as their release from Customs custody or other disposition is authorized by the Office of Foreign Assets Control. As used herein, "unfabricated nickel-bearing materials" includes: (1) Nickel ore in any stage of refinement, including nickel matte and nickel oxide; (2) primary nickel in any form, including nickel cathode, powder and flakes; (3) wrought nickel in its basic shapes and forms, including ingots, slabs, bars, plates and rods; (4) nickel waste and scrap; (5) nickel alloys in their basic shapes and forms, including ferronickel; and (6) stainless steel in its basic shapes and forms containing more than 2.5% nickel. Fabricated items such as flatware, pots and pans are not covered by the ban.

This detention order shall not apply to nickel alloys and stainless steel that are manufactured from Soviet nickel in any country other than the U.S.S.R. Nickel alloys and stainless steel that are manufactured in the U.S.S.R., however, may not be imported into the United States merely because they have been transshipped through a third country or cut, pressed, milled, drawn or otherwise wrought in another country. For example, stainless steel bars from the Soviet Union that are cut, rolled or otherwise processed short of fabrication in a third country may not be imported into the United States.

Beginning 30 days from the date of this notice, unfabricated nickel-bearing materials (not including nickel alloys and stainless steel) made from Soviet nickel may not be imported into the United States. For example, nickel rods, plates, bars or sheets wrought in a third country from nickel cathode or another form of primary nickel from the U.S.S.R. may not be imported. Importers of such materials that have questions regarding their admissibility through U.S. Customs should contact the Office of Foreign Assets Control. Inquiries may be addressed to either Raymond W. Konan, Chief Counsel, 202/376-0236, or Marilyn L. Muench, Chief of Licensing, 202/376-0408.

The Office of Foreign Assets Control is considering whether to require that imports into the United States of certain unfabricated nickel-bearing materials from countries that import nickel from the U.S.S.R. be accompanied by documentation showing that they were not manufactured in the U.S.S.R. or from Soviet nickel. If imposed, the requirement will become effective within 30 days following the date of its publication in the **Federal Register.**

The Office of Foreign Assets Control will generally issue specific licenses authorizing the release from Customs custody of unfabricated nickel-bearing materials, except nickel granules and nickel sulphate, where, prior to the date of this notice, the materials were paid for by a person in the United States or covered by an irrevocable letter of credit established in a domestic bank. Specific licenses may be issued authorizing the release from Customs of materials that depart the U.S.S.R. in transit to the United States before the date of this notice, and are presented to U.S. Customs within 60 days following that date.

This notice supersedes the earlier notices of February 4, 1969, dealing with importation of nickel granules from the U.S.S.R., and of October 3, 1969, dealing with importation of nickel sulphate from the U.S.S.R.

(Sec. 5, 40 Stat. 415, as amended, 50 U.S.C. App. 5; Sec. 620(a), 75 Stat. 445, 22 U.S.C. 2370(a); Proc. 3447, 27 FR 1085, 3 CFR 1959-1963 Comp.; E.O. 9193, 7 FR 5205, 3 CFR Comp. Supp., p. 1174; E.O. 9989, 13 FR 4891, 3 CFR, 1943-1948 Comp., p. 748)

Dated: November 21, 1983.

Dennis M. O'Connell,

Director, Foreign Assets Control.

John M. Walker, Jr.,

Assistant Secretary.

[FR Doc. 83-31567 Filed 11-21-83; 11:27 am]

BILLING CODE 4810-25-M

Sunshine Act Meetings

Federal Register
Vol. 48, No. 227
Wednesday, November 23, 1983

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

CONTENTS

1

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, November 25, 1983.

PLACE: 2033 K Street NW., Washington, D.C. Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1637-83 Filed 11-21-83; 12:05 pm]

BILLING CODE 6351-01-M

2

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 2, 1983

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1633-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

3

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday, December 6, 1983.

PLACE: 2033 K Street NW., Washington, D.C., fifth Floor Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Proposed contract market designation for the Commodity Exchange, Inc. in Aluminum

Proposed contract market designation for Chicago Mercantile Exchange in S&P Energy Subindex

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1630-83 Filed 11-21-83; 11:56 am]

BILLING CODE 6351-01-M

4

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 9, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1631-83 Filed 11-21-83; 11:59 am]

BILLING CODE 6351-01-M

5

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday December 13, 1983.

PLACE: 2033 K Street NW., Washington, D.C. Fifth Floor Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Proposed contract market designation for Chicago Merchantile Exchange on options of Deutshe Mark Futures.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1629-83 Filed 11-21-83; 11:56 am]

BILLING CODE 6351-01-M

6

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Tuesday, December 13, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Rule enforcement review

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1635-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

7

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Thursday, December 15, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Briefing on Mandated Studies

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1632-83 Filed 11-21-83; 12:00 pm]

BILLING CODE 6351-01-M

8

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 16, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[FR Doc. 83-1630 Filed 11-21-83; 12:06 pm]

BILLING CODE 6351-01-M

9

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Tuesday, December 20, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Fifth Floor Hearing Room.

STATUS: Open.

MATTER TO BE CONSIDERED:

Proposed contract market designation for the Chicago Mercantile Exchange in S&P High Technology Subindex

Proposed contract market designation for Chicago Mercantile Exchange in Gold Coins

Proposed contract market designation for Commodity Exchange in Gold Coins

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1634-83 Filed 11-21-83; 12:04 pm]

BILLING CODE 6351-01-M

10

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 23, 1983.

PLACE: 2033 K Street NW., Washington, D.C., Eighth Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1638-83 Filed 11-21-83; 12:06 pm]

BILLING CODE 6351-01-M

11

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 11 a.m., Friday, December 30, 1983.

PLACE: 2033 K Street NW., Washington, D.C., eighth Floor Hearing Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Market Surveillance Briefing

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

[S-1636-83 Filed 11-21-83; 12:05 pm]

BILLING CODE 6351-01-M

12

FEDERAL ENERGY REGULATORY COMMISSION

November 21, 1983.

TIME AND DATE: Approximately 12 noon, November 22, 1983 (following open meeting).

PLACE: Room 9306, 825 North Capitol Street NE., Washington, D.C. 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED: IN83–2–000, Various Producer-Owned Natural Gas Processing Plants.

CONTACT PERSON FOR MORE INFORMATION: Kenneth F. Plumb, Secretary, telephone (202) 357–8400.

Kenneth F. Plumb,

Secretary.

[S-1641-83 Filed 11-21-83; 1:59 pm]

BILLING CODE 6717-02-M

13

FEDERAL RESERVE SYSTEM

TIME AND DATE: 10 a.m., Monday, November 28, 1983.

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

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed alternatives for future space requirements of the Federal Reserve Bank of Dallas.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

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

Dated: November 18, 1982.

James McAfee,

Associate Secretary of the Board.

[S-1628-83 Filed 11-18-83; 4:11 pm]

BILLING CODE 6210-01-M

14

INTERNATIONAL TRADE COMMISSION

[USITC SE–83–49]

TIME AND DATE: 2 p.m., Friday, December 2, 1983.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints, if necessary.
5. Investigations 731–TA–149 and –150 (Preliminary) (Barium Chloride and Barium Carbonate from the People's Republic of China)—briefing and vote.
6. Any Items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

[S-1640-83 Filed 11-21-83; 1:44 pm]

BILLING CODE 7020-02-M

15

SYNTHETIC FUELS CORPORATION

Meeting of the Board of Directors

TIMES AND DATES:

9 a.m., November 30, 1983; and
8:30 a.m., December 1, 1983

PLACES:

Embassy Room, Dupont Plaza Hotel, Washington, D.C. (November 30, 1983); and
Room 503, 2121 K Street NW., Washington, D.C. (December 1, 1983)

SUMMARY: Interested members of the public are invited to attend and observe a meeting of the Board of Directors of the United States Synthetic Fuels Corporation to be held at the time, date and place specified below. This public announcement is made pursuant to the open meeting requirements of Section 116(f)(1) of the Energy Security Act (9 Stat. 611, 637; 42 U.S.C. 8701, 8712(f)(1) and Section 4 of the Corporation's Statement of Policy on Public Access to Board meetings. During the meeting, the Board of Directors will consider a resolution to close a portion of the meeting pursuant to Article II, Section 4 of the Corporation's By-laws, Section 116(f) of the said Act and Sections 4 and 5 of the said policy.

MATTERS TO BE CONSIDERED: *November 30, 1983.*

Open Session

1. Chairman's Opening Remarks.
2. Meeting with Advisory Committee.

Closed Session

3. Staff Briefing on Project Negotiations.
4. Consideration of Third Solicitation Oil Shale Projects.
5. Consideration of Great Plains Cool Gasification Project.
6. Consideration of Gulf Coast Lignite Project Proposal.

December 1, 1983:

Open Session

7. Approval of Minutes.
8. Report of Acting Executive Vice President.
9. Report of Audit Committee on the Management Audit.
10. Report of the Compensation Committee on Officer Reviews.
11. Election of Officers/Officer Positions.
12. Consideration of Third Solicitation Oil Shale Projects: Letters on Intent.
13. Consideration of Coal-Water Mixture Solicitation.
14. Consideration of Section 127(c) Requests.
15. Consideration of Bituminous Coal Solicitation Proposals.
16. Approval of Directors' Travel Policy.

Closed Session

17. Consideration of Gulf Coast Lignite Technical Proposal and Bid.
18. Consideration of Projects Removed from Solicitations.

19. Staff Report on Coal and Tar Sands Project Negotiations.
20. Consideration of General Coal Gasification Solicitation.

In addition, the Board of Directors will consider such other matters as may be properly brought before the meeting.

PERSON TO CONTACT FOR MORE INFORMATION: If you have any questions regarding this meeting, please contact Mr. Owen J. Malone, Assistant Secretary, at (202) 822-6336.

November 21, 1983.

United States Synthetic Fuels Corporation.

Leonard C. Axelrod,

Acting Vice President.

[S-1642-83 Filed 11-21-83; 3:51 pm]

BILLING CODE 0000-00-M

federal register

Wednesday
November 23, 1983

Part II

Department of Health and Human Services

Food and Drug Administration

Gastroenterology-Urology Devices; General Provisions and Classification of 56 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 78N-1945]

Gastroenterology-Urology Devices; General Provisions and Classification of 56 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 56 gastroenterology-urology devices. The preamble to this rule responds to comments received on the proposals regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: Norman T. Welford, National Center for Devices and Radiological Health (HFK-420), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, Md 20910; 301-427-7750.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 23, 1981 (46 FR 7562-7641), FDA published proposed regulations containing general provisions applicable to the classification of gastroenterology-urology devices. FDA also published individual proposed regulations to classify 57 gastroenterology-urology devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). FDA published a correction of several proposals in the **Federal Register** of April 7, 1981 (46 FR 20687).

Of the 57 gastroenterology-urology devices subject to the proposals, FDA is classifying 9 devices into class I, 32 devices into class II, and 9 devices into class III. Four devices are classified into either class I or class II, two depending upon how the device is powered and two for other reasons. In addition, two devices are classified into either class II or class III, depending upon other criteria. FDA is withdrawing the proposed regulation for one device.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392).

The effect of classifying a device into class I is to require that the device 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 the safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments and that either was in commercial distribution before May 28, 1976, or 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 June 30, 1986, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(l) of the act (21 U.S.C. 360j(1)).

The preamble to the general provisions described the development of the general provisions and the proposed regulations classifying gastroenterology-urology devices and the activities of the Gastroenterology-Urology Device Section of the General Medical Devices Panel (formerly the Gastroenterology-Urology Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of gastroenterology-urology devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publising as one document the general provisions and classifications of 56 gastroenterology-urology devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed to exempt manufacturers of three generic types of gastroenterology-urology devices from certain requirements of the current good manufacturing practice (GMP) regulations in Part 820 (21 CFR Part 820): Enema kit (Docket No. 78N-2060), protective garment for incontinence (Docket No. 78N-2062), and hernia support (Docket No. 78N-1967). The final rule exempts manufacturers of the three devices from certain GMP requirements. additionally, in response to comments, the agency has granted partial exemptions to manufacturers of one other device: the urine collector not connected to an indwelling catheter (Docket No. 78N-2010). If the devices are not labeled or represented as sterile, the final rule exempts the manufacturers of these four devices from all of the GMP requirements with the exception of §§ 820.180 and 820.198 relating to records and complaint files. The agency has determined that exemption of any manufacturer of a device from §§ 820.180 and 820.198 of the current GMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the current GMP regulations, if one has been granted, is still appropriate. Also, for the reasons given in the proposal, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

Changes in Classification in Final Regulations

Based on the comments received or upon consideration of additional information, FDA has changed the classification in the final regulation of each of 10 devices or accessories to these devices from that originally proposed: Gastroenterology-urology evacuator (Docket No. 78N-1994), ribdam (Docket No. 78N-2067), urological table and accessories (Docket No. 78N-2070), continent ileostomy catheter (Docket No. 78N-1972), urological clamp for males (Docket No. 78N-2009), urine collector and accessories (Docket No. 78N-2010), blood access device and accessories (Docket No. 78N-2044), nonimplanted electrical continence device (Docket No. 78N-2069), ostomy pouch and accessories (Docket No. 78N-1974), and hernia support (Docket No. 78N-1967).

The nonimplanted electrical continence device was proposed to be in class III, but is classified into class II in the final rule. The implanted blood access device and its accessories was proposed to be in class III; although the final rule places the device itself in class III, the accessories to the device are classified into class II. The eight remaining devices were proposed to be in class II, but are either completely or partially classified into class I in the final rule. The reasons for these changes are identified in the discussion below for each of these 10 devices. FDA does not believe that it is necessary to issue a new proposal concerning these changes. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device is correct. After reviewing the comments submitted on a proposal or upon reconsideration, the agency may determine that its proposed classification is incorrect. Therefore, persons interested in the classification process should 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 general provisions for gastroenterology-urology devices (see 46 FR 7562; January 23, 1981). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

Minor Changes or Clarifications

Occasionally the agency has made minor changes in a device name or identification to clarify the final regulation. Additionally, the agency is adding an explanation in § 876.1 that references in Part 876 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

Proposed Regulation to be Withdrawn

The proposed regulation for one gastroenterology-urology device, the circumcision instrument (Docket No. 78N-1990), was withdrawn in a separate document (47 FR 41139; Sept. 17, 1982). FDA has determined that the circumcision instrument is included in or is the same as the circumcision clamp identified in § 884.4530 *Obstetric-gynecologic specialized manual instrument*, which already has been classified into class II (February 26, 1980; 45 FR 12705).

Changes in Device Advisory Committee Names

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

Further, in the **Federal Register** of September 3, 1982 (47 FR 38883), FDA announced the establishment on August 5, 1982, of the Obstetrics-Gynecology Devices Panel and the Radiologic Devices Panel and the termination of the Obstetrics-Gynecology and Radiologic Devices Panel.

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, Section, and Name	Publication date in **Federal Register**
Circulatory Systems Devices Panel	Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical Chemistry Device Section	Feb. 2, 1982, 47 FR 4802 (proposals).
Clinical Toxicology Device Section	Do.
Hematology and Pathology Device Section	Sept. 11, 1979, 44 FR 53063 (proposals); Sept. 12, 1980, 45 FR 60576-60651 (final regulations).
General Medical Devices Panel:	
General Hospital and Personal Use Device Section	Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980, 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Device Section	Jan. 23, 1981, 46 FR 7562-7641 (proposals); Nov. 23, 1983 (final regulations).
Immunology and Microbiology Devices Panel:	
Immunology Device Section	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Microbiology Device Section	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel	Apr. 3, 1979, 44 FR 19894-19971 (proposals); Feb. 26, 1980, 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel:	
Ophthalmic Device Section	Jan. 26, 1982, 47 FR 3694-3749 (proposals).
Ear, Nose, and Throat Device Section	Jan. 22, 1982, 47 FR 3280-3325 (proposals).
Dental Device Section	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Respiratory and Nervous System Devices Panel:	
Anesthesiology Device Section	Nov. 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Device Section	Nov. 23, 1978, 43 FR 54640-56732 (proposals); Sept. 4, 1979, 44 FR 51726-51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
Physical Medicine Device Section	Aug. 28, 1979, 44 FR 50458-50537 (proposals).
Orthopedic Device Section	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Device Section	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

List of Gastroenterology-Urology Devices and an Identification of Those Proposed Classification Regulations That Received Public Comments

The following is a list of gastroenterology-urology devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the proposed classification regulation, the classification of each device, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, the classification of the device is being adopted as proposed. Comments were received on the proposals on 33 of the 57 gastroenterology-urology devices.

Because the proposal to classify the circumcision instrument (Docket No. 78N-1990) was withdrawn by means of a separate document (47 FR 41139; Sept. 17, 1982), the comment on that proposal, and FDA's response to it, were included in the withdrawal.

SUBPART B—DIAGNOSTIC DEVICES

Section and device	Docket No.	Class	Comments
876.1075 Gastroenterology-urology biopsy instrument.	78N-1946	II	Yes.
876.1400 Stomach pH electrode.	78N-1952	II	No.
876.1500 Endoscope and accessories.	78N-1953	II	Yes.
876.1620 Urodynamics measurement system.	78N-1950	II	Yes.
876.1725 Gastrointestinal motility monitoring system.	78N-1955	II	No.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
876.1800 Urine flow or volume measuring system.	78N-1964	II	Yes.

SUBPART C—MONITORING DEVICES

876.2040 Enuresis alarm.	78N-1958	II	No.

SUBPART D—PROSTHETIC DEVICES

876.3350 Penile inflatable implant.	78N-1968	III	No.
876.3630 Penile rigidity implant.	78N-1979	III	Yes.
876.3750 Testicular prosthesis.	78N-1981	III	Yes.

SUBPART E—SURGICAL DEVICES

876.4020 Fiberoptic light ureteral catheter.	78N-1947	II	Yes.
876.4270 Colostomy rod.	78N-1971	II	No.
876.4300 Endoscopic electrosurgical unit and accessories.	78N-1993	II	No.
876.4370 Gastroenterol-ogyurology evacuator.	78N-1994	I & II	Yes.
876.4400 Hemorrhoidal ligator.	78N-1995	II	No.
876.4480 Electrohy-draulic lithotriptor.	78N-1998	III	No.
876.4500 Mechanical lithotriptor.	78N-2001	II	Yes.
876.4530 Gastroenterol-ogyurology fiberoptic retractor.	78N-1999	I	No.
876.4560 Ribdam	78N-2067	I	Yes.
876.4590 Interlocking urethral sound.	78N-2068	II	Yes.
876.4620 Ureteral stent	78N-1984	II	Yes.
876.4650 Water jet renal stone dislodger system.	78N-1988	II	Yes.
876.4680 Ureteral stone dislodger.	78N-2002	II	No.
876.4730 Manual gastroenterology-urology surgical instrument and accessories.	78N-1996	I	Yes.
876.4770 Urethrotome	78N-2004	II	Yes.
876.4890 Urological table and accessories.	78N-2070	I & II	Yes.

SUBPART F—THERAPEUTIC DEVICES

876.5010 Biliary cathether and accessories.	78N-2005	II	No.
876.5030 Continent ileostomy catheter.	78N-1972	I	Yes.
876.5090 Suprapubic urological catheter and accessories.	78N-1989	II	Yes.
876.5130 Urological catheter and accessories.	78N-2006	II	Yes.
876.5160 Urological clamp for males.	78N-2009	I	Yes.
876.5210 Enema kit	78N-2060	I	No.
876.5220 Colonic irrigation system.	78N-2011	II & III	Yes.
876.5250 Urine collector and accessories.	78N-2010	I & II	Yes.
876.5270 Implanted electrical urinary continence device.	78N-1978	III	No.
876.5280 Implanted mechanical/hydraulic urinary continence device.	78N-1969	III	No.

