, that metallic wear debris would be generated and increase the failure rate of the device.

b. A comment recommended that the identification of this device not limit its use to treatment of degenerative and posttraumatic patellar (osteo) arthritis. The comment also suggested that FDA classify the device into class II for all intended uses, but did not furnish any additional data.

FDA disagrees with the comment. FDA proposed to classify the device into class II, when intended for treatment of degenerative and posttraumatic patellar arthritis, based on the recommendation of the Panel and FDA's review of the literature cited and summarized in the proposed rule. By limiting the proposed class II intended uses of the device to treatment of degenerative and posttraumatic patellar arthritis, FDA effectively proposed to classify the device into class III, when intended for other uses. FDA still believes that when intended for uses other than the treatment of degenerative and posttraumatic patellar arthritis, the device should be classified into class III, because there is no valid scientific evidence supporting its safety and effectiveness for such uses and section 513 of the act requires that FDA classify the device into class III when no data exists for the intended uses of the device.

Accordingly, for the reasons provided in the proposed rule, FDA is classifying the knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis into class II when intended for treatment of degenerative and posttraumatic patellar arthritis, and into class III when intended for other uses. FDA also is making clarifying changes in the codified language for the device.

31. Section 888.3640; Shoulder joint constrained prosthesis; proposed class III.

a. Comments recommended that this device be classified into class I instead of class III as proposed, arguing that the device has a high level of success and that the references FDA cited in the proposed regulation show that the device is safe and effective with only minimal complications.

FDA disagrees with the comments. The information reviewed by the Panel and summarized by FDA in the proposed regulation consisted of published data concerning implantation of the device in about 35 patients. The data reviewed by the Panel and FDA showed that 8 of the 35 patients (about 23 percent) did not achieve successful results. FDA also summarized in the proposed regulation 4 additional published studies (Refs. 447 through 450; 47 FR 29106) concerning this device in which a significant percentage of patients had adverse experiences following implantation of the device. FDA disagrees, therefore, that the references FDA cited in the proposed regulation for the shoulder joint constrained prosthesis show that the device is safe and effective with only minimal complications.

b. Comments requesting that the device be classified into class I instead of class III as proposed also argued that the device loosenings and fractures that were reported in oral presentations at the Panel meetings held in March and October of 1981 were not device-related, but rather were due to unusual stress placed on the device by the patient, such as that occurring as a result of falls, accidents, or fights.

FDA disagrees with the comments. Although one investigator at the Panel meeting did report that device loosening and fractures were associated with unusual stress, other investigators at that meeting reported loosening of the device in cases where unusual stress had not occurred. The evidence consisted of "loosening lines" at the juncture of the device and bone, shown by radiographic examination of the implanted device. Because of limited data available on both use of the device and followup of patients following its implantation, the Panel recommended that the device be classified into class III.

For the reasons provided in the proposed rule, FDA believes that the shoulder joint contrained prosthesis presents an unreasonable risk of illness or injury. FDA believes that insufficient information exists to support the conclusion that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint constrained prosthesis into class III with minor clarifying changes.

32. Section 888.3650; Shoulder joint metal/polymer non-constrained prosthesis; proposed class III.

Comments requested that FDA classify this device into class I or class II instead of class III as proposed, arguing that no adverse effects from implanting the device were described in the proposed regulation. The comments submitted additional data to support their requests (Studies 74 and 75).

FDA disagrees with the comments. In the proposed regulation, FDA cited available literature on the device (47 FR 29106; Refs. 451 and 452) and identified several adverse effects following implantation of the device in a small number of patients, such as infection and dislocation requiring reoperation. Moreover, as the author of Study 74 concluded, the 3-year followup period of patients involved in that study was

insufficient to assess either wear or loosening of the components of the device. Study 75 does not distinguish the results obtained from implanting the shoulder joint metal/polymer non-constrained prosthesis from those obtained from implanting other generic types of shoulder joint prostheses. As a result, the data in Study 75 cannot be used to assess the safety and effectiveness of the shoulder joint metal/polymer non-constrained prosthesis. Accordingly, FDA believes that the data submitted by the comments and other data considered by FDA are insufficient to support classification of the shoulder joint metal/polymer non-constrained prosthesis into class I or class II. FDA believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint metal/polymer non-constrained prosthesis into class III with minor clarifying changes.

33. Section 888.3660; Shoulder joint semi-constrained prosthesis; proposed class III.

a. Comments requested that FDA classify this device into class I or class II instead of class III as proposed, arguing that the reference that FDA cited in the proposed regulation (Ref. 453) did not identify infection and lack of biocompatibility as risks to health presented by the device.