SUBPART F—THERAPEUTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
876.5230 Nonimplanted electrical continence device.	78N-2069	II	Yes.
876.5365 Esophageal dilator.	78N-2058	II	No.
876.5450 Rectal dilator	78N-1992	II	No.
876.5470 Ureteral dilator.	78N-2057	II	No.
876.5520 Urethral dilator.	78N-2059	II	Yes.
876.5540 Blood access device and accessories.	78N-2044	II & III	Yes.
876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.	78N-2019	II	No.
876.5630 Peritoneal dialysis system and accessories.	78N-2051	II	No.
876.5665 Water purification system for hemodialysis.	78N-2047	II	Yes.
876.5820 Hemodialysis system and accessories.	78N-2014	I & II	Yes.
876.5830 Hemodialyzer with disposable insert (Kiil type).	78N-2038	II	No.
876.5860 High permeability hemodialysis system.	78N-2039	III	No.
876.5870 Sorbent hemoperfusion system.	78N-2061	III	No.
876.5880 Isolated kidney perfusion and transport system and accessories.	78N-2063	II	No.
876.5895 Ostomy irrigator.	78N-1975	II	Yes.
876.5900 Ostomy pouch and accessories.	78N-1974	I	Yes.
876.5920 Protective garment for incontinence.	78N-2062	I	Yes.
876.5955 Peritoneo-venous shunt.	78N-1980	III	Yes.
876.5970 Hernia support.	78N-1967	I	Yes.
876.5980 Gastroin-testinal tube and accessories.	78N-2072	II	No.

Summaries of Comments and FDA's Responses to Comments

FDA is responding to specific comments received on the proposed regulations for 32 gastroenterology-urology devices and to three general comments as follows:

1. One comment stated that the majority of the device classifications appeared correct; however, some changes seem desirable. The comment suggested that before the agency publishes the final regulations to classify the gastroenterology-urology devices, select committees representing the medical specialties that use these devices be asked to assist FDA in determining the final classifications of the devices. The comment believed that such a supplemental review would allow the practitioners in the medical specialties to continue to use the devices without impedance and also would allow the development of additional scientific data regarding the devices.

FDA disagrees with the comment. The agency has established the Gastroenterology-Urology Device Section of the General Medical Devices Panel, an FDA advisory committee of experts representing the medical specialties that use Gastroenterology-urology devices. The advisory committee was established as specified in section 513 (b) and (c) of the act, as amended by the 1976 amendments, and the Federal Advisory Committee Act. The classifications of gastroenterology-urology devices proposed by FDA and published in the **Federal Register** were based on recommendations of the agency's advisory committees established in accordance with these statutes. FDA solicited public nominations for members of these advisory committees and held meetings that were open to the public. The agency believes that further consultation with other scientific or medical committees is unnecessary and would be subject to the statutory provisions cited above. Additionally, final classification of a device, in itself, has a limited impact, as described at the conclusion of this preamble. FDA believes that the classification of a device will not cause hardship to the medical community or hinder innovation.

2. A comment requested an extension of the comment period because of the length of the proposed regulations.

The agency disagrees with the comment. Sixty days for public comment is reasonable. See section 520(d)(2) of the act (21 U.S.C. 360j(d)(2)) and § 10.40(b)(2) of the regulations (21 CFR 10.40(b)(2)). Moreover, FDA's proposed device classifications were based on FDA advisory committees' recommendations that have been available to the public for several years. Therefore, the agency believes that an extension of the comment period is not necessary. (Comment 8.a. below describes a limited reopening of the comment period.)

3. A comment approved of the agency's policy of merging for classification purposes similar devices into a broad generic type of device.

FDA agrees with the comment.

4. Section 876.1075; 78N-1946; Gastroenterology-urology biopsy instrument. FDA published in the **Federal Register** (46 FR 7569) a proposed regulation to classify the gastroenterology-urology biopsy instrument into class II. The one comment received on the proposal suggested that the gastroenterology-urology biopsy instyrument be classified

into class I rather than class II as was proposed. The comment stated that the device has been used for over 30 years and that it would be impossible to write safe, practical standards of use for a nonsurgeon.

FDA disagrees with the comment. The comment erroneously believes that a performance standard for the device applies to the skill ("performance") of the user of the device. Rather, a standard for the gastroenterology-urology biopsy instrument is needed because the design, mechanical properties, and tissue removal mechanisms of the device—all performance properties of the device, not the user—must be controlled by a performance standard to assure that unnecessary cutting or tissue removal does not occur. The design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, or perforation and to enable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

5. Section 876.1500; 78N–1953; Endoscope and accessories. FDA published in the **Federal Register** (46 FR 7571) a proposed regulation to classify the endoscope and accessories into class II. The one comment received on the proposal suggested that the endoscope and its accessories be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. The agency agrees that the principal hazard associated with the use of the device may be due to unskilled users. The agency believes that the endoscope and accessories should be classified into class II because the electrical, optical, mechanical, biocompatibility, and lighting characteristics of the device must be controlled by a performance standard to prevent injury to the patient resulting from devices of improper design or construction. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

6. Section 876.1620; 78N–1950; Urodynamics measurement system. FDA published in the **Federal Register** (46 FR 7573) a proposed regulation to classify the urodynamics measurement system into class II. The one comment received on the proposal suggested that the urodynamics measurement system be classified into class I rather than class II as was proposed. The comment believed that the establishment of a performance standard for the device may stop the development of new or improved devices.

FDA disagrees with the comment. FDA believes that issuance of a final regulation to classify the urodynamics measurement system into class II will not prevent the development of new or improved devices. Classifying a device, in itself, has a limited impact, which is described at the conclusion of this preamble. Moreover, the agency believes that the urodynamics measurement system should be classified into class II because the design and construction of the device must be controlled by a performance standard to ensure that air or other insoluble gas does not enter the system, that the amount and pressure of the delivered carbon dioxide or water do not overdistend the bladder, that the device can be properly cleaned and sterilized to prevent infection, that electrical properties are controlled to prevent electrical injury to the patient or the operator, and that measurement results are accurate to prevent development of inaccurate diagnostic information. Any performance standard that might be developed must be periodically evaluated to determine if it should be changed to reflect new medical, scientific, or other technological data (21 U.S.C. 360d(a)(4)). Expedited procedures are available to amend standards (21 U.S.C. 360(g)(4)(B)). Accordingly, the proposed regulation is being adopted with a minor clarifying change.

7. Section 876.1800; 78N–1964; Urine flow or volume measuring system. FDA published in the **Federal Register** (46 FR 7575) a proposed regulation to classify the urine flow or volume measuring system into class II. The one comment received on the proposal suggested that the urine flow or volume measuring system be classified into class I rather than class II as was proposed. The comment stated that the device is noninvasive and that it is unnecessary for the device to provide precise measurements.

FDA disagrees with the comments. Many users of the device may not routinely require a high degree of measurement accuracy of urine flow or volume. However, FDA believes that on those occasions when measurement accuracy is required, the user should be able to determine readily the measurement accuracy. Additionally, FDA believes that a performance standard is necessary to control the electrical properties of the device to prevent electrical injury to the patient or the operator and to enable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

Section 876.3630; 78N–1979; Penile rigidity implant. FDA published in the **Federal Register** (46 FR 7578) a proposed regulation to classify the penile rigidity implant into class III. Two comments were received on the proposal.

a. One comment stated that FDA was incorrect in its description of the Section's classification recommendations for the penile rigidity implant, because the Section recommended that the device be classified into class II, not class III as stated in the proposed regulation.

FDA agrees with the comment. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology Device Section of the General Medical Devices Panel to discuss the classification of the penile rigidity implant and other devices. During the Section meeting, the Section again recommended that the penile rigidity implant be classified into class II. FDA continues to believe, nevertheless, that the penile rigidity implant should be classified into class III. Since the Section meeting, FDA has searched the medical literature and has documented further the risks to health resulting from silicone implants (Refs. 1 through 8), as noted below.

b. A comment suggested that the penile rigidity implant be classified into class II rather than class III as was proposed. The comment stated that clinical experience with the device and available data fully support classification of the device into class II and that standards can be established that would assure its safety and effectiveness. The comment stated that the problems which occur with use of the implant are most likely the result of improper implantation, rather than inadequate performance of the device.

FDA disagrees with the comment. FDA recognizes the long history of use of this device, as well as other prostheses made of similar materials and having similar construction. FDA has examined recent scientific data available concerning silicone implants and the migration of silicone in the body. The fate and importance of the

migrated silicone in the human body are currently incompletely understood and controversial. There are many reports (Refs. 1 through 8) which contain data concerning the harmful effects of silicone with respect to biological catabolism. Some of these reports reveal occurrence of allergic reaction (Ref. 1), silicone lymphadenoma (Refs. 2, 3, and 4), morbidity due to silicone (Refs. 5 and 6), and silicone migration (Refs. 7 and 8). FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of the device. In addition, the device is purported or represented to be for use (treatment of sexual dysfunction) that is of substantial importance in preventing impairment of human health, even though implantation of the device in the treatment of erectile impotence is discretionary. Furthermore, the device is an implant, which the act (21 U.S.C. 360c(d)) requires to be classified into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Because use of the device is discretionary, FDA believes that its use must be balanced against the risks presented by unknown long-term effects of silicone migration in the body—of which a physician should fully inform the patient before the patient decides whether to have the device implanted. Accordingly, the proposed regulation is being adopted without change.

9. Section 876.3750; 78N–1981; Testicular prosthesis. FDA published in the **Federal Register** (46 FR 7580) a proposed regulation to classify the testicular prosthesis into class III. Five comments were received on the proposal.

a. One comment stated that FDA was incorrect in its description of the Section's classification recommendations for the testicular prosthesis, because the Section recommended that the device be classified into class II, not class III as stated in the proposed regulation.

FDA agrees with the comment. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology Device Section of the General Medical Devices Panel to discuss the classification of the testicular prosthesis and other devices. During the Section meeting, the Section again recommended that the testicular prosthesis be classified into class II. FDA continues to believe, nevertheless, that the testicular prosthesis should be classified into class III. Since the Section meeting, FDA has searched the medical literature and has documented further the risks to health resulting from silicone implants (Refs. 1 through 8), as noted below.

b. Three comments suggested that the testicular prosthesis should be classified into class II rather than class III as was proposed. Additionally, one comment stated that no ill effects had been observed following implantation of the device during the 20 years of clinical experience with it. Further, the comment stated that standards can be established that would assure its safety and effectiveness. The comment said that there are no reports of the release of extremely minute quantities of silicone from an intact prosthesis, but if there were such reports, there would not be any basis for clinical concern about them. The comment stated that classifying the device into class III would not resolve any of the agency's concerns about the unknown long-term effects of implanting the device.

FDA disagrees with the comments. FDA recognizes the long history of use of this device, as well as other prostheses made of similar materials and having similar construction. FDA has examined recent scientific data available concerning silicone implants and the migration of silicone in the body following the bleeding of the silicone gel through the silicone shell of a device. The fate and importance of the migrated silicone in the human body are currently incompletely understood and controversial. There are many reports (Refs. 1 through 8) which contain data concerning the harmful effects of silicone with respect to biological catabolism. Some of these reports reveal occurrence of allergic reactions (Ref. 1), silicone lymphadenoma (Refs. 2, 3, and 4), morbidity due to silicone (Refs. 5 and 6), and silicone migration (Refs. 7 and 8). The device presents a potential unreasonable risk of illness or injury to the patient. The silicone within the prosthesis may migrate in the body of the patient, as described above, with unknown long-term effects. Furthermore, the device is an implant which the act (21 U.S.C. 360c(d)) requires to be classified into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of a device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary for the device because FDA believes that the device presents a potential unreasonable risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of the device. In addition, the device is purported or represented to be for a use (reconstructive surgery) that is of substantial importance in preventing impairment of human health, even though implantion of the testicular prosthesis is discretionary cosmetic surgery. The agency has determined that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because use of the device is discretionary, use of the device must be balanced against the long-term unknown effects of silicone migration in the body—of which a physician should fully inform the patient before the patient decides whether to have the device implanted.

c. One comment stated that the occasional migration of silicone from a silicone gel-filled prosthesis should not cause the agency to classify the solid silicone testicular prosthesis into class III. Therefore, the comment suggested that the solid silicone testicular prosthesis be classified into class II instead of class III.

FDA disagrees with the comment. Recent reports in the medical literature (Refs. 3 and 4) reveal instances of silicone migration in the body from solid implants. Therefore, FDA believes that both the solid and the gel filled types of the device should be classified into class III. Accordingly, the proposed regulation is being adopted without change.

10. Section 876.4020; 78N–1947; Fiberoptic light ureteral catheter. FDA published in the **Federal Register** (46 FR 7581) a proposed regulation to classify the fiberoptic light ureteral catheter into class II. The one comment received on the proposal suggested that the fiberoptic light ureteral catheter be classified into class I rather than class II as was proposed. The comment stated that this device is no more complex than

the ureteral catheter without a fiberoptic light.

FDA disagrees with the comment's suggestion about classifying the device into class I. FDA believes that characteristics of the fiberoptic light ureteral catheter, such as the shape, size, rigidity, flexibility, surface finish, and the light intensity produced, must be controlled by a performance standard to prevent trauma, hemorrhage, or perforation, and to enable the device to be properly cleaned and sterilized to prevent infection. Elsewhere in this final rule (§ 876.5130), FDA is also classifying the ureteral catheter without a fiberoptic light into class II. Accordingly, the proposed regulation is being adopted without change.

11. Section 876.4370; 78N–1994; Gastroenterology-urology evacuator. FDA published in the **Federal Register** (46 FR 7585) a proposed regulation to classify the gastroenterology-urology evacuator into class II. The one comment received on the proposal suggested that the gastroenterology-rurology evacuator be classified into class I rather than class II as was proposed. The comment stated that this is a simple device and that establishment of a performance standard will not prevent its misuse.

FDA partially agrees with the comment. FDA now believes that the gastroenterology-urology evacuator when manually powered, should be classified into class I rather than class II as was proposed. FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manually powered device. FDA disagrees with the comment's suggestion that all gastroenterology-urology evacuators, even those that are other than manually powered, be classified into class I. FDA believes that a performance standard is necessary for the device when it is other than manually powered. The performance standard is necessary to control the design and construction of the device to prevent excessive irrigant pressure in the bladder of the patient during irrigant instillation. The electrical properties of the device must be controlled by a standard to prevent electrical injury to the patient or the operator. In this final rule, the agency is classifying into class I the gastroenterology-urology evacuator, a simple device when manually powered, and classifying the device into class II, when other than manually powered. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the changes in identification and classification described above.

12. Section 876.4500; 78N–2001; Mechanical lithotriptor. FDA published in the **Federal Register** (46 FR 7588) a proposed regulation to classify the mechanical lithotriptor into class II. The one comment received on the proposal suggested that the mechanical lithotriptor be classified into class I rather than class II as was proposed. The comment stated the device may be extremely dangerous and that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with this device may be due to unskilled users, the agency believes that the mechanical lithotriptor should be classified into class II because the mechanical design and performance of the device, especially the jaws, must be controlled by a performance standard to prevent injury to the patient. Also, the design and construction of the device must be controlled by standards to ensure that it can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

13. Section 876.4560; 78N–2067; Ribdam. FDA published in the **Federal Register** (46 FR 7590) a proposed regulation to classify the ribdam into class II. The one comment received on the proposal suggested that the ribdam be classified into class I rather than class II as was proposed. The comment stated that these devices are only large surgical rubber drains which can be cut to any size when copious drainage is expected.

FDA agrees with the comment. FDA now believes that ribdams should be classified into class I, because general controls, particularly GMP requirements, are sufficient to assure proper construction, continued use of known biocompatible materials, and uniform bulk, and thus will provide reasonable assurance of the safety and effectiveness of this simple device. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change.

14. Section 876.4590; 78N–2068; Interlocking urethral sound. FDA published in the **Federal Register** (46 FR 7591) a proposed regulation to classify the interlocking urethral sound into class II. The one comment received on the proposal suggested that the interlocking urethral sound be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the interlocking urethral sound should be classified into class II because the design of the device must be controlled by a performance standard to prevent further injury to the urethra of the patient and to ensure that the device may be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

15. Section 876.4620; 78N–1984; Ureteral stent. FDA published in the **Federal Register** (46 FR 7592) a proposed regulation to classify the ureteral stent into class II. The one comment received on the proposal suggested that the ureteral stent be classified into class I rather than class II as was proposed. The comment stated that performance standards for the device would be extremely difficult to develop because there are so many diverse designs of the device.

FDA disagrees with the comment. Although FDA recognizes the wide diversity of designs of this generic device, the agency believes that present among the various designs are enough common features to allow the establishment of a performance standard. FDA believes that the design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, perforation, or migration of the device, and to anable the device to be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

16. Section 876.4650; 78N–1988; Water jet renal stone dislodger system. FDA published in the **Federal Register** (46 FR 7593) a proposed regulation to classify the water jet renal stone dislodger system into class II. The one comment received on the proposal suggested that the water jet renal stone dislodger system be classified into class I rather than class II as was proposed. The comment asserted that the data needed to establish a performance standard for the device are not currently available.

FDA disagrees with the comment. The agency believes that a performance standard for the device is necessary to prevent kidney damage that may result from excessive water pressure delivered by the device and to enable it to be properly cleaned and sterilized to prevent infection. FDA also believes that there is sufficient information available to develop a performance standard for the device. Accordingly, the proposed regulation is being adopted without change.

17. Section 876.4730; 78N–1996; Manual gastroenterology-urology surgical instrument and accessories. FDA published in the **Federal Register** (46 FR 7595) a proposed regulation to classify the manual gastroenterology-urology surgical instrument and accessories into class I without exemptions. The one comment received on the proposal agreed with the proposed classification. Accordingly, the proposed regulation is being adopted without change.

18. Section 876.4770; 78N–2004; Urethrotome. FDA published in the **Federal Register** (46 FR 7597) a proposed regulation to classify the urethrotome into class II. The one comment received on the proposal suggested that the urethrotome be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the urethrotome should be classified into class II because the design of the cutting blade, together with its associated complex mechanical linkages and lighting system, must be controlled by a performance standard to prevent injury to the patient or the operator. Also, the design and construction must be controlled by standards to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

19. Section 876.4890; 78N–2070; Urological table and accessories. FDA published in the **Federal Register** (46 FR 7598) a proposed regulation to classify the urological table and accessories into class II. The one comment received on the proposal suggested that the urological table and accessories be classified into class I rather than class II as was proposed. The comment stated that performance standards would not improve the safety and effectiveness of manually powered urological tables and their accessories.

FDA partially agrees with the comment. FDA now believes that manually powered urological tables and accessories should be classified into class I, because any defects in the relatively simple manually powered urological table and accessories are readily apparent to the user, and the agency is therefore classifying the manually powered device to class I. FDA has determined that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the manually powered device. FDA disagrees with comment's suggestion that the electrically powered urological table and its accessories be classified into class I. FDA believes that the electrical properties of the device must be controlled by a performance standard to prevent electrical injury to the patient or operator.

In sum, the final rule classifies the urological table and accessories into class I when manually powered and into class II when electrically powered. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the changes in identification and classification described above.