FDA disagrees with the comments. Ref. 453, which contains the results of the only study available on this device, shows that, of the 28 patients in whom the device was implanted, one patient developed an infection and the device dislocated in two patients. FDA believes that the data from this one study is insufficient evidence upon which to conclude that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of the device. FDA believes that premarket approval is necessary to provide such assurance. Further, as stated earlier in this preamble, FDA bases its classification decisions as much on the Panel members' experience and expert judgments as on the information in the medical literature. It is not necessary, therefore, that all risks to health presented by a device be described in the literature in order for FDA to classify the device into class III.

b. A comment noted that FDA incorrectly stated in the proposed rule that the Panel recommended that the labeling of the device include information on the dimensions, kinematics, and the strength and wear characteristics of the device.

FDA agrees that the Panel did not make the recommendation described above for this device, although FDA inadvertently stated that it did. This error, however, had no effect on the agency's decision to propose that the device be classified into class III or to recommend that the labeling of the device include information on the dimensions, kinematics, and strength and wear characteristics of the device. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint semi-constrained prosthesis into class III with minor clarifying changes.

34. Section 888.3680; Shoulder joint glenoid (hemi-shoulder) prosthesis; proposed class III.

a. Comments said that FDA's proposed identification of this device was incorrect in limiting the device to components made only of alloys. The comments suggested that the identification be changed to include ultra-high molecular weight polyethylene (UHMWPE) in addition to alloys, arguing that the device made of alloys with UHMWPE is as safe and effective as the device made only with alloys.

FDA agrees with the comments. FDA agrees that, when made of alloys with UHMWPE, the device is as safe and effective as it is when made of alloys alone. In the final rule, therefore, FDA is changing the identification of the device to state that the device may be composed of UHMWPE with alloys.

b. Comments recommended that FDA classify this device into class I instead of class III as proposed, arguing that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the comments. Because the device is intended to be implanted in the human body, the act requires that it be classified into class III unless FDA determines that premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness. On the basis of the information currently available, FDA cannot make this determination for this device. Insufficient information exists to support the conclusion that general controls or performance standards would provide reasonable assurance of the safety and effectiveness of this device. FDA believes that premarket approval is necessary to provide such assurance. Accordingly, FDA is adopting the proposed regulation classifying the shoulder joint glenoid (hemi-shoulder) prosthesis into class III with clarifying changes in the identification of the device.

35. Section 888.3720; Toe joint constrained uncemented prosthesis; proposed class II.

a. Comments suggested that this proposed generic type of device be split into the following three generic types of devices: toe joint elastomer unconstrained uncemented prosthesis, toe joint elastomer/polyester fiber composite constrained porous ingrowth prosthesis, and toe joint polymer/elastomer constrained uncemented prosthesis.

FDA disagrees with the comments. FDA recognizes that the proposed generic type of device encompasses devices of various designs, materials, and fixation techniques. However, despite these variations, devices subject to the regulation do not differ significantly in purpose, design, materials, function, or any other feature relating to safety or effectiveness (see the definition of generic type of device in 21 CFR 860.3(i)). In addition, FDA believes that the same regulatory controls are required to provide reasonable assurance of the safety and effectiveness of all the devices encompassed within the proposed generic type of device.

b. Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health of adverse tissue reaction and infection occur very infrequently. These comments provided additional data to support their requests (Studies 76 through 79).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of intection, and also the long-term potential for infection from an implant. FDA believes that the general controls of Class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the toe joint constrained uncemented prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material

composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the toe joint constrained uncemented prosthesis into class II with minor clarifying changes.

36. Section 888.3730; Toe joint phalangeal (hemi-toe) prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health of adverse tissue reaction and infection occur very infrequently. These comments submitted additional data to support their requests (Studies 77 and 80).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the toe joint phalangeal (hemi-toe) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the toe joint phalangeal prosthesis into class II with minor clarifying changes.

37. Section 888.3770; Wrist joint carpal trapezium prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health cited in the proposed rule occur very infrequently. These comments provided additional data to support their requests (Study 81). One of the studies submitted by the comments (Study 82), was summarized by FDA in the proposal and identified as Ref. 486 (47 FR 29052 at 29113).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint carpal trapezium prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint carpal trapezium prosthesis into class II with minor clarifying changes.

38. Section 888.3780; Wrist joint polymer constrained uncemented prosthesis; proposed class II.

Comments requested that FDA classify this device into class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation occur very infrequently. The comments provided additional data to support their requests (Studies 83 through 85).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint polymer constrained uncemented prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint polymer constrained uncemented prosthesis into class II with minor clarifying changes.

39. Section 888.3810; Wrist joint ulnar (hemi-wrist) prosthesis; proposed class II.

Comments requested that FDA classify this device in class I instead of class II as proposed, arguing that the risks to health identified in the proposed regulation occur very infrequently. The comments provided additional data to support their requests (Studies 87 and 88). One of the studies submitted by the comments (Study 86), was summarized by FDA in the proposal and identified as Ref. 500 (47 FR 29052 at 29117).

FDA disagrees with the comments. FDA's review of the additional data submitted in the comments reveals that the device continues to present the risks to health described in the proposed regulation, i.e., loss or reduction of joint function, adverse tissue reaction, and infection. As discussed earlier in this preamble in paragraphs 1 and 2 and in the preamble to the proposed rule, the risk of infection concerns short-term frequency of occurrences of infection, and also the long-term potential for infection from an implant. FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the wrist joint ulnar (hemi-wrist) prosthesis. FDA believes that performance standards are necessary to provide reasonable assurance of the safety and effectiveness of the device, and that sufficient evidence is available to establish such standards. FDA believes that a performance standard is needed to control the design, material composition, and mechanical properties of the device, such as its flexibility, rigidity, strength, and surface finish. Accordingly, FDA is adopting the proposed regulation classifying the wrist joint ulnar (hemi-wrist) prosthesis into class II with minor clarifying changes.

H. Exemptions for Class I Orthopedic Devices

Exemptions From Current Good Manufacturing Practices (CGMP) Requirements

Although FDA proposed to grant exemptions from most CGMP requirements for the nonpowered dynamometer (§ 888.1250) and the nonpowered goniometer (§ 888.1520), in this final rule FDA is classifying each of the two devices into class I without such

an exemption. FDA now believes that in order to control the risks to health that may result from incorrect measurement of a patient's muscle strength (§ 888.1250) or incorrect measurement of the range of motion of a patient's joints (§ 888.1520) due to device defects caused by inadequate manufacturing practices, each of the devices should be subject to all of the requirements of the CGMP regulations for noncritical devices.

Exemptions From Requirement of Premarket Notification

FDA proposed to exempt eight class I orthopedic devices from the requirement of premarket notification. In this final rule, FDA is exempting the eight devices from the premarket notification procedures; however, the exemption for the orthopedic manual surgical instrument (§ 888.4540) is limited and will apply only to those devices made of the same materials that were used in the device before May 28, 1976.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule proposing to exempt from the requirement of premarket notification, or exempt with limitations, seven orthopedic devices being classified into class I in this final rule.

I. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel name and Publication Date in "Federal Register"

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

Clinical Chemistry and Clinical Toxicology Devices Panel—February 2, 1982, 47 FR 4802–4929 (proposals)

Hematology and Pathology Devices Panel—September 11, 1979, 44 FR 53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations)

General Hospital and Personal Use Devices Panel—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations)

Gastroenterology-Urology Devices Panel—January 23, 1981, 46 FR 7562–7641 (proposals); November 23, 1983, 48 FR 53012–53029 (final regulations)

Immunology Devices Panel—April 22, 1980, 45 FR 27204–27359 (proposals); November 9, 1982, 47 FR 50814–50840 (final regulations)

Microbiology Devices Panel—April 22, 1980, 45 FR 27204–27359 (proposals); November 9, 1982, 47 FR 50814–50840 (final regulations)

Obstetrics-Gynecology Devices Panel—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations)

Radiologic Devices Panel—January 29, 1982, 47 FR 4406–4451 (proposals)

Ophthalmic Devices Panel—January 26, 1982, 47 FR 3694–3749 (proposals)

Ear, Nose, and Throat Devices Panel—January 22, 1982, 47 FR 3280–3325 (proposals); November 6, 1986, 51 FR 40378–40393 (final regulations)

Dental Devices Panel—December 30, 1980, 45 FR 85962–86168 (proposals)

Anesthesiology and Respiratory Therapy Devices Panel—November 2, 1979, 44 FR 63292–63426 (proposals); July 16, 1982, 47 FR 31130–31150 (final regulations)

Neurological Devices Panel—November 23, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations)

Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices)—August 28, 1979, 44 FR 50458–50537 (proposals); November 23, 1983, 48 FR 53032–53054 (final regulations)

Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices)—July 2, 1982, 47 FR 29052–29140 (proposals); September 4, 1987 (final regulations)

General and Plastic Surgery Devices Panel—January 19, 1982, 47 FR 2810–2853 (proposals)

J. Minor Changes or Clarifications

Occasionally the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Additionally, the agency is adding new sections in Subpart A to explain the various effective dates for premarket approval requirements for devices classified into class III and to define various terms used in the names and identifications of orthopedic devices. FDA also is adding new paragraph (c) in the classification regulation for devices classified into class III to declare, where applicable, the effective date of premarket approval requirements for the device.

K. Transitional Devices

The amendments include transitional provisions applicable to devices intended for human use that were declared to be drugs before enactment of the amendments. (See section 520(l)(1) of the act (21 U.S.C. 360j(l)(1).) The transitional provisions assure that devices formerly regarded as drugs continue to be subject to appropriate regulatory controls as the amendments are being implemented. Thus, a device previously considered a drug is classified into class III unless the agency in response to a petition has reclassified it into class I or class II.