20. Section 876.5030; 78N–1972; Continent ileostomy catheter. FDA published in the **Federal Register** (46 FR 7600) a proposed regulation to classify the continent ileostomy catheter into class II. The one comment received on the proposal suggested that the continent ileostomy catheter be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA agrees with the comment. The agency now believes that the continent ileostomy catheter should be classified into class I. FDA has determined that general controls, particularly requirements of current GMP regulations, are sufficient to control the risk of infection and otherwise will provide reasonable assurance of the safety and effectiveness of the device. The agency also agrees that the principal hazard associated with the use of the device may be due to unskilled users. In the final rule, the agency is classifying the continent ileostomy catheter into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification.

21. Section 876.5090; 78N–1989; Suprapubic urological catheter and accessories. FDA published in the **Federal Register** (46 FR 7601) a proposed regulation to classify the suprapubic urological catheter and accessories into class II. The one comment received on the proposal suggested that the suprapubic urological catheter and accessories be classified into class I rather than class II as was proposed. The comment stated that use of the device may be extremely hazardous to patients; however, the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the suprapubic urological catheter and accessories should be classified into class II because the shape, size, rigidity, surface finish, and strength of the device must be controlled by performance standard to prevent injury to the patient resulting from a device of improper design or construction and to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

22. Section 876.5130; 78N–2006; Urological catheter and accessories. FDA published in the **Federal Register** (46 FR 7602) a proposed regulation to classify the urological catheters and accessories into class II. The one comment received on the proposal suggested that the urological catheter and accessories be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA partially agrees with the comment. Although the principal hazard associated with the use of the device may be due to unskilled users, the agency believes that the urological catheter and accessories should be classified into class II because the shape, size, rigidity, surface finish, and strength of the device must be controlled by a performance standard to prevent injury to the patient resulting from devices of improper design or construction and to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted without change.

23. Section 876.5160; 78N–2009; Urological clamp for males. FDA published in the **Federal Register** (46 FR 7603) a proposed regulation to classify the urological clamp for males into class II. The one comment received on the proposal suggested that the urological clamp for males be classified into class I rather than class II as was proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction.

FDA agrees with the comment. FDA now believes that the urological clamp for males should be classified into class I. The agency believes that general controls, particularly requirements of current GMP regulations, are sufficient to ensure consistency of clamping pressure and the continued use of known biocompatible materials for this simple device and thus will provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that the principal hazards associated with the use of the device may be due to unskilled users. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA believes that it is unnecessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification.

24. Section 876.5220; 78N–2011; Colonic irrigation system. FDA published in the **Federal Register** (46 FR 7606) a proposed regulation to classify the colonic irrigation system into class II when intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations, and into class III when intended for all other uses, including use routinely for general well being. The one comment received on the proposal agreed with the classification set forth in the proposed regulation. The comment also was presented at the meeting on April 13, 1981 of the Gastroenterology-Urology Device Section. The comment described several risks and hazards concerning the use of the colonic irrigation system. The comment emphasized the need for appropriate labeling for the device.

FDA agrees with the comment. FDA believes that the risks to health presented by the colonic irrigation system will be controlled through the establishment of a performance standard for the device when it is intended for colon cleansing when medically indicated and premarket approval of the device when intended for other uses, including colon cleansing for general well being. Accordingly, the proposed regulation is being adopted without change.

25. Section 876.5250; 78N–2010; Urine collector and accessories. FDA published in the **Federal Register** (46 FR 7607) a proposed regulation to classify the urine collector and accessories into class II. Four comments were received on the proposal.

a. One comment suggested that the urine collector and accessories be divided into two categories, depending upon whether it is intended for external or internal use. The comment suggested that the urine collector and accessories intended for external use be classified into class I rather than into class II as was proposed and that the urine collector and accessories intended for connection to an indwelling catheter be classified into class II. The comment stated that when the device is not intended for connection to an indwelling catheter, general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A second comment stated that the development of a performance standard for a urine collector intended for external use is unlikely to improve the safety and effectiveness of the device; therefore, the device should be classified into class I when not intended for connection to an indwelling catheter.

FDA agrees with both comments. FDA now believes that general controls, particularly requirements of the current GMP regulations, are sufficient to control the risks to health, such as infection, presented by the urine collector and accessories when it is not intended for connection to an indwelling catheter. Therefore, FDA is changing the identification of the urine collector and accessories to divide the generic device into two categories, depending upon whether or not it is intended for connection to an indwelling catheter. In the final rule, when the device is not intended for connection to an indwelling catheter, it is classified into class I; and when the device is intended for connection to an indwelling catheter, it is classified into class II. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal regarding this decision.

b. A comment suggested that some urinary drainage bags (defined as sterile, disposable, single use, urine collectors) be classified into class I and that others, such as incontinence devices and leg bags, should remain in class II. The comment stated that some urinary drainage bags have no physical contact with the patient until they are attached to an indwelling catheter. The comment also objected to including the urinary drainage bag in the generic type of device, urine collector and accessories, because the urinary drainage bag alone does not cause the risk to health of infection that is associated with the device, as stated in the proposed regulation.

FDA disagrees with the comment. FDA believes that the design, construction, and performance of the urinary drainage bag in the urine collector system has an influence on both the microbial count of the urine in the urinary drainage bag and the rate of infection in patients using the urine collector and accessories when connected to an indwelling catheter. FDA has searched the medical literature and documented the risks of infection to patients that are presented by a urine collector and accessories when connected to an indwelling catheter (Refs. 9 through 13). The literature review shows that patients using a urine collector attached to an indwelling catheter frequently develop infections of the urinary tract with possible serious health risks. The literature states that certain design and construction characteristics, such use of anti-reflex valves, special venting systems, closed irrigation sites, ports to add disinfectants, drainage tubes designed to prevent access of bacteria to the bag, and sample collection ports, all may aid in the reduction of the potential of infection presented by the device (Refs. 9, 11, and 13). Therefore, FDA has determined that the urinary drainage bag should be included in the generic device, the urine collector and accessories. FDA believes that a performance standard is necessary to control the risks to health presented by the urine collector and accessories intended for connection to an indwelling catheter.

c. A comment requested that the urine collector and accessories for external use be exempt from the current GMP regulations. The comment stated that, based on current manufacturing practices and user experience with the device, application of the current GMP regulations is unlikely to improve the safety or effectiveness of the urine collector and accessories not intended for connection to an indwelling catheter.

FDA agees with the comment. FDA believes that the quality and any defects of the urine collector and accessories not intended for connection to an indwelling catheter are readily apparent to the user and that general controls alone are sufficient to provide reasonable assurance of the safety and

effectiveness of the device. Therefore, the agency has determined that a manufacturer of a urine collector and accessories that is not intended for connection to an indwelling catheter and that is not labeled or otherwise represented as sterile be exempt, in the manufacture of the device, from all requirements in the current GMP regulations except § 820.180 with respect to general requirements concerning records, and § 820.198 with respect to complaint files. The agency believes that such a manufacturer must still be required to comply with complaint file requirements, to insure that the manufacturer has an adequate system for complaint investigation and followup, and with the general requirements concerning records, to insure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, and can determine whether the exemption from other sections of the current GMP regulations is still appropriate. A manufacturer of a urine collector and accessories that is labeled or otherwise represented as sterile, whether or not intended for connection to an indwelling catheter, is, in the manufacture of this device, subject to the current GMP regulations in their entirety. Accordingly, the proposed regulation is being adopted with the changes in identification, classification, and exemptions described above.

26. Section 876.5320; 78N–2069; Nonimplanted electrical continence devise. FDA published in the **Federal Register** (46 FR 7611) a proposed regulation to classify the nonimplanted electrical continence device into class III. The one comment received on the proposal suggested that the nonimplanted electrical continence device be classified into class II rather than class III as was proposed. The comment stated that the low-level current and voltage used in the device are harmless and the effects are local. It is mainly used to increase patient awareness of incontinence by conditioning or biofeedback. Further, the comment stated the device is safe and essentially used externally.

FDA agrees with the comment. Therefore, FDA now believes that the concerns of the Obstetrical and Gynecological Device Classification Panel about the safety and effectiveness of the device apply to AC-powered devices. FDA is unaware of any nonimplanted electrical continence device that is AC-powered. Accordingly, the Panel's concerns do not apply to battery-operated electrical continence devices, which produce a safe, low level of electrical current and have been shown to be effective in properly selected patients (Ref. 14) and thus do not provide a potential unreasonable risk of illness or injury to the patient. FDA believes that establishment of performance standards for the device will control the electrical currents produced by the battery-powered device and will provide reasonable assurance of the safety and effectiveness of the device. FDA believes that sufficient information exists to establish performance standards for the battery-powered nonimplanted electrical continence device. The agency also believes that general controls are insufficient to assure the safety and effectiveness of the battery-powered device.

In the final rule, the agency is classifying the device into class II instead of class III as was proposed. For the reasons stated above in this preamble, FDA does not believe it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the change in classification described above and a clarifying change in identification.

27. Section 876.5520; 78N–2059; Urethral dilator. FDA published in the **Federal Register** (46 FR 7615) a proposed regulation to classify the urethral dilator into class II. The one comment received on the proposal suggested that the urethral dilator be classified into class I rather than class II as was proposed, because class I is more appropriate due to the long history of use of the device.

FDA disagrees with the comment. FDA believes that the design and construction of the device and the materials used in the device must be controlled by a performance standard to ensure that the size, shape, rigidity, flexibility, surface finish, and strength of the device are appropriate to prevent trauma, hemorrhage, or perforation. The calibration must be controlled to prevent overdilation of the urethra. The design and construction must be controlled to ensure that the device can be properly cleaned and sterilized to prevent infection. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

28. Section 876.5540; 78N–2044; Blood access device and accessories. FDA published in the **Federal Register** (46 FR 7616) a proposed regulation to classify the implanted blood access device and accessories into class III and the nonimplanted blood access device and accessories into class II. The one comment received on the proposal stated that the final regulation classifying blood access devices and accessories should not be published, because it will prevent the development of improved devices and hamper technological advances in the field of nephrology.

FDA disagrees with the comment. FDA believes that issuance of a final regulation to classify the blood access device and accessories will not prevent the development of new or improved devices. Classifying a device, in itself, has a limited impact, which is described at the conclusion of this preamble. However, on its own initiative, FDA classified into class II the accessories to the implanted blood access device, because the agency now believes that performance standards are sufficient to control the risks to health presented by the accessories to both the implanted and the nonimplanted device. For the reasons stated above in this preamble, FDA does not believe it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with the noted change in classification and clarifying changes in the identification of the device.

29. Section 876.5665; 78N–2047; Water purification system for hemodialysis. FDA published in the **Federal Register** (46 FR 7622) a proposed regulation to classify the water purification system for hemodialysis into class II. The one comment received on the proposal suggested that the water purification system for hemodialysis be classified into class I rather than class II as was proposed. The comment asserted that the device has been used in hemodialysis for over 15 years, during which time there have been no major problems associated with its use. The comment also stated that the general controls of class I are sufficient to assure the safety and effectiveness of the water purification system for hemodialysis.

FDA disagrees with the comment. In the proposed regulation to classify into class II the water purification system for hemodialysis, FDA cited the risks to health of both toxic and pyrogenic reactions. Several other hazards associated with the device are described in the contract report cited in the proposed regulation. FDA believes that the design and construction of the device and the materials used in the device must be controlled by a performance standard to ensure that the device delivers properly purified water to prevent toxic or pyrogenic reactions in the patient and to enable the device to be properly cleaned and sterilized to

prevent infection. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

30. Section 876.5820; 78N–2014; Hemodialysis system and accessories. FDA published in the **Federal Register** (46 FR 7623) a proposed regulation to classify the hemodialysis system and accessories into class II. The regulation proposed to classify certain accessories into class II and other accessories into class I. Two comments were received on the proposal.

a. One comment agreed with the classification of the hemodialysis system and certain accessories into class II. The comment also requested that FDA clarify a statement in paragraph 3 of the preamble to the proposed regulation. The statement was in the summary of the reasons that the Section recommended that the extraluminal blood pump and its accessories be classified into class II.

FDA agrees with the comment. Clarification is needed, and the sentence identified should read as follows: "The design and construction of the extraluminal blood pump and its accessories must be controlled by a performance standard to prevent damage to blood cells or inadequate blood flow due to improper design, and to prevent blood loss due to poor fitting connections or laceration of the tubing."

b. One comment noted that dialysate or dialysate concentrate for hemodialysis was excluded from the proposed classification regulations. The comment further stated that dialysate concentrate should be classified in class II and included in the hemodialysis system and accessories.

FDA agrees with the comment. Dialysate concentrate for hemodialysis is considered to be part of the hemodialysis system and was not specifically identified in the proposed classification regulations. However, in the interest of clarity, FDA is revising the regulation to include dialysate concentrate for hemodialysis by name. FDA is unaware of the commercial marketing of dialysate. Dialysate concentrate for hemodialysis is used (following its dilution with suitable water to make dialysate) in all of the hemodialysis delivery systems classified in this final rule, e.g., § 876.5600 *Sorbent regenerated dialysate delivery system for hemodialysis.* Additionally, as a further point of clarification, it is pointed out that prepackaged dialysis solutions and concentrates that are intended to be introduced directly into the body (e.g., for peritoneal dialysis) are subject to regulation as drugs. The agency has changed the identification of the hemodialysis system and accessories to include dialysate concentrate as part of the dialysate delivery system in the hemodialysis system and accessories. Accordingly, the proposed regulation is being adopted with clarifying changes in the identification of the device.

31. Section 876.5895; 78N–1975; Ostomy irrigator. FDA published in the **Federal Register** (46 FR 7632) a proposed regulation to classify the ostomy irrigator into class II. The one comment received on the proposal suggested that the ostomy irrigator be classified into class I rather than class II as was proposed. The comment stated that the device is simple, made of proven materials, and that no complaints of tissue irritation, trauma, hemorrhage, or perforation had been received due to the device between 1967 and 1980. The comment said that any adverse effects are essentially caused by misuse or abuse of the device by users. The comment stated that the size or shape of the irrigating cone had little relationship to the prevention of leakage of stool or irrigant solutions.

FDA disagrees with the comment. FDA believes that the ostomy irrigator should be classified into class II because the design, materials, and construction of the device must be controlled by a performance standard to ensure that the shape, size, rigidity, flexibility, surface finish, and strength of the device will not cause trauma, hemorrhage, or perforation, or allow leakage of stool or irrigant solution that may cause skin irritation. Although adverse effects may occur due to misuse or abuse of the device by users, FDA believes that general controls are insufficient to control the risks to health presented by the device and the establishment of a performance standard would minimize the risks. Accordingly, the proposed regulation is being adopted without change.

32. Section 876.5900; 78N–1974; Ostomy pouch and accessories. FDA published in the **Federal Register** (46 FR 7633) a proposed regulation to classify the ostomy pouch and accessories into class II. The one comment received on the proposal suggested that the ostomy pouch and accessories be classified into class I rather than class II as was proposed. The comment further stated that the only possible cause of adverse tissue reaction can be the adhesive, and that a review of the company's complaint files for 5 years indicated that the incidence of skin irritation is about 0.00002 percent, with no systemic toxic effects reported. The comment also stated that the design and construction of the ostomy pouch had little to do with the prevention of leakage, slippage, or damage to the stoma.

FDA agrees with the comment. FDA now believes that the ostomy pouch and accessories should be classified into class I. In the final rule, the agency is classifying the device into class I instead of class II as was proposed. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. As stated in the proposed regulation to classify the ostomy pouch and accessories, the General Hospital and Personal Use Device Section of the General Medical Devices Panel recommended that the ostomy pouch and accessories be exempt from the current GMP regulations (21 CFR Part 820) under section 520(f) of the act. The agency disagrees with this recommendation and believes that compliance with the current GMP regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the current GMP regulations will help prevent production of ostomy pouches and accessories having defects, such as containers that leak, and will ensure the continued use of known biocompatible materials in this relatively simple device. Accordingly, the proposed regulation is being adopted with the change in classification described above and a minor clarifying change.

33. Section 876.5920; 78N–2062; Protective garment for incontinence. FDA published in the **Federal Register** (46 FR 7635) a proposed regulation to classify the protective garment for incontinence into class I. Five comments were received on the proposal.

a. One comment agreed with the proposed classification of the protective garment for incontinence into class I.

b. One comment stated that FDA was incorrect in its description of the Section's classification recommendation for the protective garment for incontinence, because the Section recommended that the device be classified into class II, not class I as stated in the proposed regulation.

FDA agrees with the comment stating that FDA was incorrect in its description of the Section's classification recommendation. Because the comment was correct, the agency published a correction, stated its disagreement with the Section, and reopened the comment period for the proposed classification regulation for this device in the **Federal Register** of April 7, 1981 (46 FR 20687). At the same time, FDA announced that on April 13, 1981 a meeting would be held of the Gastroenterology-Urology

Device Section of the General Medical Devices Panel to discuss the classification of the protective garment for incontinence and other devices. During the Section meeting, the Section recommended that the protective garment for incontinence be classified into class I, thus agreeing with the position taken by FDA in the proposed, and now in the final, rule.

c. Two comments believed that a protective garment for incontinence is not a medical device, as device is defined in section 201(h) of the act (21 U.S.C. 321(h)).

FDA disagrees with the comments. Although incontinence is a normal physiological state in infants, so that a diaper intended for use by infants is not a device, incontinence in persons other than infants is frequently the result of a disease process. Thus, protective garments for incontinence are intended to mitigate the consequences of the disease. Thus, FDA believes that a protective garment for incontinence that is intended for use of persons other than infants is a medical device, as defined in section 201(h) of the act.

d. One comment suggested that the identification of the protective garment for incontinence device be limited to those products that make medical claims in their labeling. The comment was concerned that the protective garment for incontinence may be included as a medical device because of its intended use, rather than because of its labeling claims.

FDA disagrees with the comment. As stated in the preamble to the proposed general provisions (46 FR 7563), FDA will regulate a product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." Section 201(h) of the act (21 U.S.C. 321(h)). FDA will determine the intended use of a multipurpose product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, are regulated as medical whether or not medical claims are made for them. Thus, the agency believes that a protective garment for incontinence that is intended for use of persons other than infants is intended only for medical uses and FDA will regulate the product as a medical device whether or not medical claims are made in its labeling. This determination is consistent with a letter of February 15, 1978 (Ref. 15) sent by FDA's Bureau of Medical Devices to the person who submitted the comment. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

34. Section 876.5955; 78N–1980; Peritoneo-venous shunt. FDA published in the **Federal Register** (46 FR 7636) a proposed regulation to classify the peritoneo-venous shunt into class III. The one comment received on the proposal was orally presented at the meeting on April 13, 1981 of the Gastroenterology-Urology Device Section of the General Medical Devices Panel. The comment agreed that the peritoneo-venous shunt should be classified into class III and stated several risks and hazards associated with the peritoneo-venous shunt. The comment also indicated that classification into class III would permit FDA to attach to its premarket approval orders any restrictions necessary on the sale, distribution, or use of the device to assure its safety and effectiveness. Further, the comment emphasized the need for complete labeling for the device.

FDA agrees with the comment. Accordingly, the proposed regulation is being adopted without change.

35. Section 876.5970; 78N–1967; Hernia support. FDA published in the **Federal Register** (46 FR 7638) a proposed regulation to classify the hernia support into class II with a partial exemption from the current GMP regulations. Two comments received on the proposal suggested that the hernia support be classified into class I rather than class II as was proposed. One comment further stated that there are no proven risks to health associated with this device and that the real risk to health comes from not wearing a hernia support.