FDA is including in this final rule sections codifying the statutory classification into class III of the following two commercially distributed, transitional orthopedic devices: bone heterograft (§ 888.3015) and polymethylmethacrylate (PMMA) bone cement (§ 888.3027).

L. Studies Submitted by Comments

Some comments submitted copies of clinical studies to support their requests for changes in the classification of certain devices. These studies are available in the Dockets Management Branch and may be seen by interested persons between 9:00 a.m. and 4:00 p.m., Monday through Friday.

1. Axon, A.T.R., et al., "Disinfection in Upper-digestive-tract Endoscopy in Britain," *Lancet*, pp. 1093–1094, 1981.

2. Dandy, D.J., and R.W. Jackson, "The Impact of Arthroscopy on the Management of Disorders of the Knee," *Journal of Bone and Joint Surgery* (British Volume), 57–B:346–348, 1975.

3. Fiddian, N.J., and H. Poirier, "The Morbidity of Arthroscopy of the Knee," *Journal of Bone and Joint Surgery* (British Volume), 63–B:630, 1981.

4. Fraider, C.T., "Arthroscopic Surgery of the Knee: History and State of the Art," *Journal of American Osteopathic Association*, 80:817–822, 1981.

5. Henderson, C.E., and C.N. Hopson, "Pneumoscrotum as a Complication of Arthroscopy," *Journal of Bone and Joint Surgery* (American Volume), 64–A:1238–1240, 1982.

6. Ikeuchi, H., "Arthroscopic Treatment of the Discoid Lateral Meniscus, Technique and Long-term Results," *Clinical Orthopaedics and Related Research*, 167:19–28, 1982.

7. Jackson, R.W., "Current Concepts Review, Arthroscopic Surgery," Accepted by: *Journal of Bone and Joint Surgery*.

8. Jackson, R.W., and I. Abe, "The Role of Arthroscopy in the Management of Disorders of the Knee. An Analysis of 2000 Consecutive Examinations," *Journal of Bone and Joint Surgery*, 54–B:310–322, 1972.

9. Johnson, L.L., "Diagnostic and Surgical Arthroscopy. The Knee and other Joints," 2d Ed., C.V. Mosby, St. Louis, 1981. (Sterilization and disinfection, pp. 22–24; care of instruments between patients, p. 41; complications, pp. 58–60; intra-articular shaver, pp. 217–221; surgical equipment and instruments, pp. 221–240.)

10. Johnson, L.L., et al., "A Cold Sterilization Method for Arthroscopes Using Activated Dialdehyde," *Orthopedic Review*, 6:75–77, 1977.

11. Johnson, L.L., et al., "Two Percent Glutaraldehyde: A Disinfectant in Arthroscopy and Arthroscopic Surgery," *Journal of Bone and Joint Surgery* (American Volume), 64–A:237–239, 1982.

12. Lindenbaum, B.L., "Complications of Knee Joint Arthroscopy," *Clinical Orthopaedics and Related Research*, 160:158, 1981.

13. Lysholm, J., et al., "Arthroscopy in the Early Diagnosis of Injuries to the Knee Joint," *Acta Orthopaedica Scandinavica*, 52:111–118, 1981.

14. Mulhollan, J.S., "Complications of Arthroscopic Surgery," Presentation, International Arthroscopy Association Course on Surgery of the Knee, Bermuda, 1981.

15. O'Connor, R.L., "Arthroscopy," J.B. Lippincott Co., Philadelphia, 1977. (Incandescent lamp, pp. 2, 4–5; cleaning and sterilization, pp. 10–13; indications, pp. 14–15; contraindications, p. 20; complications, pp. 20–22.)

16. Perry, G.B., and R.A. Moyer, "Arthroscopic Instrument Breakage. Expedient Method for Retrieving Metal Fragments," *Orthopedic Review*, 11:141–142, 1982.

17. Schonholtz, G.J., "Arthroscopy and Arthroscopic Surgery," *Maryland State Medical Journal*, 56–59, 1981.

18. Whipple, T.L., and F. Bassett, "Arthroscopic Examination of the Knee. Polypuncture Technique with Percutaneous Intra-articular Manipulation," *Journal of Bone and Joint Surgery*, 60–A:444–453, 1978.

19. Swanson, A.B., "Improving the End Bearing Characteristics of Lower Extremity Amputation Stumps—A Preliminary Report," *Inter-Clinic Information Bulletin*, 5(5):1–7, 1966.

20. Swanson, A.B., "Bone Overgrowth in the Juvenile Amputee and its Control by the Use of Silicone Rubber Implants," *Inter-Clinic Information Bulletin*, 8(5):9–18, 1969.

21. Swanson, A.B., "Silicone-Rubber Implants to Control the Overgrowth Phenomenon in the Juvenile Amputee," *Inter-Clinic Information Bulletin*, 11(9):5–8, 1972.

22. Murray, W.R., "Treatment of Deep Wound Infection After Total Hip Arthroplasty," *in* "American Academy of Orthopedic Surgeons Symposium on Osteoarthritis," C.V. Mosby Co., St. Louis, 1976.

23. MacEwen, C.D., W.P. Bunnell, and K. Sriram, "Acute Neurological Complications in the Treatment of Scoliosis. A Report of the Scoliosis Research Society," *Journal of Bone and Joint Surgery* (American Volume), 57–A:404–408, April 1975.

24. Erwin, W.D., J.H. Dickson, and P.R. Harrington, "Clinical Review of Patients with Broken HARRINGTON® Rods," *Journal of Bone and Joint Surgery* (American Volume), 62–A:1302–1307, December 1980.

25. Machemson, A., and C. Elfstroem, "Intravital Wireless Telemetry of Axial Forces in Harrington Distraction Rods in Patients with Idiopathic Scolisis," *Journal of Bone and Joint Surgery* (American Volume), 53–A:445–465, April 1971.

26. Sinclair, C.B., and C.A. Lubon, "Design of a Lifelong Harrington Rod," *Journal of Biomedical Engineering*, 4(2):133–136, April 1982.

27. Groth, H.E., "Oregon Total Ankle—A Clinical Report," unpublished report.

28. Groth, H.E., and J.M. Shilling, "Tissue Responses to Carbon-Reinforced Polyethylene," *Journal of Orthopedic Research*, 1:129–135, 1983.

29. Groth, H.E., et al., "Postmortem Analysis of Carbon-Fiber Reinforced UHMWPE Prostheses Retrieved from a Single Subject After a Service Life of 12 to 15 Months," Transactions of the Orthopedic Research Society, February 21–23, 1978.

30. Segal, N.M. and R.N. Stauffer, "Mayo Clinic Ankle Arthroplasty: Four Years Experience," Transactions of the Orthopedic Research Society, February 21–23, 1978.

31. Samuelson, K.M., "ICLW Ankle Arthroplasty," Transactions of the Orthopedic Research Society, February 21–23, 1978.

32. Groth, H.E., "The Oregon Ankle—A Review of Forty-one Cases," Transactions of the Orthopedic Research Society, February 21–23, 1978.

33. Farling, G.M. and K. Greer, "An Improved Bearing Material for Joint Replacement Prostheses: Carbon Fibre-reinforced Ultra High Molecular Weight Polyethylene," *in* "Mechanical Properties of Biomaterials," Edited by Hastings, G.W. and D.F. Williams, John Wiley and Sons, Ltd., pp. 53–64, 1980.

34. Coonrad, R.W., "History of Total Elbow Arthroplasty," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

35. Volz, R.G., "Development and Clinical Analysis of a New Semi-constrained Total Elbow Prosthesis," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

36. Inglis, A.E., "Tri-Axial Total Elbow Replacement: Indications, Surgical Technique, and Results," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

37. Morrey, B.F., et al., "Total Elbow Arthroplasty: A Five-Year Experience at the Mayo Clinic," *Journal of Bone and Joint Surgery*, 63–A:1050–1063, 1981.

38. Coonrad, R.W., "Seven-Year Follow-up of Coonrad Total Elbow Replacement," *in* "Symposium of Total Joint Replacement of the Upper Extremity," New York, September 1979, The C.V. Mosby Co., St. Louis, pp. 91–99, 1982.

39. Dryer, R.F., J.A. Buckwalter, and R.L. Sprague, "Hinged Total Elbow Replacement," *Orthopedics*, 4(7):763–768, 1981.

40. Swanson, A.B., et al., "Comminuted Fractures of the Radial Head," *Journal of Bone and Joint Surgery*, 68(4):1039–1049, 1981.

41. Madden, J.W., letter to the Food and Drug Administration, December 28, 1982.

42. Swanson, J.W., and J.E. Lebeau, "The Effect of Implantation on the Physical Properties of Silicone Rubber," *Journal of Biomedical Materials Research*, 8:357–367, 1974.

43. Swanson, A.B., et al., "Durability of Silicone Implants—An In Vivo Study," *Orthopedic Clinics of North America*, 4(4):1097–1112, 1973.

44. Madden, J.W., et al., "A Rational Postoperative Management Program for Metacarpophalangeal Joint Implant Arthroplasty," *Journal of Hand Surgery*, 2(5):358–366, 1977.

45. Frisch, E.E., "Medical Grade High Performance Silicone Elastomer," First International Symposium, Frontiers of Biomedical Polymers, University of Akron, Akron, OH, June 2–3, 1981.

46. Swanson, A.B., "Implant Arthroplasty in the Hand and Upper Extremity and Its Future," *Surgical Clinics of North America*, 61(2):369–382, 1981.

47. Swanson, A.B., "Flexible Implant Arthroplasty for Arthritic Finger Joints," *Journal of Bone and Joint Surgery*, 54–A(3):435–456, 1972.