FDA agrees with the suggestion that the hernia support be classified into class I. FDA now believes that the quality and any defects of the device are readily apparent to the user and that general controls alone are sufficient to ensure the continued use of known biocompatible materials and otherwise provide reasonable assurance of the safety and effectiveness of the device. In the final rule, the agency is classifying the device into class I with a partial exemption from the current GMP regulations. For the reasons stated above in this preamble, FDA does not believe that it is necessary to issue a new proposal concerning this decision. Accordingly, the proposed regulation is being adopted with this change in classification and exemptions described above.

References

The following information has been placed in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Pearl, R. M., et al., "Complications following Silicone Injections for Augmentation of the Contours of the Face," *Plastic and Reconstructive Surgery*, 61:888–891, 1978.

2. Kircher, T., "Silicone Lymphadenopathy. A Complication of Silicone Elastomer Finger Joint Prostheses, "*Human Pathology*, 11:240–244, 1980.

3. Christie, A. J., et al., "Silicone Lymphadenopathy and Synovitis. Complications of Silicone Elastomer Finger Joint Prostheses," *Journal of the American Medical Association*, 237:1463–1464, 1977.

4. Christie, A. J., et al., "Recurrence of Silicone Lymphadenopathy," *Journal of the American Medical Association*, 245:1316, 1981.

5. Ellenbogen, R., et al., "Injectable Fluid Silicone Therapy. Human Morbidity and Mortality," *Journal of the American Medical Association*, 234:308–309, 1975.

6. Rudolph, R., et al., "Myofibroblasts and Free Silicone Around Breast Implants," *Plastic and Reconstructive Surgery*, 62:185–196, 1978.

7. Gibbons, D. F., et al., "Wear and Degradation of Retrieved Ultrahigh Molecular Weight Polyethylene and other Polymeric Implants," *In* "Corrosion and Degradation of Implant Materials," B. C. Syrett and A. Acharya (Eds.), pp. 20–40, ASTM STP 684, 1979.

8. Leong, A. S. Y., et al., "Refractile Particles in Liver of Hemodialysis Patients," *Lancet*, 889–890, 1981.

9. Ansell, J. "Some Observations on Catheter Care," *Journal of Chronic Diseases*, 15:675–682, 1962.

10. Maizels, M. and A. J. Schaeffer, "Decreased Incidence of Bacteriuria Associated with Periodic Instillations of Hydrogen Peroxide into the Urethral Catheter Drainage Bag," *Journal of Urology*, 123:841–845, 1981.

11. Stamm, W. E., "Guidelines for Prevention of Catheter Associated Urinary Tract Infections," *Annals of Internal Medicine*, 82:386–390, 1975.

12. Fincke, B. B. and G. Friedland, "Prevention and Management of Infection in the Catheterized Patient," *Urology Clinic of North America*, 3(2)313–321, 1976.

13. Garibaldi, R. A., J. P. Burke, et al., "Factors Predisposing to Bacteriuria During Indwelling Urethral Catheterization," *New England Journal of Medicine*, 291:215–219, 1974.

14. Godec, C. and A. Cass, "Acute Electrical Stimulation for Urinary Incontinence," *Urology*, 12:340–342, 1978.

15. Letter from the Division of Compliance Operations, Bureau of Medical Devices, to a medical device manufacturer, February 15, 1978.

List of Subjects in 21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 876, to read as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

Subpart A—General Provisions

Subpart B—Diagnostic Devices

Subpart C—Monitoring Devices

Subpart D—Prosthetic Devices

Subpart E—Surgical Devices

Subpart F—Therapeutic Devices

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 876.1 Scope.

(a) This part sets forth the classification of gastroenterology-urology 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 provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Diagnostic Devices

§ 876.1075 Gastroenterology-urology biopsy instrument.

(a) *Identification.* A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* Class II (performance standards).

§ 876.1400 Stomach pH electrode.

(a) *Identification.* A stomach pH electrode is a device used to measure intragastric and intraesophageal pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

(b) *Classification.* Class II (performance standards).

§ 876.1500 Endoscope and accessories.

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification

regulations in other parts of the device classification regulations.

(b) *Classification.* Class II (performance standards).

§ 876.1620 Urodynamics measurement system.

(a) *Identification.* A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydrualic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.

(b) *Classification.* Class II (performance standards).

§ 876.1725 Gastrointestinal motility monitoring system.

(a) *Identification.* A gastrointestinal motility monitoring system is a device used to measure peristalic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

(b) *Identification.* Class II (performance standards).

§ 876.1800 Urine flow or volume measuring system.

(a) *Identification.* A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduct the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.

(b) *Classification.* Class II (performance standards).

Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.

(a) *Identification.* An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.

(b) *Classification.* Class II (performance standards).

Subpart D—Prosthetic Devices

§ 876.3350 Penile inflatable implant.

(a) *Identification.* A penile inflatable implant is a device that consists of two inflatable cylinders implanted in the penis, connected to a reservoir filled with radiopaque fluid implanted in the abdomen, and a subcutaneous manual pump implanted in the scrotum. When the cylinders are inflated, they provide rigidity to the penis. This device is used in the treatment of erectile impotence.

(b) *Classification.* Class III (premarket approval).

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a single semi-rigid rod or a pair of semi-rigid rods implanted in the penis to provide rigidity. It is used in the treatment of erectile impotence.

(b) *Classification.* Class III (permarket approval).

§ 876.3750 Testicular prosthesis.

(a) *Identification.* A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.

(b) *Classification.* Class III (premarket approval).

Subpart E—Surgical Devices

§ 876.4020 Fiberoptic light ureteral catheter.

(a) *Identification.* A fiberoptic light ureteral catheter is a device that consists of a fiberoptic bundle that emits light throughout its length and is shaped so that it can be inserted into the ureter to enable the path of the ureter to be seen during lower abdominal or pelvic surgery.

(b) *Classification.* Class II (performance standards).

§ 876.4270 Colostomy rod.

(a) *Identification.* A colostomy rod is a device used during the loop colostomy procedure. A loop of colon is surgically brought out through the abdominal wall and the stiff colostomy rod is placed through the loop temporarily to keep the colon from slipping back through the surgical opening.

(b) *Classification.* Class II (performance standards).

§ 876.4300 Endoscopic electrosurgical unit and accessories.

(a) *Identification.* An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

(b) *Classification.* Class II (performance standards).

§ 876.4370 Gastroenterology-urology evacuator.

(a) *Identification.* A gastroenterology-urology evacuator is a device used to remove debris and fluids during gastroenterological and urological procedures by drainage, aspiration, or irrigation. This generic type of device includes the fluid evacuator system, manually powered bladder evacuator, and the AC-powered vacuum pump.

(b) *Classification.* (1) Class II (performance standards) for the gastroenterology-urology evacuator when other than manually powered.

(2) Class I (general controls) for the gastroenterology-urology evacuator when manually powered.

§ 876.4400 Hemorrhoidal ligator.

(a) *Identification.* A hemorrhoidal ligator is a device used to cut off the blood flow to hemorrhoidal tissue by means of a ligature or band placed around the hemorrhoid.

(b) *Classification.* Class II (performance standards).

§ 876.4480 Electrohydraulic lithotriptor.

(a) *Identification.* An electrohydraulic lithotriptor is an AC-powered device used to fragment urinary bladder stones. It consists of a high voltage source connected by a cable to a bipolar electrode that is introduced into the

urinary bladder through a cystoscope. The electrode is held against the stone in a water-filled bladder and repeated electrical discharges between the two poles of the electrode cause electrohydraulic shock waves which disintegrate the stone.

(b) *Classification.* Class III (premarket approval).

§ 876.4500 Mechanical lithotriptor.

(a) *Identification.* A mechanical lithotriptor is a device with steel jaws that is inserted into the urinary bladder through the urethra to grasp and crush bladder stones.

(b) *Classification.* Class II (performance standards).

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

(a) *Identification.* A gastroenterology-urology fiberoptic retractor is a device that consists of a mechanical retractor with a fiberoptic light system that is used to illuminate deep surgical sites.

(b) *Classification.* Class I (general controls).

§ 876.4560 Ribdam.

(a) *Identification.* A ribdam is a device that consists of a broad strip of latex with supporting ribs used to drain surgical wounds where copious urine drainage is expected.

(b) *Classification.* Class I (general controls).

§ 876.4590 Interlocking urethal sound.

(a) *Identification.* An interlocking urethral sound is a device that consists of two metal sounds (elongated instruments for exploring or sounding body cavities) with interlocking ends, such as with male and female threads or a rounded point and mating socket, used in the repair of a ruptured urethra. The device may include a protective cap to fit over the metal threads.

(b) *Classification.* Class II (performance standards).

§ 876.4620 Ureteral stent.

(a) *Identification.* A ureteral stent is a tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction.

(b) *Classification.* Class II (performance standards).

§ 876.4650 Water jet renal stone dislodger system.

(a) *Identification.* A water jet renal stone dislodger system is a device used to dislodge stones from renal calyces (recesses of the pelvis of the kidney) by means of a pressurized stream of water through a conduit. The device is used in the surgical removal of kidney stones.

(b) *Classification.* Class II (performance standards).

§ 876.4680 Ureteral stone dislodger.

(a) *Identification.* A ureteral stone dislodger is a device that consists of a bougie or a catheter with an expandable wire basket near the tip, a special flexible tip, or other special construction. It is inserted through a cystoscope and used to entrap and remove stones from the ureter. This generic type of device includes the metal basket and the flexible ureteral stone dislodger.

(b) *Classification.* Class II (performance standards).

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification.* A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop.

(b) *Classification.* Class I (general controls).

§ 876.4770 Urethrotome.

(a) *Identification.* A urethrofome is a device that is inserted into the urethra and used to cut urethral strictures and enlarge the urethra. It is a metal instrument equipped with a dorsal-fin cutting blade which can be elevated from its sheath. Some urethrotomes incorporate an optical channel for visual control.

(b) *Classification.* Class II (performance standards).

§ 876.4890 Urological table and accessories.

(a) *Identification.* A urological table and accessories is a device that consists of a table, stirrups, and belts used to support a patient in a suitable position for endoscopic procedures of the lower urinary tract. The table can be adjusted into position manually or electrically.

(b) *Classification.* (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I (general controls) for the manually powered urological table and accessories.

Subpart F—Therapeutic Devices

§ 876.5010 Biliary catheter and accessories.

(a) *Identification.* A biliary catheter and accessories is a tubular flexible device used for temporary or prolonged drainage of the biliary tract, for splinting of the bile duct during healing, or for preventing stricture of the bile duct. This generic type of device may include a bile collecting bag that is attached to the biliary catheter by a connector and fastened to the patient with a strap.

(b) *Classification.* Class II (performance standards).

§ 876.5030 Continent ileostomy catheter.

(a) *Identification.* A continent ileostomy catheter is a flexible tubular device used as a form during surgery for continent ileostomy and it provides drainage after surgery. Additionally, the device may be inserted periodically by the patient for routine care to empty the ileal pouch. This generic type of device includes the rectal catheter for continent ileostomy.

(b) *Classification.* Class I (general controls).

§ 876.5090 Suprapubic urological catheter and accessories.

(a) *Identification.* A suprapubic urological catheter and accessories is a flexible tubular device that is inserted through the abdominal wall into the urinary bladder with the aid of a trocar and cannula. The device is used to pass fluids to and from the urinary tract. This generic type of device includes the suprapubic catheter and tube, Malecot catheter, catheter punch instrument, suprapubic drainage tube, and the suprapubic cannula and trocar.

(b) *Classification.* Class II (performance standards).

§ 876.5130 Urological catheter and accessories.

(a) *Identification.* A urological catheter and accessories is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract. This generic type of device includes radiopaque urological catheters, ureteral catheters, urethral catheters, coudé catheters, balloon retention type catheters, straight catheters, upper urinary tract catheters, double lumen female urethrographic

catheters, disposable ureteral catheters, male urethrographic catheters, and urological catheter accessories including ureteral catheter stylets, ureteral catheter adapters, ureteral catheter holders, ureteral catheter stylets, ureteral catheterization trays, and the gastro-urological irrigation tray (for urological use).

(b) *Classification.* Class II (performance standards).

§ 876.5160 Urological clamp for males.

(a) *Identification.* A urological clamp for males is a device used to close the urethra of a male to control urinary incontinence or to hold anesthetic or radiography contrast media in the urethra temporarily. It is an external clamp.

(b) *Classification.* Class I (general controls).

§ 876.5210 Enema kit.

(a) *Identification.* An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (§ 876.5220).

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

§ 876.5220 Colonic irrigation system.

(a) *Identification.* A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (§ 876.5210).

(b) *Classification.* (1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations.

(2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.

§ 876.5250 Urine collector and accessories.

(a) *Identification.* A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) a urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.

(b) *Classification.* (1) Class II (performance standards) for a urine collector and accessories intended to be connected to an indwelling catheter.

(2) Class I (general controls) for a urine collector and accessories not intended to be connected to an indwelling catheter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 876.5270 Implanted electrical urinary continence device.

(a) *Identification.* An implanted electrical urinary device is a device intended for treatment of urinary incontinence that consists of a receiver implanted in the abdomen with electrodes for pulsed-stimulation that are implanted either in the bladder wall or in the pelvic floor, and a battery-powered transmitter outside the body.

(b) *Classification.* Class III (premarket approval).

§ 876.5280 Implanted mechanical/hydraulic urinary continence device.

(a) *Identification.* An implanted mechanical/hydraulic urinary continence device is a device used to treat urinary incontinence by the application of continuous or intermittent pressure to occlude the urethra. The totally implanted device may consist of a static pressure pad, or a system with a container of radiopaque fluid in the abdomen and a manual pump and valve under the skin surface that is connected by tubing to an adjustable pressure pad or to a cuff around the urethra. The fluid is pumped as needed from the container to inflate the pad or cuff to pass on the urethra.

(b) *Classification.* Class III (premarket approval).

§ 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (§ 884.5940).

(b) *Classification.* Class II (performance standards).

§ 876.5365 Esophageal dilator.

(a) *Identification.* An esophageal dilator is a device that consists of a cylindrical instrument that may be hollow and weighted with mercury or a metal olive-shaped weight that slides on a guide, such as a string or wire and is used to dilate a stricture of the esophagus. This generic type of device includes esophageal or gastrointestinal bougies and the esophageal dilator (metal olive).

(b) *Classification.* Class II (performance standards).

§ 876.5450 Rectal dilator.

(a) *Identification.* A rectal dilator is a device designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument.

(b) *Classification.* Class II (performance standards).

§ 876.5470 Ureteral dilator.

(a) *Identification.* A ureteral dilator is a device that consists of a specially shaped catheter or bougie and is used to dilate the ureter at the place where a stone has become lodged or to dilate a ureteral stricture.

(b) *Classification.* Class II (performance standards).

§ 876.5520 Urethral dilator.

(a) *Identification.* A urethral dilator is a device that consists of a slender hollow or solid instrument made of metal, plastic, or other suitable material in a cylindrical form and in a range of sizes and flexibilities. The device may include a mechanism to expand the portion of the device in the urethra and indicate the degree of expansion on a dial. It is used to dilate the urethra. This generic type of device includes the mechanical urethral dilator, urological bougies, metal or plastic urethral sound, urethrometer, filiform, and filiform follower.

(b) *Classification.* Class II (performance standards).

§ 876.5540 Blood access device and accessories.

(a) *Identification.* A blood access device and accessories is a device intended to provide access to a patient's blood for hemodialysis or other chronic uses. When used in hemodialysis, it is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis. The device includes implanted blood access devices, nonimplanted blood access devices, and accessories for both the implanted and nonimplanted blood access devices.

(1) The implanted blood access device consists of various flexible or rigid tubes, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes various shunts and connectors specifically designed to provide access to blood, such as the arteriovenous (A–V) shunt cannula and vessel tip.

(2) The nonimplanted blood access device consists of various flexible or rigid tubes, such as catheters, cannulae or hollow needles, which are inserted into appropriate blood vessels or a vascular graft prosthesis (§§ 870.3450 and 870.3460), and are intended to remain in the body for less than 30 days. This generic type of device includes fistula needles, the single needle dialysis set (coaxial flow needle), and the single needle dialysis set (alternating flow needle).

(3) Accessories common to either type include the shunt adaptor, cannula clamp, shunt connector, shunt stabilizer, vessel dilator, disconnect forceps, shunt guard, crimp plier, tube plier, crimp ring, joint ring, fistula adaptor, and declotting tray (including contents).

(b) *Classification.* (1) Class III (premarket approval) for the implanted blood access device.

(2) Class II (performance standards) for the nonimplanted blood access device.

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access device.

§ 876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.

(a) *Identification.* A sorbent regenerated dialysate delivery system for hemodialysis is a device that is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a sorbent cartridge and the means to circulate dialysate through this cartridge and the dialysate compartment of the dialyzer. The device is used with the extracorporeal blood system and the dialyzer of the hemodialysis system and accessories (§ 876.5820). The device includes the means to maintain the temperature, conductivity, electrolyte balance, flow rate and pressure of the dialysate, and alarms to indicate abnormal dialysate conditions. The sorbent cartridge may include absorbent, ion exchange and catalytic materials.

(b) *Classification.* Class II (performance standards).

§ 876.5630 Peritoneal dialysis system and accessories.

(a) *Identification.* (1) A peritoneal dialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that consists of a peritoneal access device, an administration set for peritoneal dialysis, a source of dialysate, and, in some cases, a water purification mechanism. After the dialysate is instilled into the patient's peritoneal cavity, it is allowed to dwell there so that undesirable substances from the patient's blood pass through the lining membrane of the peritoneal cavity into this dialysate. These substances are then removed when the dialysate is drained from the patient. The peritoneal dialysis system may regulate and monitor the dialysate temperature, volume, and delivery rate together with the time course of each cycle of filling, dwell time, and draining of the peritoneal cavity or manual controls may be used. This generic device includes the semiautomatic and the automatic peritoneal delivery system.

(2) The peritoneal access device is a flexible tube that is implanted through the abdominal wall into the peritoneal cavity and that may have attached cuffs to provide anchoring and a skin seal. The device is either a single use peritioneal catheter, intended to remain in the peritoneal cavity for less than 30 days, or a long term peritoneal catheter. Accessories include stylets and trocars to aid in the insertion of the catheter and an obturator to maintain the patency of the surgical fistula in the abdominal wall between treatments.

(3) The disposable administration set for peritoneal dialysis consists of tubing, an optional reservoir bag, and appropriate connectors. It may include a peritoneal dialysate filter to trap and remove contaminating particles.

(4) The source of dialysate may be sterile prepackaged dialysate (for semiautomatic peritoneal dialysate delivery systems or "cycler systems") or dialysate prepared from dialysate concentrate and sterile purified water (for automatic peritoneal dialysate delivery systems or "reverse osmosis" systems). Prepackaged dialysate intended for use with either of the peritoneal dialysate delivery systems is regulated by FDA as a drug.

(b) *Classification.* Class II (performance standards).

§ 876.5665 Water purification system for hemodialysis.

(a) *Identification.* A water purification system for hemodialysis is a device that is intended for use with a hemodialysis system and that is intended to remove organic and inorganic substances and microbial contaminants from water used to dilute dialysate concentrate to form dialysate. This generic type of device may include a water softener, sediment filter, carbon filter, and water distillation system.

(b) *Classification.* Class II (performance standards).

§ 876.5820 Hemodialysis system and accessories.