48. Swanson, A.B., and G. Swanson, "Joint Replacement in the Rheumatoid Metacarpophalangeal Joint," *in* "American Academy of Orthopedic Surgeons Symposium on Total Joint Replacement of the Upper Extremity," Edited by A.E. Inglis, The C.V. Mosby Company, St. Louis, pp. 238–254, 1982.

49. Swanson, A.B., et al., "Silicone Implants in Dogs—A Ten Year Histopathological Study," unpublished paper.

50. Swanson, A.B., et al., "Bone Remodeling Phenomena in Flexible (Silicone) Implant Arthroplasty in the Metacarpophalangeal Joints—Long Term Study," Kappa Delta Award Presentation, 49th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, January, 21, 1982.

51. Swanson, A.B., letter to the Food and Drug Administration, December 26, 1982.

52. Madden, J.W., letter to the Food and Drug Administration, December 28, 1982.

53. Rae, T. and M. Rushton, "The Biocompatibility of Carbon Fibers, High Density Polyethylene and the Resultant Composite Material," *in* "International Symposium on Biomaterials," Durham, England, pp. 23–28, 1982.

54. Hess, W.E., "Mueller-Type Hip with Poly-Two™ Acetabular Component: A Clinical Evaluation," unpublished report.

55. Dobbs, H.S., "Survivorship of Total Hip Replacements," *Journal of Bone and Joint Surgery*, 62–B(2):168, 1980.

56. Stauffer, R., "Ten-Year Follow-Up Study of Total Hip Replacement," *Journal of Bone and Joint Surgery*, 64–A(7):983, 1982.

57. Sutherland, C., "Ten-Year Follow-Up of One Hundred Consecutive Mueller Curved-Stem Total Hip Replacement Arthroplasties," *Journal of Bone and Joint Surgery*, 64–A(7):970, 1982.

58. Reuban, J.D., et al., "Comparative Mechanical Properties of Forty-Five Total Hip Stems," *Clinical Orthopaedics and Related Research*, 141:55–65, 1979.

59. Dutton, R.O., et al., "Tharies Surface Replacement for Osteonecrosis of the Femoral Head," *Journal of Bone and Joint Surgery*, 64–A:1225–1237, 1982.

60. Amstutz, H.C., "Recent Advances in Total Hip Resurfacing," unpublished manuscript.

61. Amstutz, H.C., "Total Hip Resurfacing: An Endangered Species with a Future," *Orthopedic Survey*, 5(2):123–127, 1981.

62. Wright, T.M., T. Fukubayashi, and A.H. Burstein, "The Effect of Carbon Fibre Reinforcement on Contact Area, Contact Pressure, and Time-Dependent Deformation in Polyethylene Tibial Components," *Journal of Biomedical Materials Research*, 15:719–730, 1981.

63. Salvati, E.A., et al., "Infection Rates After 3175 Total Hip and Total Knee Replacements Performed With and Without a Horizontal Unidirectional Filtered Air-Flow System," *Journal of Bone and Joint Surgery*, 64–A(4):525–535, 1982.

64. Shetly, H.R., "*In Vivo* Wear Performance of Poly-Two* Plateaus in Cloutier™ I Total Knee Tibial Components," unpublished technical report.

65. Cloutier, J., "Cloutier II Total Knee: A Clinical Evaluation," unpublished report.

66. Zimmer, USA, internal report.

67. Cracchiolo, A., et al., "A Prospective Comparative Clinical Analysis of the First Generation Knee Replacement: Polycentric vs. Geometric Knee Arthroplasty," *Clinical Orthopaedics and Related Research*, 145:37–46, 1979.

68. Blazina, M.E., et al., "Patellofemoral Replacement," *Clinical Orthopaedics and Related Research*, 0(144):98–102, 1979.

69. Mallory, T.H., D. Smalley, and J. Danyi, "Townley Anatomic Total Knee Arthroplasty Using Total Tibial Components with Crucial Release," *Clinical Orthopaedics and Related Research*, 0(169):197–201, 1982.

70. Kettelkamp, D.B., "Knee Implants: Review of Current Status," *Journal of Continuing Education in Orthopedics*, 21–29, 1978.

71. Flynn, L.M., "Experiences with U.C.I. Total Knee," *Clinical Orthopaedics and Related Research*, 0(135):188–191, 1978.

72. Lacey, J.A., "A Statistical Review of 100 Consecutive 'U.C.I.' Low Friction Knee Arthroplastics with Analysis of Results," *Clinical Orthopaedics and Related Research*, 0(132):163–166, 1978.

73. Accardo, N.J., et al., "Moiles Total Knee Replacement Procedure," *Orthopedics*, 2(1):37–45, 1979.

74. Neer, C.S., K.C. Watson, and F.J. Stanton, "Recent Experience in Total Shoulder Replacement," *Journal of Bone and Joint Surgery*, 64–A:310–337, 1982.