(a) *Identification.* A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable

membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer.

(1) The extracorporeal blood system and accessories consists of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis (§ 876.5540) to the blood compartment of the dialyzer and back to the patient.

(2) The conventional dialyzer allows a transfer of water and solutes between the blood and the dialysate through the semipermeable membrane. The semipermeable membrane of the conventional dialyzer has a sufficiently low permeability to water that an ultrafiltration controller is not required to prevent excessive loss of water from the patient's blood. This conventional dialyzer does not include hemodialyzers with the disposable inserts (Kiil type) (§ 876.5830) or dialyzers of high permeability (§ 876.5860).

(3) The dialysate delivery system consists of mechanisms that monitor and control the temperature, conductivity, flow rate, and pressure of the dialysate and circulates dialysate through the dialysate compartment of the dialyzer. The dialysate delivery system includes the dialysate concentrate for hemodialysis (liquid or powder) and alarms to indicate abnormal dialysate conditions. This dialysate delivery system does not include the sorbent regenerated dialysate delivery system for hemodialysis (§ 876.5600), the dialysate delivery system of the peritoneal dialysis system and accessories (§ 876.5630), or the controlled dialysate delivery system of the high permeability hemodialysis system § 876.5860).

(4) Remote accessories to the hemodialysis system include the unpowered dialysis chair without a scale, the powered dialysis chair without a scale, the dialyzer holder set, dialysis tie gun and ties, and hemodialysis start/stop tray.

(b) *Classification.* (1) Class II (performance standards) for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system.

(2) Class I (general controls) for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties.

§ 876.5830 Hemodialyzer with disposable insert (kiil type).

(a) *Identification.* A hemodialyzer with disposable inserts (Kiil type) is a device that is used as a part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that includes disposable inserts consisting of layers of semipermeable membranes which are sandwiched between support plates. The device is used with the extracorporeal blood system and the dialysate delivery system of the hemodialysis system and accessories (§ 897.5820).

(b) *Classification.* Class II (performance standards).

§ 876.5860 High permeability hemodialysis system.

(a) *Identification.* A high permeability hemodialysis system is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions, and that has a dialyzer with a semipermeable membrane that is more permeable to water than the semipermeable membrane of the conventional dialyzer. The device system consists of an extracorporeal blood system, a high permeability dialyzer, and a controlled dialysate delivery system that incorporates an ultrafiltration controller to prevent excessive loss of water from the patient's blood. This highly permeable, semipermeable membrane may also permit greater loss of higher molecular weight substances from the blood, compared with the conventional dialyzer of the hemodialysis system and accessories (§ 876.5820). The extracorporeal blood system is the same generic type of extracorporeal blood system that is used in the hemodialysis system and accessories (§ 876.5820). The controlled dialysate delivery system also is similar to the conventional disalysate delivery system of the hemodialysis system and accessories (§ 876.5820), with the addition of an ultrafiltration controller to regulate the rate of the removal of water from the patient's blood and ensure that the pressure on the dialysate side of the membrane is always lower than on the blood side. This generic type of device includes the sealed dialysate delivery system.

(b) *Classification.* Class III (premarket approval).

§ 876.5870 Sorbent hemoperfusion system.

(a) *Identification.* A sorbent hemoperfusion system is a device that consists of an extracorporeal blood system similar to that identified in the hemodialysis system and accessories (§ 876.5820) and a container filled with adsorbent material that removes a wide range of substances, both toxic and normal, from blood flowing through it. The adsorbent materials are usually activated-carbon or resins which may be coated or immobilized to prevent fine particles entering the patient's blood. The generic type of device may include lines and filters specifically designed to connect the device to the extracorporeal blood system. The device is used in the treatment of poisoning, drug overdose, hepatic coma, or metabolic disturbances.

(b) *Classification.* Class III (premarket approval).

§ 876.5880 Isolated kidney perfusion and transport system and accessories.

(a) *Identification.* An isolated kidney perfusion and transport system and accesssories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

(b) *Classification.* Class II (performance standards).

§ 876.5895 Ostomy irrigator.

(a) *Identification.* An ostomy irrigator is a device that consists of a container for fluid, tubing with a cone-shaped tip or a soft and flexible catheter with a retention shield and that is used to wash out the colon through a colostomy, a surgically created opening of the colon on the surface of the body.

(b) *Classification.* Class II (performance standards).

§ 876.5900 Ostomy pouch and accessories.

(a) *Identification.* An ostomy pouch and accessories is a device that consists of a bag that is attached to the patient's skin by an adhesive material and that is intended for use as a receptacle for collection of fecal material or urine following an ileostomy, colostomy, or ureterostomy (a surgically created opening of the small intestine, large intestine, or the ureter on the surface of the body). This generic type of device and its accessories includes the ostomy pouch, ostomy adhesive, the disposable colostomy appliance, ostomy collector, colostomy pouch, urinary ileostomy bag, urine collecting ureterostomy bag,

ostomy drainage bag with adhesive, stomal bag, ostomy protector, and the ostomy size selector, but excludes ostomy pouches which incorporate arsenic-containing compounds.

(b) *Classification.* Class I (general controls).

§ 876.5920 Protective garment for incontinence.

(a) *Identification.* A protective garment for incontinence is a device that consists of absorbent padding and a fluid barrier and that is intended to protect an incontinent patient's garment from the patient's excreta. This generic type of device does not include diapers for infants.

(b) *Classification.* Class I (general controls). 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.

§ 876.5955 Peritoneo-venous shunt.

(a) *Identification.* A peritoneo-venous shunt is an implanted device that consists of a catheter and a pressure activated one-way valve. The catheter is implanted with one end in the peritoneal cavity and the other in a large vein. This device enables ascitic fluid in the peritoneal cavity to flow into the venous system for the treatment of intractable ascites.

(b) *Classification.* Class III (premarket approval).

§ 876.5970 Hernia support

(a) *Identification.* A hernia support is a device, usually made of elastic, canvas, leather, or metal, that is intended to be placed over a hernial opening (a weakness in the abdominal wall) to prevent protrusion of the abdominal contents. This generic type of device includes the umbilical truss.

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

§ 876.5980 Gastrointestinal tube and accessories

(a) *Identification.* A gastrointestinal tube and accessories is a device that consists of flexible or semi-rigid tubing used for instilling fluids into, withdrawing fluids from, splinting, or suppressing bleeding of the alimentary tract. This device may incorporate an integral inflatable balloon for retention or hemostasis. This generic type of device includes the hemostatic bag, irrigation and aspiration catheter (gastric, colonic, etc.), rectal catheter, sterile infant gavage set, gastrointestinal string and tubes to locate internal bleeding, double lumen tube for intestinal decompression or intubation, feeding tube, gastroenterostomy tube, Levine tube, nasogastric tube, single lumen tube with mercury weight balloon for intestinal intubation or decompression, and gastro-urological irrigation tray (for gastrological use).

(b) *Classification.* Class II (performance standards).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule and has determined that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this 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 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 510(f)(2)(B) of the act (21 U.S.C. 360(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approval 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.

Effective date. This regulation is effective December 23, 1983.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: November 14, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31320 Filed 11-22-83; 8:45 am]

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November 23, 1983

Part III

Department of Health and Human Services

Food and Drug Administration

Physical Medicine Devices; General Provisions and Classification of 82 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 890

[Docket No. 78N-1182]

Physical Medicine Devices; General Provisions and Classification of 82 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 82 physical medicine devices. The preamble to this rule responds to comments received on the proposals regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 23, 1983.

FOR FURTHER INFORMATION CONTACT: James G. Dillon, National Center for Devices and Radiological Health (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1979 (44 FR 50458-50537), FDA published proposed general provisions applicable to the classification of physical medicine devices and individual proposed regulations to classify 82 physical medicine devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). Of the 82 physical medicine devices subject to proposals, FDA is classifying 32 devices into class I, 42 devices into class II, 2 devices into class III, 5 devices into either class II or class III, depending upon the intended use of the device and has withdrawn the proposed regulation to classify one device. Additionally, FDA is codifying the reclassification of one device.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392). 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 and that either was in commercial distribution before May 28, 1976, or 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 June 30, 1986, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the general provisions described the development of the general provisions and the proposed regulations classifying physical medicine devices and the activities of the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel (formerly the Physical Medicine Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of physical medicine devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received and FDA's responses to these comments are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publishing as one final regulation the general provisions and classifications of 82 physical medicine devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed and is publishing final regulations to exempt six class I physical medicine devices from the premarket notification procedures in Subpart E of Part 807 (21 CFR Part 807) and from the current good manufacturing practice (CGMP) regulations in Part 820 (21 CFR Part 820), with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The six devices are the plinth (Docket No. 78N-1206), the arm sling (Docket No. 78N-1208), the wheelchair accessories (Docket No. 78N-1225), the daily activity assist devices (Docket No. 78N-1229), the exercise components (Docket No. 78N-1243), and the nonmeasuring exercise equipment (Docket No. 78N-1245).

In response to comments, the agency is also exempting 13 additional class I devices from premarket notification procedures and the CGMP regulations (other than §§ 820.180 and 820.198). The 13 devices are the prosthetic and orthotic accessories (Docket No. 78N-1194), cane (Docket No. 78N-1195), crutch (Docket No. 78N-1198), the external limb orthotic component (Docket No. 78N-1200), the external limb prosthetic component (Docket No. 78N-1201), the limb orthosis (Docket No. 78N-1203), the truncal orthosis (Docket No. 78N-1204), the congenital hip dislocation abduction splint (Docket No. 78N-1209), the Denis Brown splint (Docket No. 78N-1210), the cane, crutch, and walker tips or pads (Docket No. 78N-1217), the mechanical walker (Docket No. 78N-1219), the cold pack (Docket No. 78N-1253), and the moist heat pack (Docket No. 78N-1256).

In response to comments, one device is being exempted only from the CGMP regulations (other than §§ 820.180 and 820.198): traction accessories (Docket No. 78N-1263).

Also, on its own initiative, FDA is providing an exemption from most requirements of the CGMP regulations for four physical medicine devices: electrode cable (Docket No. 78N-1184), nonpowered communication system (Docket No. 78N-1212), wheelchair platform scale (Docket No. 78N-1228), and the nonpowered sitz bath (Docket No. 78N-1232).

The final regulation for each of the above 24 generic types of devices exempts the manufacturers of the devices from all of the CGMP requirements with the exception of §§ 820.180 and 820.198. The agency has determined that exemption of devices from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The general requirements concerning records ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate. The complaint file requirements ensure that device manufacturers have

adequate systems for complaint investigation and followup. Also for the reasons given in the proposals, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

Three manufacturers' petitions (79P-0277, 79P-0279 through 79P-0287, 79P-0289, 79P-0291, 79P-0293, 79P-0295 through 79P-0298, 80P-0323, 80P-0324, 80P-0336, and 81P-0388) requested exemptions from the CGMP regulations for certain physical medicine devices. As described under the heading "Summaries of Comments and FDA's Responses to Comments," FDA granted exemptions from the CGMP regulations to the petitioners and any other manufacturer of some of these generic types of devices. However, for each of the two devices listed below, the agency granted only the petitioner an exemption from the CGMP regulations and other manufacturers of these two generic types of devices are not exempt from the CGMP regulations.

Device name	Docket No.
Flotation cushion	78N-1199
Wheelchair components	78N-1226

FDA is now reviewing all CGMP exemption petitions previously granted to determine whether additional supporting data are necessary as a condition to the continuation of these exemptions.

The exemptions from the CGMP regulations in response to the petitions do not extend to § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files and do not apply to devices that are labeled or otherwise represented as sterile.

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

Classification of Biofeedback Devices

The Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel recommended, and FDA proposed, that powered myoelectric biofeedback devices be classified into class II. FDA provided a period of 60 days for interested persons to submit written comments to FDA. No comments were received that objected to classifying powered myoelectric biofeedback devices into class II. However, a comment pointed out that the device identification would apply only to those devices that monitor EMG muscle contraction and relaxation.

FDA agrees with this comment. However, the regulation to classify biofeedback devices (21 CFR 882.5050) published in the September 4, 1979 **Federal Register** (44 FR 51762) with the rules classifying neurological devices applies to physical medicine biofeedback devices. Therefore, FDA has determined that physical medicine biofeedback devices already have been classified into class II in that regulation. The agency published in the **Federal Register** of November 14, 1980 (45 FR 75230) a separate withdrawal of the proposed rule for powered myoelectric biofeedback devices (Docket No. 78N-1183).

Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

Classification of Powered Finger Exercisers

FDA is codifying its 1978 order reclassifying powered finger exercisers (§ 890.5410, Docket No. 77P-0328) from class III to class II. This codification provides details about the reclassification of these devices.

Minor Changes or Clarifications

Occasionally the agency has made minor changes in device names or identifications to clarify the final regulations. Additionally, the agency is adding an explanation in § 890.1 that references in Part 890 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Changes in Device Advisory Committee Names

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

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/section name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Hematology Devices Panel:	
Clinical Chemistry Device Section.	Feb. 2, 1982; 47 FR 4802-4929 (proposals).
Clinical Toxicology Device Section.	Feb. 2, 1982; 47 FR 4802-4929 (proposals).
Hematology and Pathology Device Section.	Sept. 11, 1979, 44 FR 52950-53063 (proposals); Sept. 12, 1980, 45 FR 60576-60651 (final regulations).
General Medical Devices Panel:	
General Hospital and Personal Use Device Section.	Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980, 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Device Section.	Jan. 23, 1981, 46 FR 7562-7641 (proposals).
Immunology and Microbiology Devices Panel:	
Immunology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Microbiology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel.	Apr. 3, 1979, 44 FR 19694-19971 (proposals); Feb. 26, 1980, 45 FR 12662-12720 (final regulations).
Radiologic Devices Panel.	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic, Ear, Nose, and Throat; and Dental Devices Panel:	
Ophthalmic Device Section.	Jan. 26, 1982, 47 FR 3694-3749 (proposals).
Ear, Nose, and Throat Device Section.	Jan. 22, 1982, 47 FR 3280-3325 (proposals).
Dental Device Section.	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Respiratory and Nervous System Devices Panel:	
Anesthesiology Device Section.	Nov. 2, 1979, 44 FR 63292-633426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Device Section.	Nov. 28, 1978, 43 FR 54640-56732 (proposals); Sept. 4, 1979, 44 FR 51726-51778 (final regulations).
Surgical and Rehabilitation Devices Panel:	
Physical Medicine Device Section	Aug. 28, 1979, 44 FR 50458-50537 (proposals); Nov. 23, 1983 (final regulations).
Orthopedic Device Section.	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Device Section.	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

List of Physical Medicine Devices and an Identification of Those Proposed Classification Regulations That Received Public Comment

The following is a list of physical medicine devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the classification regulation, the classification of each device, and an identification (yes or no) of whether public comments were received on the proposed classification regulation. If no comments were received, the classification of the device is being adopted as proposed.

SUBPART B—PHYSICAL MEDICINE DIAGNOSTIC DEVICES

Section and device	Docket No.	Class	Comments
890.1175 Electrode cable.	78N-1184	I	No.
890.1225 Chronaximeter.	78N-1185	II	No.
890.1375 Diagnostic electromyograph.	78N-1186	II	Yes.
890.1385 Diagnostic electromyograph needle electrode.	78N-1187	II	No.
890.1450 Powered reflex hammer.	78N-1188	II	No.
890.1575 Force-measuring platform.	78N-1189	II	No.
890.1600 Intermittent pressure measurement system.	78N-1190	II	No.
890.1615 Miniature pressure transducer.	78N-1191	II	No.
890.1850 Diagnostic muscle stimulator.	78N-1192	II	No.
890.1925 Isokinetic testing and evaluation system.	78N-1193	II	No.

SUBPART C [RESERVED]

SUBPART D—PHYSICAL MEDICINE PROSTHETIC DEVICES

Section and device	Docket No.	Class	Comments
890.3025 Prosthetic and orthotic accessory.	78N-1194	I	Yes.
890.3075 Cane.	78N-1195	I	Yes.
890.3100 Mechanical chair.	78N-1196	I	Yes.
890.3110 Electric positioning chair.	78N-1197	II	No.
890.3150 Crutch.	78N-1198	I	Yes.
890.3175 Flotation cushion.	78N-1199	I	Yes.
890.3410 External limb orthotic component.	78N-1200	I	Yes.
890.3420 External limb prosthetic component.	78N-1201	I	Yes.
890.3450 Mechanical automobile hand and foot driving control.	78N-1202	II	No.
890.3475 Limb orthosis.	78N-1203	I	Yes.
890.3490 Truncal orthosis.	78N-1204	I	Yes.
890.3500 External assembled lower limb prosthesis.	78N-1205	II	Yes.
890.3520 Plinth.	78N-1206	I	No.
890.3610 Rigid pneumatic structure orthosis.	78N-1207	III	No.
890.3640 Arm sling.	78N-1208	I	Yes.

SUBPART C [RESERVED]—Continued

Section and device	Docket No.	Class	Comments
890.3665 Congential hip dislocation abduction splint.	78N-1209	I	Yes.
890.3675 Denis Brown splint.	78N-1210	I	Yes.
890.3690 Powered wheeled stretcher.	78N-1211	II	No.
890.3700 Nonpowered communication system.	78N-1212	I	No.
890.3710 Powered communication system.	78N-1213	II	No.
890.3725 Powered environmental control system.	78N-1214	II	No.
890.3750 Mechanical table.	78N-1215	I	No.
890.3760 Powered table.	78N-1216	II	No.
890.3790 Cane, crutch, and walker tips and pads.	78N-1217	I	Yes.
890.3800 Motorized three-wheeled vehicle.	78N-1218	II	No.
890.3825 Mechanical walker.	78N-1219	I	Yes.
890.3850 Mechanical wheelchair.	78N-1220	I	Yes.
890.3860 Powered wheelchair.	78N-1221	II	No.
890.3880 Special grade wheelchair.	78N-1222	II	No.
890.3890 Stair-climbing wheelchair.	78N-1223	III	No.
890.3900 Standup wheelchair.	78N-1224	II	No.
890.3910 Wheelchair accessory.	78N-1225	I	Yes.
890.3920 Wheelchair component.	78N-1226	I	Yes.
890.3930 Wheelchair elevator.	78N-1227	II	No.
890.3940 Wheelchair platform scale.	78N-1228	I	No.

SUBPART E [RESERVED]

SUBPART F—PHYSICAL MEDICINE THERAPEUTIC DEVICES

Section and device	Docket No.	Class	Comments
890.5050 Daily activity assist device.	78N-1229	I	No.
890.5100 Immersion hydrobath.	78N-1230	II	No.
890.5110 Paraffin bath.	78N-1231	II	No.
890.5125 Nonpowered sitz bath.	78N-1232	I	No.
890.5150 Powered patient transport.	78N-1233	II	No.
890.5160 Air-fluidized bed.	78N-1234	II	No.
890.5170 Powered flotation therapy bed.	78N-1235	II	No.
890.5180 Manual patient rotation bed.	78N-1236	I	No.
890.5225 Powered patient rotation bed.	78N-1237	II	No.
890.5250 Moist steam cabinet.	78N-1238	II	No.
890.5275 Microwave diathermy.	78N-1239	II & III	No.
890.5290 Shortwave diathermy.	78N-1241	II & III	Yes.
890.5300 Ultrasonic diathermy.	78N-1242	II & III	No.
890.5350 Exercise component.	78N-1243	I	Yes.
890.5360 Measuring exercise equipment.	78N-1244	II	Yes.
890.5370 Nonmeasuring exercise equipment.	78N-1245	I	Yes.
890.5380 Powered exercise equipment.	78N-1246	II	Yes.
890.5410 Powered finger exerciser.	77P-0328	II	No.