75. Clayton, M.L., D.C. Ferlic, and P.D. Jeffers, "Prosthetic Arthroplasties of the Shoulder," *Clinical Orthopedics*, 164:184–191, 1982.

76. Cracchiolo, A., A.B. Swanson, and G. Swanson, "The Arthritic Great Toe Metatarsophalangeal Joint: A Review of Flexible Silicone Implant Arthroplasy from Two Medical Centers," *Clinical Orthopaedics and Related Research*, 157:64–69, 1981.

77. Swanson, A.B., R.M. Lunsden, and G. Swanson, "Silicone Implant Arthroplasty of the Great Toe: A Review of Single Stem and Flexible Hinge Implants," *Clinical Orthopaedics and Related Research*, 142:30–43, 1979.

78. Kampner, S.L., "Total Joint Replacement in Bunion Surgery," *Orthopedic Surgery*, 2(4):215–216, 1979.

79. Gudmundsson, G., and K. Robertsson, "Silastic Arthroplasty of the First Metatarsophalangeal Joint," *Acta Orthopaedica Scandinavica*, 51:575–578, 1980.

80. Molster, A.O., O.D. Lunde, and M. Rait, "Hallux Rigidus Treated with the Swanson Silastic Hemi-Joint Prosthesis," unpublished paper.

81. Swanson, A.B., G. Swanson, and J.J. Watermeier, "Trapezium Implant Arthroplasty," *Journal of Hand Surgery*, 6(2):125–1414, 1981.

82. Swanson, A.B., "Disabling Arthritis at the Base of the Thumb," *Journal of Bone and Joint Surgery*, 54–A(3):456–471, 1972.

83. Goodman, M.J., et al., "Arthroplasty of the Rheumatoid Wrist with Silicone Rubber: An Early Education," *Journal of Hand Surgery*, 5(2):114–121, 1980.

84. Swanson, A.B., and G. Swanson, "Flexible Implant Arthroplasty of the Radiocarpal Joint: Surgical Technique and Long Term Results," American Academy of Orthopedic Surgeons Symposium on Total Joint Replacement of the Upper Extremities, Edited by A. Inglis, C.V. Mosby Co., St. Louis, 1982.

85. Swanson, A.B., "Flexible Implant Arthroplasty for Arthritic Disabilities of the Radiocarpal Joint," *Orthopedic Clinics of North America*, 4(2):383–394, 1973.

86. Swanson, A.B., "Implant Arthroplasty for Disabilities of the Distal Radioulnar Joint," *Orthopedic Clinics of North America*, 4(2):373–382, 1973.

87. Swanson, A.B., A. Pareinel, and J.H. Herndon, "Long Term Follow-up on Implant Arthroplasty of the Distal Radioulnar Joint—An X-Ray and Clinical Study," Orthopedic Transactions, *Journal of Bone and Joint Surgery*, 1(1):111–112, 1977.

88. Swanson, A.B., and G.R. Chambers, "Ulnar Head Implant Resection Arthroplasty for Disabilities of the Distal Radio-Ulnar Joint—Long Term Results," Orthopedic Transactions, *Journal of Bone and Joint Surgery*, 5(1):115, 1981.

M. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

N. Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined that 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 final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into Class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is 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 approval 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.

List of Subjects in 21 CFR Part 888

Orthopedic devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 888, to read as follows:

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

Subpart E—Surgical Devices

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

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 surgical device) is listed in 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.

§ 888.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket

approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

§ 888.5 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 name of the prosthesis includes this information.

§ 888.6 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. FDA is defining the following standard terms for categorizing the degree of constraint.

(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 joint 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.

Subpart B—Diagnostic Devices

§ 888.1100 Arthroscope.

(a) *Identification.* An arthroscope is an electrically powered endoscope Intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

(b) *Classification.* Class II.

§ 888.1240 AC-powered dynamometer.

(a) *Identification.* An AC-powered dynamometer is an AC-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.

§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

§ 888.3000 Bone cap.

(a) *Identification.* A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used 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.

§ 888.3010 Bone fixation cerclage.

(a) *Identification.* A bone fixation cerclage is a device intended to be implanted that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. 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.

§ 888.3015 Bone heterograft.

(a) *Identification.* Bone heterograft is a device intended to be implanted that is made from mature (adult) bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 888.3.

§ 888.3020 Intramedullary fixation rod.

(a) *Identification.* An intramedullary fixation rod is a device intended to be implanted 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.

§ 888.3025 Passive tendon prosthesis.

(a) *Identification.* A passive tendon prosthesis is a device intended to be implanted made of silicon 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.

§ 888.3027 Polymethylmethacrylate (PMMA) bone cement.

(a) *Identification.* Polymethylmethacrylate (PMMA) bone cement (luting agent) is a device intended to be implanted that is made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid or copolymers containing polymethylmethyacrylate and polystyrene. The device is intended

for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to the living bone.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 888.3.