SUBPART F—PHYSICAL MEDICINE THERAPEUTIC DEVICES—Continued

Section and device	Docket No.	Class	Comments
890.5500 Infrared lamp.	78N-1248	II	Yes.
890.5525 Iontophoresis device.	78N-1249	II & III	Yes.
890.5575 Powered external limb overload warning device.	78N-1250	II	No.
890.5650 Powered inflatable tube massager.	78N-1251	II	No.
890.5660 Therapeutic massager.	78N-1252	II	No.
890.5700 Cold pack.	78N-1253	I	Yes.
890.5710 Hot or cold disposable pack.	78N-1254	I	No.
890.5720 Water circulating hot or cold pack.	78N-1255	II	No.
890.5730 Moist heat pack.	78N-1256	I	Yes.
890.5740 Powered heating pad.	78N-1257	II	No.
890.5765 Pressure-applying device.	78N-1258	I	No.
890.5850 Powered muscle stimulator.	78N-1259	II	No.
890.5860 Ultrasound and muscle stimulator.	78N-1260	II & III	No.
890.5880 Multi-function physical therapy table.	78N-1261	II	No.
890.5900 Powered traction equipment.	78N-1262	II	No.
890.5925 Traction accessory.	78N-1263	I	Yes.
890.5940 Chilling unit.	78N-1264	II	No.
890.5950 Powered heating unit.	78N-1265	II	No.
890.5975 Therapeutic vibrator.	78N-1266	II	No.

Summaries of Comments and FDA's Responses to Comments

FDA is responding to specific comments received on the proposed regulations for 29 physical medicine devices and to several general comments as follows:

1. A comment was received objecting to the language of § 890.1. The comment suggested that the language be changed to limit the scope of the rule to products intended for therapeutic or diagnostic use in a medical or other professional setting by a health care professional.

The agency disagrees with this comment. The act requires FDA to classify all medical devices, whether intended for use by licensed practitioners or by the consumer in the home. The agency does not believe that it is necessary to change proposed § 890.1 for clarification. FDA will regulate a product that has both medical and nonmedical uses as a medical device if it is intended for a medical purpose, that is, for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the

circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them. Examples of claims relevant to physical medicine devices that would cause a product to be considered a device include, but are not limited to, claims relating to the following: Re-education, correction, improvement, or maintenance of bodily functions impaired by abnormal bodily states or physiologic functions. Examples of abnormal bodily states or physiologic functions include, but are not limited to, the following: (1) Neuromuscular disorders (such as stroke, muscular dystrophy, multiple sclerosis, and cerebral palsy); (2) limb amputations; and (3) musculoskeletal disorders (such as arthritis, tendonitis, fractures, and low back pain). FDA has changed the regulations classifying many physical medicine devices to clarify that the regulations apply only to those products intended for medical purposes.

2. A comment objected to the general classification process and to the process for classifying physical medicine devices. The comment stated that the American Orthotic and Prosthetic Association's (AOPA) February 7, 1979 presentation to the Section for exemption of 40 orthotic/prosthetic devices from requirements under sections 510, 519, and 520(f) of the act (21 U.S.C. 360, 360i, and 360j(f)), and the Section recommendation to accept AOPA's request for these exemptions, should have been stated under each regulation involved, rather than in the proposed General Provisions (44 FR 50461) portion. The comment suggested that, for each device, FDA provide a separate description of the agency's response to the Section's recommended exemption and also provide a second comment period.

FDA disagrees with the comment. The preamble to the proposed General Provisions for this part included a description of AOPA's request and the Section's recommendation. This description provided adequate notice and opportunity to comment and met the statutory requirement that, for a class I device, FDA publish a panel recommendation that includes a recommendation on whether the device should be exempted from the requirements of section 510, 519, or 520(f) of the act. Although FDA could have repeated this information in the individual documents, the act does not require that this be done. FDA has reviewed the Section's recommendations on these exemptions, AOPA's request, and other comments and is presenting the agency's decisions in this classification regulation under the heading "Summaries of Comments and FDA's Responses to Comments" and the docket number involved. Additional information on exemptions is found above under the heading "Exemptions for Class I Devices." Accordingly, the agency believes that it would be an unnecessary procedural step to publish a reproposal to classify each of the 40 orthotic/prosthetic devices as suggested by the comment.

3. One comment suggested that the device registration and listing classification name and product code issued by FDA for use by industry to accomplish device listing should be used or cross-referenced by FDA as part of the identification of the device in its classification regulation.

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

4. Section 890.1375; Docket No. 78N–1186; Diagnostic electromyograph.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50467), a proposed regulation to classify diagnostic electromyographs into class II.

a. One comment suggested that the word "diagnostic" should be deleted from the device's name. The comment suggested that the device is not diagnostic until correlated with clinical and other laboratory data by the physician.

The agency believes that inclusion of "diagnostic" in the device's name is appropriate. The intended use of the electromyograph is to gather data to enable a physician to make a diagnosis or prognosis of a patient's condition. Although these data may need to be correlated with other information, they will be used in diagnosis. Also, this regulation applies only to the electromyograph's diagnostic use.

b. A comment suggested that this device not be classified into class II, because this classification may cause the use of the device to be restricted.

The agency disagrees with this comment because classification of a device, and restrictions on its use under section 520(e) of the act, are not interdependent, as the comment implies. This device presents risks to health that can, and should, be controlled by performance standards. Establishment of performance standards may, but need not, restrict the use of diagnostic electromyographs. The application of these standards will provide reasonable assurance of the safety and effectiveness of the device. Therefore, the agency rejects the comment not to classify diagnostic electromyographs into class II.

c. Forty-one comments objected to a recommendation made by the Section to restrict the use of the device to a physician trained in electromyography. In particular, the comments were concerned that physical therapists would be excluded from using the devices.

Because these comments do not relate to classification but rather to restrictions that may be imposed on the device in the future in separate proceedings, FDA has determined it is not necessary to revise § 890.1375 at this time. FDA advises, however, its present position is

that the restriction to physicians should apply only to the use of the device with needle electrodes, and that its use with surface electrodes not be so restricted. FDA agrees with the comments that there are competent health professionals, other than physicians, who are capable of performing diagnostic electromyography; however, FDA believes the interpretation of the data and the final diagnostic determination should be made by a qualified physician. On December 28, 1979, FDA referred these comments to the Section which essentially agreed with FDA's position stated above. Also, the Section revised their recommended restriction of use to read: "The Section recommends that the device be restricted to use, when used with needle electrodes, by or under the direct supervision of a physician trained in diagnostic electromyography."

Accordingly, the proposed regulation is being adopted with a minor clarifying change.

5. Section 890.3025; Docket No. 78N-1194; Prosthetic and orthotic accessories.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50472), a proposed regulation to classify prosthetic and orthotic accessories into class I.

a. Three comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

The Section shares the views expressed in the comments. The Section held a meeting on December 12, 1979, at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic prosthetic devices, including prosthetic and orthotic accessories, be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA argued that the prosthetic and orthotic accessories are simple and noncritical, and that the additional burden and expense of complying with these requirements is not justified. The Section agreed with AOPA and recommended that manufacturers of these devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The Section believes that this generic type of device is safe and has a demonstrated quality and safety record over a period of time and that application of the above requirements is not justified. For the reasons given in the proposals, FDA disagrees in part with the comment's request and the recommendations of the Section that manufacturers of the device be exempt from records and reports requirements. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. FDA believes that manufacturers of prosthetic and orthotic accessories should be exempt from premarket notification procedures and from most requirements of the CGMP regulations. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the CGMP regulations is unlikely to improve the safety and effectiveness of the device. FDA has determined that the exemption of devices from the CGMP regulations (21 CFR Part 820) should not extend to § 820.180 relating to general requirements concerning records, or § 820.198 relating to complaint files. See the discussion under the heading "Exemptions for Class I Devices" for further explanation of the agency's policies concerning exemptions.

b. The agency on its own initiative has made minor changes in the identification of the device to clarify that the rule also applies to casting bandages. Casting bandages were inadvertently omitted from the list of examples in the proposal.

Accordingly, the proposed rule is being adopted with these changes.

6. Section 890.3075; Docket No. 78N-1195; Cane.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50475), a proposed regulation to classify canes into class I.

Two comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the CGMP regulations under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA did not provide the rationale to exempt canes as it did for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for canes. The Section agreed with the comments and recommended that manufacturers of this device be exempt from the requirements of premarket notification, records and reports, and CGMP's.

FDA disagrees in part with the comments and the recommendations of the Section. For the reasons given in the proposals, FDA believes that any manufacturer of a device should be subject to the records and reports requirements of section 519 of the act.

In response to the comments received and the Section's recommendation that manufacturers of canes be exempt from the premarket notification procedures and the CGMP's, FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures under section 510(k) of the act and Subpart E of Part 807 of the regulations. For the reasons given in the proposals, FDA believes that any manufacturer of a device not exempted under § 807.65 (21 CFR 807.65) must be subject to registration and device listing, under section 510 (a) through (j) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning canes. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice concerning new products within this generic type of device.

Additionally, FDA is changing the final regulation to provide that manufacturers of canes be exempt, in the manufacture of the device, from all requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the CGMP regulations, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that

manufacturers of canes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of canes must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the CGMP regulations is still appropriate.

There are two procedures by which FDA may exempt a manufacturer of a device from complying with any or all of the requirements of the CGMP regulations. First, a manufacturer of a device subject to any requirement under the CGMP regulations may petition the agency pursuant to section 520(f)(2)(A) of the act for a variance or an exemption from the requirement. A variance or an exemption granted in response to such a petition applies only to the manufacturer who submitted the petition. However, FDA may conclude that an exemption granted in response to a petition may be applied to all manufacturers of the device; in this case, if the device has been classified in a final regulation, FDA will publish in the **Federal Register** a notice of its decision and its intention to change the codified classification of the device to grant the exemption to all manufacturers of the device. Second, in classifying a medical device into class I under section 513 of the act (21 U.S.C. 360c), the agency may determine that certain of the requirements of the CGMP regulations shall not apply to the device. In that instance, the exemption applies to all manufacturers of the generic type of device that is the subject of the classification regulation. The agency may grant an exemption under either procedure only if it determines that compliance with the requirement is not necessary to assure that the device will be safe and effective and otherwise in compliance with the act. The agency previously granted two manufacturers' petitions (79P-0285, 79P-0286, and 80P-0336) for exemption of their "aluminum canes," "telescoping aluminum canes," "wood canes," and "canes" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. As explained above, those exemptions applied only to the two petitioners. The agency's policies and criteria for granting exemptions were discussed in the preamble to the proposed general provisions for this part, published in the **Federal Register** of August 28, 1979 (44 FR 50458). Additional information regarding the procedures for petitioning for exemptions or variances from the CGMP regulations is available, as described in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671). See the discussion in this preamble under the heading "Exemptions for Class I Devices" for more information regarding the agency's policies regarding exemptions.

Accordingly, the proposed rule is being adopted with the noted changes.

7. Section 890.3100; Docket No. 78N-119; Mechanical chair.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50476), a proposed regulation to classify mechanical chairs into class I.

The one comment received on the proposal stated that this device should be exempt from premarket notification under section 510(k) and the CGMP requirements under section 520(f) of the act.

FDA disagrees with the comment because the agency cannot make the required finding under section 510(g)(4) of the act that compliance is not necessary for the protection of the public health. Premarket notification by these manufacturers assures that FDA learns of new products and of significant modifications of existing products for which premarket approval may be required. FDA disagrees with the comment that manufacturers of mechanical chairs be exempt from the CGMP regulations. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of mechanical chairs having defects that could harm users. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly the proposed rule is being adopted with a minor clarifying change.

8. Section 890.3150; Docket No. 78N-1198; Crutch.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50477), a proposed regulation to classify crutches into class I.

Two comments stated that this device should be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative of AOPA, one of the commentors, discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices, including crutches, be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA argued that a crutch is a simple and noncritical device, and that the additional burden and expense of complying with these requirements is not justified. The Section agreed with AOPA and recommended that manufacturers of the device be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The Section believes that this generic type of device is safe and has a demonstrated quality and safety record over a period of time and that application of the above requirements is not justified for this generic type of device. For the reasons given in the proposals, FDA disagrees with the Section's recommendation that manufacturers of the device be exempt from records and reports requirements. In response to the comments received and the Section's recommendation that manufacturers of crutches be exempt from the premarket notification procedures and the CGMP's, FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures and section 510(k) of the act and Subpart E of Part 807 of the regulations. Additionally, FDA is changing the final regulation to provide that manufacturers of crutches be exempt, in the manufacture of the device, from all requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted two manufacturers' petitions (80P-0324 and 81P-0388) for exemption of their "crutch" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with the noted changes.

9. Section 890.3175; Docket No. 78N-1199; Flotation cushion.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50478), a

proposed regulation to classify flotation cushions into class I.

a. Two comments requested a change in the identification to expand the regulation to include various materials as outer coverings of the device. The comments suggested that the outer covering include material such as elastomeric foam, plastic, rubber, and any other nonflammable material.

FDA agrees with this comment in part and is making minor changes to the identification of the device to clarify that the regulation permits various outer coverings and that it only applies to flotation cushions intended for medical purposes.

b. One comment suggested that the inner fillings include materials such as foam, metal, and plastic springs.

FDA rejects this comment because these materials would not necessarily provide a flotation media, and would be covered in § 890.3920 in this document, classifying wheelchair components (Docket No. 78N-1226), in which the wheelchair cushion is included. However, the agency recognizes that there may be materials other than those listed in the proposal that would provide a flotation media, and is making minor changes to the identification to make it clear that the rule also applies to those materials.

c. Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and the CGMP requirements under section 520 of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP's. The representative stated that AOPA had also submitted a comment to the proposal requesting the above exemptions for flotation cushions. AOPA did not provide the rationale to exempt this device, as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all of the requirements are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of flotation cushions should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA also believes that manufacturers of flotation cushions should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that all manufacturers of flotation cushions be exempt from the CGMP regulations. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of flotation cushions having defects that could harm users. The agency has, however, previously granted an individual manufacturer's petition (79P-0287) for exemption of its "invalid ring" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* and the discussion under the heading "Exemptions for Class I Devices" for further discussion of exemptions.

Accordingly, the proposed regulation is being adopted with a minor clarifying change.

10. Section 890.3410; Docket No. 78N-1200; External limb orthotic component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50478), a proposed regulation to classify external limb orthotic components into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes, however, that this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes this device should be exempt from CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion regarding exemptions.

Accordingly, the proposed rule is being adopted with these changes.

11. Section 890.3420; Docket No. 78N-1201; External limb prosthetic component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50479), a proposed regulation to classify external limb prosthetic components into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes, however, that this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes this device should be exempt from CGMP's in Part 820, with the exception of § 820.180, with respect to general

requirements concerning records, and § 820.198, with respect to complaint files. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion regarding exemptions.

Accordingly, the proposed rule is being adopted with these and minor editorial changes.

12. Section 890.3475; Docket No. 78N-1203; Limb orthosis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50481), a proposed regulation to classify limb orthoses into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section heard a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time, and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations. FDA believes that this device should not be exempt from records and reports regulations established under section 519 of the act. The agency has determined that compliance with the CGMP regulations, except for § 820.180, general requirements concerning records, and § 820.198, complaint files, is not required to assure that limb orthoses will be safe and effective and otherwise in compliance with the act. See the discussion in FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further information on exemptions. The agency previously granted a manufacturer's petitions (79P-0279, 79P-0282, 79P-0293, 79P-0296, 79P-0297 and 79P-0298) for exemption of its "knee joint brace," "knee joint brace (x-back)," "ankle joint brace," "elbow brace," "wrist brace," and "wrist brace splint" from the requirements of the CGMP regulations, except § 820.180, concerning records, and § 820.198, complaint files.

Accordingly, the proposed rule is being adopted with these changes.

13. Section 890.3490; Docket No. 78N-1204; Truncal orthosis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50481), a proposed regulation to classify truncal orthoses into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. The agency agrees that compliance with the CGMP regulations, except for § 820.180, general requirements concerning records, and § 820.198, complaint files, is not required to assure that truncal orthoses will be safe and effective and otherwise in compliance with the act. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. The agency previously granted a manufacturer's petitions (79P-0277, 79P-0280, 79P-0289, and 79P-0295) for exemption of its "cervical orthosis," "sacroiliac orthosis," "rib fracture orthosis," "posture aid brace," and "abdominal belt" from the requirement of the CGMP regulations, except § 820.180, requirements concerning records, and § 820.198, complaint files.

Accordingly, the proposed regulation is being adopted with these changes.

14. Section 890.3500; Docket No. 78N-1205; External assembled lower limb prosthesis.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50482), a proposed regulation to classify external assembled lower limb prostheses into class II.

a. A comment stated that this device should be exempt from premarket notification under section 510 and the CGMP requirements under section 520(f) of the act.

FDA disagrees with the comment that this device should be exempt from premarket notification requirements under section 510 because the agency cannot make the required finding under section 510(g)(4) of the act that compliance is not necessary for the protection of public health. FDA also disagrees with the comment that this device should be exempt from the CGMP's under section 520(f) of the act. Compliance with the CGMP's will help prevent production of devices having defects that could cause harm to users.

b. A comment questioned why the proposed rule did not include an upper limb device.

On December 12, 1979, FDA referred this comment to the Section which stated that it was unaware of any preassembled upper limb prostheses being manufactured or offered for sale. FDA also is not aware of any of these devices being marketed.

Accordingly, the regulation is being adopted as proposed.

15. § 890.3640; Docket No. 78N-1208; Arm sling.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50485), a proposed regulation to classify arm slings into class I.

Three comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

FDA proposed that this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations, and in this respect, the comments suggest no change in the final rule. FDA disagrees with the comments that this device be exempt from records and reports regulations under section 519 of the act. FDA also proposed that this device be exempt from the CGMP's in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. Thus, the comments suggest no change

regarding CGMP exemption. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions. The agency previously granted a manufacturer's petition (79P-0284) for exemption of its "arm sling" from the requirement of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files.

Accordingly, the regulation is being adopted as proposed with only a minor clarifying change.

16. Section § 890.3665; Docket No. 78N-1209; Congenital hip dislocation abduction splint.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50487), a proposed regulation to classify congenital hip dislocation abduction splints into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA disagrees with the comment that manufacturers of this device should be exempt from records and reports regulations established under section 519 of the act. FDA agrees with the comment that manufacturers of this device should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes.

17. Section 890.3675; Docket No. 78N-1210; Denis Brown splint.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50487), a proposed regulation to classify Denis Brown splints into class I.

Four comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On February 7, 1979, the Section met to hear a presentation from AOPA requesting exemptions from the requirements of premarket notification, records and reports, and the CGMP's for this device. AOPA stated that the device is simple and noncritical, and does not justify the additional burden and expense of complying with these requirements. The Section agreed with AOPA and recommended that manufacturers of this device be granted exemptions from sections 510, 519, and 520(f) of the act. The Section believes that this is a safe device with a demonstrated quality and safety record over a period of time and that application of requirements under the above provisions of the act is not justified for this device. FDA believes that manufacturers of this device should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of this device should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes and minor clarifying changes.

18. Section 890.3790; Docket No. 78N-1217; Cane, crutch, and walker tips and pads.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50493), a proposed regulation to classify cane, crutch, and walker tips into class I.

a. One comment suggested that crutch pads and hand grips should also be included in this regulation.

The agency agrees with this comment and has made minor changes in the name and identification of the device to incorporate other rubber (and rubber substitute) accessories in this regulation.

b. Three comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for cane, crutch, and walker tips or pads. AOPA did not provide the rationale to exempt these devices, as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for these devices. The Section recommends that manufacturers of these devices not be required to comply with premarket notification, records and reports, or CGMP's because they are simple devices that present no undue risks to health when used in a normal manner for the purpose recommended. FDA believes that manufacturers of these devices should comply with section 501 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA also believes that manufacturers of these devices should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of these devices should be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted two manufacturers' petitions (79P-0291 and 81P-0388) for exemption of their "crutch handgrips" and "crutch tips, grips, and pads" from the requirements of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes and minor clarifying changes.

19. Section 890.3825; Docket No. 78N-1219; Mechanical walker.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50494), a proposed regulation to classify mechanical walkers into class I.

Two comments stated that this device should be exempt from premarket notification under section 510(k), records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. AOPA did not provide the rationale to exempt this device as it had for other devices, and the representative stated the AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. However, FDA, in part, disagrees with the recommendation of the Section. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA is changing the final regulation to require that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but be exempt from premarket notification procedures under section 510(k) of the act and Subpart E of Part 807 of the regulations. Additionally, FDA is changing the final regulation to provide that manufacturers of a mechanical walker be exempt, in the manufacture of the device, from requirements in the CGMP regulations except § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. The agency previously granted a manufacturer's petition (80P-0323) for exemption of its "mechanical walker" from the requirement of the CGMP regulations, except § 820.180, general requirements concerning records, and § 820.198, complaint files. See the response to comments in paragraph number 6 for §890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these changes.

20. Section 890.3850; Docket No. 78N-1220; Mechanical wheelchair.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50495), a proposed regulation to classify mechanical wheelchairs into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA has also submitted a comment on the proposal requesting the above exemptions for mechanical wheelchairs. AOPA did not provide the rationale to exempt mechanical wheelchairs as it had for other devices and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for mechanical wheelchairs. The Section disagreed with the comments and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of this device should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that manufacturers of mechanical wheelchairs be exempt from the CGMP regulations under section 520(f) of the act. The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of a mechanical wheelchair having defects that could harm users.

Accordingly, the proposed rule is being adopted with a minor clarifying change.

21. Section 890.3910; Docket No. 78N-1225; Wheelchair accessory.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50499), a proposed regulation to classify wheelchair accessories into class I.

Two comments stated that this device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the exemptions above for wheelchair accessories. AOPA did not provide the rationale to exempt wheelchair accessories as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of these devices if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for this device. The Section agreed with the comment and recommended that manufacturers of this device be exempt from the requirements of premarket notification, records and reports, and CGMP's. FDA proposed that manufacturers of this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulation, thus, in this respect, the comments did not suggest a change in the regulations. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA proposed that manufacturers of this device be exempt from the CGMP regulations with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comments suggested no changes in the CGMP exemptions in the regulation.

Accordingly, the regulation is being adopted with only a minor clarifying change.

22. Section 890.3920; Docket No. 78N-1226; Wheelchair component.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50500), a proposed regulation to classify wheelchair components into class I.

Two comments stated that this device should be exempt from premarket

notification under section 510, records and reports requirements under section 519, and the CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, the 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for wheelchair components. AOPA did not provide the rationale to exempt wheelchair components as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of this device if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for wheelchair components. The Section disagreed with the comment and recommended that manufacturers of this device not be granted exemptions. The Section believes that all requirements of general controls are necessary to ensure the safety and effectiveness of this device. FDA believes that manufacturers of wheelchair components should not be exempt from premarket notification requirements under section 510 of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA also believes that manufacturers of wheelchair components should not be exempt from records and reports regulations established under section 519 of the act. FDA disagrees with the comments that manufacturers of wheelchair components be exempt from the CGMP regulations under section 520(f) of the act. The agency believes that compliance with these regulations is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the CGMP regulations will help prevent production of wheelchair components having defects that could harm users. the agency has, however, previously granted an individual manufacturer's petition (79P-0283) for exemption of its "wheelchair cushion" from the requirements of the CGMP regulations except § 820.180, general requirements concerning records, and § 820.198, complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* and the discussion under the heading "Exemptions for Class I Devices" for further discussion of exemptions.

Accordingly, the proposed regulation is being adopted without change.

23. Section 890.5275; Docket No. 78N-1239; Microwave diathermy.

FDA published in the **Federal Register** of August 28, 1979; (44 FR 50511), a proposed regulation to classify microwave diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III for use in the treatment of malignancies, because insufficient data exist concerning the safety and effectiveness of the device for this use.

FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because microwave diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, microwave diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III microwave diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of microwave diathermies for the treatment of malignancies or if FDA reclassifies microwave diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5275 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of microwave diathermies or any reclassification. FDA believes that investigations are still being done to show whether microwave diathermies are safe and effective when intended for the teatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established, and the necessary parameters to assure the effectiveness of diathermy may be addressed in the future in a performance standard.

24. Section 890.5290; Docket No. 78N-1241; Shortwave diathermy.

FDA published in the **Federal Register** August 28, 1979 (44 FR 50512), a proposed regulation to classify shortwave diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

One comment objected that "pain" should not be the only specific class II indication for the device's use and suggested that FDA provide details on the "selected medical conditions" that comprise the device's class II indications.

On December 13, 1979, FDA referred the comment to the Section. Also, at this meeting, a representative of Diapulse Corp. presented a brief history of its shortwave device and described the manner in which the device works without producing "therapeutic deep heat" in the tissues. The Diapulse Corp. representative asked the Section to expand the class II identification for shortwave diathermy to include indications for use other than "relief of pain." The Section members agreed that relief of pain is not the only class II indication for use of the device. The Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that shortwave diathermies be classified into class III when used in the treatment of malignancies because insufficient data exist concerning the safety and effectiveness of the device for this use. In determining the final classification for shortwave diathermy, FDA considered the comment received on the proposal.

the Section's recommendation, and the information presented to the Section. FDA has changed the final regulation to clarify the distinction between deep heat threatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because shortwave diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, shortwave diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III shortwave diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of shortwave diathermies for the treatment of malignancies or if FDA reclassifies shortwave diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5290 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of shortwave diathermies or any reclassification. FDA believes that investigations are still being done to show whether shortwave diathermies are safe and effective when intended for the treatment of malignancies. FDA advises that the Diapulse and similar machines which claim to produce therapeutic effect by modes of action other than deep heat are not classified into class II, but are in class III, as stated in this regulation. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat" because the effective therapeutic temperatures for diathermy have been established, and the necessary parameters to assure the effectiveness of diathermy may be addressed in the future in a performance standard.

25. Section 890.5300; Docket No. 78N-1242; Ultrasonic diathermy.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50514), a proposed regulation to classify ultrasonic diathermies into class II for use in applying therapeutic deep heat and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III when used in the treatment of malignancies, because insufficient data exist concerning the safety and effectiveness of the device for this use. FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because ultrasonic diathermies intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, ultrasonic diathermies intended for treatment of malignancies are subject to premarket approval without the 30-month grace period applicable to class III ultrasonic diathermies of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of ultrasonic diathermies for the treatment of malignancies or if FDA reclassifies ultrasonic diathermies for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulations of these uses, the agency will amend § 890.5300 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of ultrasonic diathermies or any reclassification. FDA believes that investigations are still being done to show whether ultrasonic diathermies are safe and effective when intended for the treatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established and are known in the medical community. FDA has already published under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602), a safety performance standard for ultrasonic diathermies, 21 CFR 1050.10 *Ultrasonic therapy products*, that was effective February 17, 1979. FDA may address additional necessary parameters to ensure the effectiveness of diathermy during the development, in the future, of a new or revised performance standard.

26. Section 890.5350; Docket No. 78N-1243; Exercise component.

FDA published in the **Federal Register** August 28, 1979 (44 FR 50515), a proposed regulation to classify exercise components into class I.

a. One comment stated this device should be exempt from premarket notification under section 510 and the CGMP requirements under section 520(f) of the act.

FDA agrees in part with the comment. FDA proposed that this device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulation. FDA also proposed that this device be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comment suggested no changes in exemptions. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

b. Eleven comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees in part with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying minor changes in the identification of the device. Accordingly, the proposed regulation is being adopted with these changes.

27. Section 890.5360; Docket No. 78N-1244; Measuring exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50516), a proposed regulation to classify

measuring exercise equipment into class II.

a. One comment stated that odometers and timers should not be included as measuring instrumentation for these devices.

The agency disagrees with this comment. Accurate exercise measurements are necessary for the safe and effective use of therapeutic equipment. Odometers and timers on therapeutic equipment provide information that is used for evaluation and treatment planning purposes.

b. Twelve comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments FDA has made clarifying changes in the identification of the device. Accordingly, the proposed regulation is being adopted with these changes.

28. Section 890.5370; Docket No. 78N-1245; Nonmeasuring exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50517), a proposed regulation to classify nonmeasuring exercise equipment into class I.

a. One comment stated that this device should be exempt from premarket notification under section 510 and CGMP requirements under section 520(f) of the act.

FDA agrees in part with the comment. FDA proposed that the device be exempt from premarket notification requirements under section 510 of the act and Subpart E of Part 807 of the regulations. FDA also proposed that this device be exempt from the CGMP's in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files, thus, the comment suggested no change in exemptions. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

b. Twelve comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices, and that if the rule is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying changes in the identification of the device. Accordingly, the proposed rule is being adopted with these changes.

29. Section 890.5380; Docket No. 78N-1246; Powered exercise equipment.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50518), a proposed regulation to classify powered exercise equipment into class II.

a. One comment objected to the listing of treadmills and exercise bicycles as examples of powered exercise equipment.

The agency rejects this comment. Powered treadmills and exercise bicycles, when intended for medical purposes, are medical devices.

b. Eight comments stated that exercise equipment for use in recreational and sporting activities should not be regulated as medical devices, and that if the regulation is not intended to include these devices, the wording of the identification should be changed to clarify this.

FDA agrees with these comments. With respect to exercise equipment, FDA regulates as devices only those products that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for §890.1 for examples of medical purposes.

In response to these comments, FDA has made clarifying changes in the identification of the device. Accordingly, the proposed rule is being adopted with these changes.

30. Section 890.5410; Docket No. 77P-0328; Powered finger exerciser.

Section 513(f) of the act classifies into class III a device that is first offered for commercial distribution after enactment of the Medical Device Amendments and that is not substantially equivalent to a preamendments device. On May 17, 1977, C. R. Bard, Inc., 700 E. 22d St., Lawrence, KA 66004, submitted to FDA a petition (77P-0328) for reclassification of a device it intended to market, the Ketcham Hand Exerciser, a device classified into class III pursuant to section 513(f) of the act. The Section reviewed the petition and recommended that the device be reclassified into class II.

In the **Federal Register** of November 11, 1977 (42 FR 58787), FDA published a notice of the Section's recommendation and provided a period of 60 days for interested persons to submit comments to FDA. FDA received no comments on the recommendation. Because FDA agreed with the Section's recommendation, FDA granted the petition and reclassified the device into class II by order in the form of a letter to the sponsor dated January 4, 1978.

This regulation codifies the 1978 order. The order and the regulation apply to any powered finger exerciser that is substantially equivalent to the reclassified device. FDA determines substantial equivalence by reviewing premarket notification submissions under section 510(k) of the act and Subpart E of Part 807 of the regulations.

31. Section 890.5500; Docket No. 78N-1248; Infrared lamp.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50519), a proposed regulation to classify infrared lamps into class II.

a. One comment disagreed with the proposal to classify infrared lamps into class II. The comment suggested that the device be classified into class I because the risks to health are "common to all electrical devices incorporating light bulbs." The comment further stated that the skin is able to detect the radiation of the device, thereby preventing burns, and that any electrical device may present a hazard of electrical shock.

The agency agrees that most of the risks to health involved are similar to those of many electrical devices incorporating light bulbs. However, the agency does not agree with the recommendation that infrared lamps intended for topical heating for medical purposes be classified into class I. Not all patients being treated may have a normal sensory system to pain and temperature, and a serious burn can result. The Section recommended classification into class II for all AC-powered devices to ensure compliance with an electrical safety standard. The agency agrees with the Section that a performance standard is necessary for this device and rejects the comment.

b. One comment suggested that the identification of the infrared lamp is too broad.

The agency disagrees with the comment. FDA has attempted to make device identifications sufficiently broad to include all devices that are intended for medical purposes. See the agency's response to comments in paragraph number 1 for § 890.1 for further discussion of what is meant by "intended use" of a device.

Accordingly, the proposed regulation is being adopted with only minor clarifying changes.

32. Section 890.5525; Docket No. 78N-1249; Iontophoresis device.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50520), a proposed regulation to classify into class II iontophoresis devices for specialized uses (diagnosis of cystic fibrosis, application of fluoride in dentistry, and for local anesthesia of the intact tympanic membrane) and to classify into class III the device for all other uses.

Three comments were received, each of which objected to proposed § 890.5525(d) classifying into class III iontophoresis devices for uses other than diagnosing cystic fibrosis, application of fluoride in dentistry, or anesthetizing the tympanic membrane. One comment was from a physician who stated that he has safely and successfully used iontophoresis for the transmission of a local anesthetic and a steroid compound. A manufacturer objected specifically to FDA's proposal to classify into class III iontophoresis devices for sweat inhibition. Another manufacturer argued that such classification is unnecessary for current uses and would limit future applications of iontophoresis devices.

On December 12, 1979, FDA held a public meeting of the Section. The Section disagreed with the comment. The Section agreed with FDA's analysis of the literature cited in the preamble to the proposal and emphasized that the device is able to deliver systemically active medications that may be harmful because the dosage level administered to the patient is unpredictable. The Section believes that use of iontophoresis devices in diagnosing cystic fibrosis, applying fluoride to the teeth, and anesthetizing the intact tympanic membrane have been shown in the literature to be both safe and effective. The Section believes there are insufficient data to support other uses of the device. The Section believes that existing data are insufficient to ensure the safety and effectiveness of the device for its use in sweat inhibition.

In addition to regulating medical devices, FDA also regulates the safety and effectiveness of drugs. The classification of the iontophoresis device as a device in no manner affects the regulatory status of drugs that are, or may be, used with the device. Such drugs continue to be regulated under the act as drugs. Any person who intends for a drug to be used with a medical device, such as an iontophoresis device, must assure that the drug is in compliance with all applicable requirements of the act, including the premarket approval required for new drugs and antibiotic drugs.

During the Section's evaluation of the safety and effectiveness of the use of an iontophoresis device with drugs in diagnosing cystic fibrosis, the Section considered the application of the device in conjunction with specific drugs. The Section did not, however, consider whether these drugs are safe and effective. The agency proposed to classify into class II iontophoresis devices for use in the diagnosis of cystic fibrosis, for the dental application of fluoride, and for the local anesthetizing of the intact tympanic membrane. However, this final regulation classifies the iontophoresis device into class II for use in the diagnosis of cystic fibrosis or for other uses only when the labeling of the drug intended for use with the device bears adequate directions for use of the iontophoresis device with that drug. At the present time, the agency is unaware of any marketed drug that has labeling providing adequate directions for its use with an iontophoresis device for the dental application of fluoride or the anesthetizing of the intact tympanic membrane. Therefore, the effect of this change in the identification of the device is to classify into class III iontophoresis devices for these two uses. The agency advises further that § 890.5525 will apply to those iontophoresis devices that were on the market before May 28, 1976, the enactment date of the Medical Device Amendments of 1976, and substantially equivalent devices offered after that date. New, not substantially equivalent devices offered for marketing after May 28, 1976, including devices previously marketed that have been substantially altered (e.g., by providing new indications in the labeling), are classified by statute (21 U.S.C. 360c(f)) into class III and must undergo premarket approval before marketing unless reclassified.

Accordingly, the proposed regulation is being adopted with the noted changes and other minor clarifications in the identification of the device.

33. Section 890.5700; Docket No. 78N-1253; Cold pack.

Section 890.5730; Docket No. 78N-1256; Moist heat pack.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50525 and 44 FR 50528), proposed regulations to classify both the cold pack and the moist heat pack into class I.

A comment stated that both devices should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted comments to the proposals requesting the above exemptions for the cold pack and the moist heat pack. AOPA did not provide the rationale to exempt these devices as it had for the other 40 devices, and the representative stated that AOPA would withdraw its recommendation for exemption of the cold pack and the moist heat pack if the Section believed there was no justification for exemptions. The Section agreed to review and comment on exemptions for the cold pack and the moist heat pack. The Section disagreed with the comment and recommended that manufacturers of both of these devices not be granted exemptions. The Section believes that all general control requirements are necessary to ensure the safety and effectiveness of both of these devices. FDA disagrees in part with the recommendations of the Section. FDA believes that manufacturers of both devices should comply with section 510 (a) through (j) of the act, but be exempt from premarket notification requirements under section 510(k) of the act and Subpart E of Part 807 of the regulations. FDA believes that manufacturers of both devices should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of both devices should be exempt from CGMP's in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files. See FDA's response to comments in paragraph number 6 for § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the two proposed rules are being adopted with these changes and with minor clarifying changes.

34. Section 890.5860; Docket No. 78N-1260; Ultrasound and muscle stimulator.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50531), a proposed regulation to classify ultrasound and muscle stimulators into class II when used for applying therapeutic deep heat and muscle stimulation and into class III for all other uses.

No comments were received regarding the proposed regulation to classify this device. However, the Section recommended that minor changes be

made in the identification to clarify that the device be classified into class II for uses in addition to the relief of pain, but specifically excluding use of the device in the treatment of malignancies. The Section also recommended that, to be therapeutically effective, the ultrasound component of the device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44° C. The Section recommended that the device be classified into class III when used in the treatment of malignancies because insufficient data exist concerning the safety and effectiveness of the device for this use. FDA has changed the final regulation to clarify the distinction between deep heat treatment and other modes of action and to include uses in addition to relief of pain. These changes are in the identification and classification sections of the regulation. FDA agrees with the Section recommendation that the device intended for the treatment of malignancies should be classified into class III. However, because ultrasound and muscle stimulators intended for the treatment of malignancies are investigational, and are not in commercial distribution, the devices intended for these uses are already classified into class III by section 513(f) of the act. Accordingly, ultrasound and muscle stimulators intended for treatement of malignancies are subject to premarket approval without the 30-month grace period applicable to class III ultrasound and muscle stimulators of the type that were in commercial distribution before May 28, 1976, the enactment date of the Medical Device Amendments. If FDA approves for commercial distribution any use of ultrasound and muscle stimulators for the treatment of malignancies or if FDA reclassifies ultrasound and muscle stimulators for the treatment of malignancies by an order following a petition under section 513(f)(2) of the act and 21 CFR 860.134 justifying less stringent regulation of these uses, the agency will amend § 890.5860 to add provisions describing, as appropriate, the statutory classification into class III of these additional approved uses of ultrasound and muscle stimulators or any reclassification. FDA believes that investigations are still being done to show whether ultrasound and muscle stimulators are safe and effective when intended for the treatment of malignancies. FDA does not believe a reference to therapeutic temperatures such as 44° C is necessary to define "deep heat." The effective therapeutic temperatures for diathermy have been established and are known in the medical community. FDA has already published a safety performance standard for ultrasonic diathermies, 21 CFR 1050.10 *Ultrasonic therapy products*, that was effective February 17, 1979. FDA may address additional necessary parameters to ensure the effectiveness of diathermy during the development, in the future, of a new or revised performance standard.