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted 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 are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are 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 devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is a device intended to be implanted 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 may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3050 Spinal interlaminal fixation orthosis.

(a) *Identification.* A spinal interlaminal fixation orthosis is a device intended to be implanted 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 may be 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.

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification.* A spinal intervertebral body fixation orthosis is a device intended to be implanted 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 used 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.

§ 888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted 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 ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted made exclusively of alloys, such as cobalt-chromium-molybdenum, or made from these alloys with a ultra-high molecular weight polyethylene bushing, and used to replace an elbow 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 is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

(a) *Identification.* An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.

(b) *Classification.* Class II.

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

(a) *Identification.* An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is a device intended to be implanted 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 protheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3210 Finger joint metal/metal constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3220 Finger joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/polymer constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3230 Finger joint polymer constrained prosthesis.

(a) *Identification.* A finger joint polymer constrained prosthesis is a device intended to be implanted 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 pf polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve.

(b) *Classification.* Class II.

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted 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 components made of alloys, such as cobalt-chromium-molybdenum, and is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted 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 intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 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 a two-part device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 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 a two-part device intended to be implanted 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 for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted 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 ultra-high molecular weight polyethylene with carbon fibers composite. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis is a device intended to be implanted 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 bone cement (§ 888.3027) as well as designs which have large window-like holes in the stem of the device and which are intended for use without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) *Classification.* Class II.

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

(a) *Identification.* A hip joint (hemi-hip) acetabular metal cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis is a two-part device intended to be implanted 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 is intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis is a two-part device intended to be implanted 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 bone cement (§ 888.3027) or implanted by impaction.

(b) *Classification.* Class II.

§ 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic resurfacing prosthesis is a device intended to be implanted 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.

§ 888.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted 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 use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of 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 for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite non-constrained cemented prosthesis is a device intended to be implanted to replace part of 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 use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted 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 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace part of 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 into the metallic tibial component. The generic class also includes devices whose upper and lower components are linked with a solid bolt passing through a journal bearing of greater radius, permitting some rotation in the transverse plane, a minimal arc of abduction/adduction. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of 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 for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of 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 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 use with bone cement (§ 888.3027). The patellar component is designed to be implanted only with its femoral component.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis is a device intended to be implanted 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 surfacing component may be attached to the resected patella either with a metallic

screw or bone cement. All stemmed metallic components within this generic type are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) *Identification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted 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 prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted 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 prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* (1) Class II when intended for treatment of degenerative and posttraumatic patellar arthritis.

(2) Class III when intended for uses other than treatment of degenerative and posttraumatic patellar arthritis.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval for the device intended for uses described in paragraph (b)(2). See § 888.3.

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is a device intended to be implanted to replace part of 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 prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

(a) *Identification.* A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date

has been established of the requirement for premarket approval. See § 888.3.

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class II.

§ 888.3720 Toe joint polymer constrained prosthesis.

(a) *Identification.* A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted 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.

§ 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.

(a) *Identification.* A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.

(b) *Classification.* Class II.

§ 888.3750 Wrist joint carpal lunate polymer prosthesis.

(a) *Identification.* A wrist joint carpal lunate prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal lunate bone of the wrist.

(b) *Classification.* Class II.

§ 888.3760 Wrist joint carpal scaphoid polymer prosthesis.

(a) *Identification.* A wrist joint carpal scaphoid polymer prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal scaphoid bone of the wrist.

(b) *Classification.* Class II.

§ 888.3770 Wrist joint carpal trapezium polymer prosthesis.

(a) *Identification.* A wrist joint carpal trapezium polymer prosthesis is a one-piece device made of silicone elastomer or silicone elastomer/polyester material intended to be implanted to replace the carpal trapezium bone of the wrist.

(b) *Classification.* Class II.

§ 888.3780 Wrist joint polymer constrained prosthesis.

(a) *Identification.* A wrist joint polymer constrained prosthesis is a device made of polyester-reinforced silicone elastomer intended to be implanted 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.

§ 888.3790 Wrist joint metal constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal constrained cemented prosthesis is a device intended to be implanted 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 888.3.

§ 888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted 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 one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or 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 prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted 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.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) *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.

(b) *Classification.* Class I. 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 (§ 888.3027) into surgical sites.

(b) *Classification.* Class I.

§ 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 (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a tube-like device usually made of plastic 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 (§ 888.3027).

(b) *Classification.* Class I.

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(b) *Classification.* Class I. 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. If the device is made of the same materials that were used in the device before May 28, 1976, 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.

§ 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 surgery.

(b) *Classification.* Class I. 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. 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. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations 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. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 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, toe cap, cast support, and walking iron.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

§ 888.5980 Manual cast application 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. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Dated: June 15, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

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