35. Section 890.5925; Docket No. 78N-1263; Traction accessory.

FDA published in the **Federal Register** of August 28, 1979 (44 FR 50534), a proposed regulation to classify traction accessories into class I.

a. A comment pointed out that traction accessories are also being reviewed by the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel and that the final classification of this device should be postponed until FDA has published its classification of traction accessories in response to the Orthopedic Section's recommendations.

The agency disagrees with the comment to postpone classification of the device. However, the agency realizes that there may be some confusion between the physical medicine and orthopedic traction accessories. Therefore, the agency has made minor changes to the identification of the device to clarify that this rule applies only to those devices that are intended for use with power traction equipment. FDA advises it has published in the **Federal Register** proposed regulations to classify orthopedic devices, including the traction accessories mentioned by the comment (July 2, 1982; 47 FR 29052).

b. Three comments stated that the device should be exempt from premarket notification under section 510, records and reports requirements under section 519, and CGMP requirements under section 520(f) of the act.

On December 12, 1979, the Section held a meeting at which a representative from AOPA discussed its request of February 7, 1979, that 40 orthotic/prosthetic devices be exempt from the requirements of premarket notification, records and reports, and the CGMP regulations. The representative stated that AOPA had also submitted a comment to the proposals requesting the above exemptions for traction accessories. AOPA did not provide the rationale to exempt this device as it had for other devices, and the representative stated that AOPA would withdraw its recommendation for exemption of these devices if the Section believed there was no justification for exemption. The Section agreed to review and comment on exemptions for traction accessories. The Section agreed with the comments and recommended that manufacturers of these devices be exempt from the requirements of premarket notification, records and reports, and CGMP's. FDA only partially agrees with the recommendations of the Section. FDA believes that manufacturers of this device should not be exempt from premarket notification requirements under section 510(k) of the act because the agency cannot make the required finding (under section 510(g)(4) of the act) that compliance is not necessary for the protection of the public health. FDA believes that manufacturers of this device should not be exempt from records and reports regulations established under section 519 of the act. FDA believes that manufacturers of this device should be exempt from the CGMP's in Part 820 with the exception for § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files. See FDA's response to comments in paragraph number 6 of § 890.3075 *Cane* for further discussion of exemptions.

Accordingly, the proposed rule is being adopted with these and minor clarifying changes.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 890 to read as follows:

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.
890.1 Scope.

Subpart B—Physical Medicine Diagnostic Devices

890.1175 Electrode cable.
890.1225 Chronaximeter.
890.1375 Diagnostic electromyograph.
890.1385 Diagnostic electromyograph needle electrode.
890.1450 Powered reflex hammer.
890.1575 Force-measuring platform.
890.1600 Intermittent pressure measurement system.
890.1615 Miniature pressure transducer.
890.1850 Diagnostic muscle stimulator.

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)).

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine 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 may not show merely that the device is accurately described by the section title and identification provisions 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, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in the Subpart representing one use of the device, rather than in two or more Subparts.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Physical Medicine Diagnostic Devices

§ 890.1175 Electrode cable.

(a) *Identification.* An electrode cable is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

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

§ 890.1225 Chronaximeter.

(a) *Identification.* A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.

(b) *Classification.* Class II (performance standards).

§ 890.1375 Diagnostic electromyograph.

(a) *Identification.* A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.

(b) *Classification.* Class II (performance standards).

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) *Identification.* A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medial purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).

(b) *Classification.* Class II (performance standards).

§ 890.1450 Powered reflex hammer.

(a) *Identification.* A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

(b) *Classification.* Class II (performance standards).

§ 890.1575 Force-measuring platform.

(a) *Identification.* A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

(b) *Classification.* Class II (performance standards).

§ 890.1600 Intermittent pressure measurement system.

(a) *Identification.* An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.

(b) *Classification.* Class II (performance standards).

§ 890.1615 Miniature pressure transducer.

(a) *Identification.* A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(b) *Classification.* Class II (performance standards).

§ 890.1850 Diagnostic muscle stimulator.

(a) *Identification.* A diagnostic muscle stimulator is a device used mainly with an electromyograph machine to initiate muscle activity. It is intended for medical purposes, such as to diagnose motor nerve or sensory neuromuscular disorders and neuromuscular function.

(b) *Classification.* Class II (performance standards).

§ 890.1925 Isokinetic testing and evaluation system.

(a) *Identification.* An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints.

(b) *Classification.* Class II (performance standards).

Subpart C—[Reserved]

Subpart D—Physical Medicine Prosthetic Devices

§ 890.3025 Prosthetic and orthotic accessory.

(a) *Identification.* A prosthetic and orthotic accessory is a device intended for medical purposes to support, protect, or aid in the use of a cast, orthosis (brace), or prosthesis. Examples of prosthetic and orthotic accessories include the following: A pelvic support band and belt, a cast shoe, a cast bandage, a limb cover, a prosthesis alignment device, a postsurgical pylon, a transverse rotator, and a temporary training splint.

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

§ 890.3075 Cane.

(a) *Identification.* A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

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

§ 890.3100 Mechanical chair.

(a) *Identification.* A mechanical chair is a manually operated device intended for medical purposes that is used to assist a disabled person in performing an activity that the person would otherwise find difficult to do or be unable to do. Examples of mechanical chairs include the following: A chair with an elevating seat used to raise a person from a sitting position to a standing position and a chair with casters used by a person to move from one place to another while sitting.

(b) *Classification.* Class I (general controls).

§ 890.3110 Electric positioning chair.

(a) *Identification.* An electric positioning chair is a device with a motorized positioning control that is intended for medical purposes and that can be adjusted to various positions. The device is used to provide stability for patients with athetosis (involuntary spasms) and to alter postural positions.

(b) *Classification.* Class II (performance standards).

§ 890.3150 Crutch.

(a) *Identification.* A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.

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

§ 890.3175 Flotation cushion.

(a) *Identification.* A flotation cushion is a device intended for medical purposes that is made of plastic, rubber, or other type of covering, that is filled with water, air, gel, mud, or any other substance allowing a flotation media, used on a seat to lessen the likelihood of skin ulcers.

(b) *Classification.* Class I (general controls).

§ 890.3410 External limb orthotic component.

(a) *Identification.* An external limb orthotic component is a device intended for medical purposes for use in conjunction with an orthosis (brace) to increase the function of the orthosis for a patient's particular needs. Examples of external limb orthotic components include the following: A brace-setting twister and an external brace stirrup.

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

§ 890.3420 External limb prosthetic component.

(a) *Identification.* An external limb prosthetic component is a device intended for medical purposes that, when put together with other appropriate components, constitutes a total prosthesis. Examples of external limb prosthetic components include the following: Ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves.

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

§ 890.3450 Mechanical automobile hand and foot driving control.

(a) *Identification.* A mechanical automobile hand or foot driving control is a device intended for medical purposes to enable persons who have limited use of their arms or legs to drive an automobile. The device allows the hand operation of the gas, brake, and clutch pedals or foot operation of the steering and gear shift.

(b) *Classification.* Class II (performance standards).

§ 890.3475 Limb orthosis.

(a) *Identification.* A limb orthosis (brace) is a device intended for medical

purposes that is worn on the upper or lower extremities to support, to correct, or to prevent deformities or to align body structures for functional improvement. Examples of limb orthoses include the following: A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe.

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

§ 890.3490 Truncal orthosis.

(a) *Identification.* A truncal orthosis is a device intended for medical purposes to support or to immobilize fractures, strains, or sprains of the neck or trunk of the body. Examples of truncal orthoses are the following: Abdominal, cervical, cervical-thoracic, lumbar, lumbo-sacral, rib fracture, sacroiliac, and thoracic orthoses and clavicle splints.

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

§ 890.3500 External assembled lower limb prosthesis.

(a) *Identification.* An external assembled lower limb prosthesis is a device that is intended for medical purposes and is a preassembled external artificial limb for the lower extremity. Examples of external assembled lower limb prostheses are the following: Knee/shank/ankle/foot assembly and thigh/knee/shank/ankle/foot assembly.

(b) *Classification.* Class II (performance standards).

§ 890.3520 Plinth.

(a) *Identification.* A plinth is a flat, padded board with legs that is intended for medical purposes. A patient is placed on the device for treatment or examination.

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

§ 890.3610 Rigid pneumatic structure orthosis.

(a) *Identification.* A rigid pneumatic structure orthosis is a device intended for medical purposes to provide whole body support by means of a pressurized suit to help thoracic paraplegics walk.

(b) *Classification.* Class III (premarket approval).

§ 890.3640 Arm sling.

(a) *Identification.* An arm sling is a device intended for medical purposes to immobilize the arm, by means of a fabric band suspended from around the neck.

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

§ 890.3665 Congenital hip dislocation abduction splint.

(a) *Identification.* A congenital hip dislocation abduction splint is a device intended for medical purposes to stabilize the hips of a young child with dislocated hips in an abducted position (away from the midline).

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

§ 890.3675 Denis Brown splint.

(a) *Identification.* A Denis Brown splint is a device intended for medical purposes to immobilize the foot. It is used on young children with tibial torsion (excessive rotation of the lower leg) or club foot.

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

§ 890.3690 Powered wheeled stretcher.

(a) *Identification.* A powered wheeled stretcher is a battery-powered table with wheels that is intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions).

(b) *Classification.* Class II (performance standards).

§ 890.3700 Nonpowered communication system.

(a) *Identification.* A nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

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

§ 890.3710 Powered communication system.

(a) *Identification.* A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen.

(b) *Classification.* Class II (performance standards).

§ 890.3725 Powered environmental control system.

(a) *Identification.* A powered environmental control system is an AC- or battery-powered device intended for medical purposes that is used by a patient to operate an environmental control function. Examples of environmental control functions include the following: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.

(b) *Classification.* Class II (performance standards).

§ 890.3750 Mechanical table.

(a) *Identification.* A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various

positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class I (general controls).

§ 890.3760 Powered table.

(a) *Identification.* A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class II (performance standards).

§ 890.3790 Cane, crutch, and walker tips and pads.

(a) *Identification.* Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.

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

§ 890.3800 Motorized three-wheeled vehicle.

(a) *Identification.* A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons.

(b) *Classification.* Class II (performance standards).

§ 890.3825 Mechanical walker.

(a) *Identification.* A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.

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

§ 890.3850 Mechanical wheelchair.

(a) *Identification.* A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class I (general controls).

§ 890.3860 Powered wheelchair.

(a) *Identification.* A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification.* Class II (performance standards).

§ 890.3880 Special grade wheelchair.

(a) *Identification.* A special grade wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. It is intended to be used in all environments for long-term use, e.g., for paraplegics, quadraplegics, and amputees.

(b) *Classification.* Class II (performance standards).

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs.

(b) *Classification.* Class III (premarket approval).

§ 890.3900 Standup wheelchair.

(a) *Identification.* A standup wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device incorporates an external manually controlled mechanical system that is intended to raise a paraplegic to an upright position by means of an elevating seat.

(b) *Classification.* Class II (performance standards).

§ 890.3910 Wheelchair accessory.

(a) *Identification.* A wheelchair accessory is a device intended for medical purposes that is sold separately from a wheelchair and is intended to meet the specific needs of a patient who uses a wheelchair. Examples of wheelchair accessories are the following: armboard, lapboard, pusher cuff, crutch and cane holder, restraint, overhead suspension sling, head and trunk support, and blanket and leg rest strap.

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

§ 890.3920 Wheelchair component.

(a) *Identification.* A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.

(b) *Classification.* Class I (general controls).

§ 890.3930 Wheelchair elevator.

(a) *Identification.* A wheelchair elevator is a motorized lift device intended for medical purposes to provide a means for a disabled person to move a wheelchair from one level to another.

(b) *Classification.* Class II (performance standards).

§ 890.3940 Wheelchair Platform scale.

(a) *Identification.* A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.

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

Subpart E—[Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§ 890.5050 Daily activity assist device.

(a) *Identification.* A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5100 Immersion hydrobath.

(a) *Identification.* An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) *Classification.* Class II (performance standards).

§ 890.5110 Paraffin bath.

(a) *Identification.* A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the patient's appendages (e.g., hands or fingers) are placed to relieve pain and stiffness.

(b) *Classification.* Class II (performance standards).

§ 890.5125 Nonpowered sitz bath.

(a) *Identification.* A nonpowered sitz bath is a device intended for medical purposes that consists of a tub to be filled with water for use in external hydrotherapy to relieve pain or pruritis and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas.

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

§ 890.5150 Powered patient transport.

(a) *Identification.* A powered patient transport is a motorized device intended for medical purposes to assist transfers of patients to and from the bath, beds, chairs, treatment modalities, transport vehicles, and up and down flights of stairs. This generic type of device does not include motorized threewheeled vehicles or wheelchairs.

(b) *Classification.* Class II (performance standards).

§ 890.5160 Air-fluidized bed.

(a) *Identification.* An air-fluidized bed is a device employing the circulation of filtered air through ceramic spherules (small, round ceramic objects) that is intended for medical purposes to treat or prevent bedsores, to treat severe or extensive burns, or to aid circulation.

(b) *Classification.* Class II (performance standards).

§ 890.5170 Powered flotation therapy bed.

(a) *Identification.* A powered flotation therapy bed is a device that is equipped with a mattress that contains a large volume of constantly moving water, air, mud, or sand. It is intended for medical purposes to treat or prevent a patient's bedsores, to treat severe or extensive burns, or to aid circulation. The mattress may be electrically heated.

(b) *Classification.* Class II (performance standards).

§ 890.5180 Manual patient rotation bed.

(a) *Identification.* A manual patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, or to aid circulation.

(b) *Classification.* Class I (general controls).

§ 890.5225 Powered patient rotation bed.

(a) *Identification.* A powered patient rotation bed is a device that turns a patient who is restricted to a reclining position. It is intended for medical purposes to treat or prevent bedsores, to treat severe and extensive burns, urinary tract blockage, and to aid circulation.

(b) *Classification.* Class II (performance standards).

§ 890.5250 Moist steam cabinet.

(a) *Identification.* A moist steam cabinet is a device intended for medical purposes that delivers a flow of heated, moisturized air to a patient in an enclosed unit. It is used to treat arthritis and fibrosis (a formation of fibrosis tissue) and to increase local blood flow.

(b) *Classification.* Class II (performance standards).

§ 890.5275 Microwave diathermy.

(a) *Microwave diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* A microwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Microwave diathermy for all other uses*—(1) *Identification.* A microwave diathermy for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

§ 890.5290 Shortwave diathermy.

(a) *Shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* A shortwave diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Shortwave diathermy for all other uses*—(1) *Identification.* A shortwave diathermy for all other uses except for the treatment of milignancies is a device that applies to the body electromagnetic engergy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

§ 890.5300 Ultrasonic diathermy.

(a) *Ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions—Identification.* An ultrasonic diathermy for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of

the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasonic diatermy for all other uses*—(1) *Identification.* An ultrasonic diatermy for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

§ 890.5350 Exercise component.

(a) *Identification.* An exercise component is a device that is used in conjunction with other forms of exercise and that is intended for medical purposes, such as to redevelope muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include weights, dumbbells, straps, and adaptive hand mitts.

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

§ 890.5360 Measuring exercise equipment.

(a) *Identification.* Measuring exercise equipment consist of manual devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. These devices also include instrumentation, such as the pulse rate monitor, that provide information used for physical evaluation and physical planning purposes. Examples include a therapeutic exercise bicycle with measuring instrumentation, a manually propelled treadmill with measuring instrumentation, and a rowing machine with measuring instrumentation.

(b) *Classification.* Class II (performance standards).

§ 890.5370 Nonmeasuring exercise equipment.

(a) *Identification.* Nonmeasuring exercise equipment consist of devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a prone scooter board, parallel bars, a mechanical treadmill, an exercise table, and a manually propelled exercise bicycle.

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

§ 890.5380 Powered exercise equipment.

(a) *Identification.* Powered exercise equipment consist of powered devices intended for medical purposes, such as to redevelop muscles or restore motion to joints or for use as an adjunct treatment for obesity. Examples include a powered treadmill, a powered bicycle, and powered parallel bars.

(b) *Classification.* Class II (performance standards).

§ 890.5410 Powered finger exerciser.

(a) *Identification.* A powered finger exerciser is a device intended for medical purposes to increase flexion and the extension range of motion of the joints of the second to the fifth fingers of the hand.

(b) *Classification.* Class II (performance standards).

§ 890.5500 Infrared lamp.

(a)Identification. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

(b) *Classification.* Class II (performance standards).

§ 890.5525 Iontophoresis device.

(a) *Iontophoresis device intended for certain specified uses*—(1) *Identification.* An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug. When used in the diagnosis of cystic fibrosis, the sweat is collected and its composition and weight are determined.

(2) *Classification.* Class II (performance standards).

(b) *Iontophoresis device intended for any other purposes*—(1) *Identification.* An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

§ 890.5575 Powered external limb overload warning device.

(a) *Identification.* A powered external limb overload warning device is a device intended for medical purposes to warn a patient of an overload or an underload in the amount of pressure placed on a leg.

(b) *Classification.* Class II (performance standards).

§ 890.5650 Powered inflatable tube massager.

(a) *Identification.* A powered inflatable tube massager is a powered device intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

(b) *Classification.* Class II (performance standards).

§ 890.5660 Therapeutic massager.

(a) *Identification.* A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

(b) *Classification.* Class II (performance standards).

§ 890.5700 Cold pack.

(a) *Identification.* A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.

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

§ 890.5710 Hot or cold disposable pack.

(a) *Identification.* A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

(b) *Classification.* Class I (general controls).

§ 890.5720 Water circulating hot or cold pack.

(a) *Identification.* A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

(b) *Classification.* Class II (performance standards).

§ 890.5730 Moist heat pack.

(a) *Identification.* A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.

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

§ 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (performance standards).

§ 890.5765 Presssure-applying device.

(a) *Identification.* A presssure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

(b) *Classification.* Class I (general controls).

§ 890.5805 Powered muscle stimulator.

(a) *Identification.* A powered muscle stimulator is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.

(b) *Classification.*

Class II (performance standards).

§ 890.5860 Ultrasound and muscle stimulator.

(a) *Ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions*—(1) *Identification.* An ultrasound and muscle stimulator for use in applying therapeutic deep heat for selected medical conditions is a device that applies to specific areas of the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended to generate deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contactures, but not for the treatment of malignancies. The device also passes electrical currents throught the body area to stimulate or relax muscles.

(2) *Classification.* Class II (performance standards).

(b) *Ultrasound and muscle stimulator for all other uses*—(1) *Identification.* An ultrasound and muscle stimulator for all other uses except for the treatment of malignancies is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles as described in paragraph (a) of this section.

(2) *Classification.* Class III (premarket approval).

§ 890.5880 Multi-function physical therapy table.

(a) *Identification.* A multi-function physical therapy table is a device intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy.

(b) *Classification.* Class II (performance standards).

§ 890.5900 Power traction equipment.

(a) *Identification.* Powered traction equipment consists of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the patient's body.

(b) *Classification.* Class II (performance standards).

§ 890.5925 Traction accessory.

(a) *Identification.* A traction accessory is a nonpowered accessory device intended for medical purposes to be used with powered traction equipment to aid in exerting therapeutic pulling forces on the patient's body. This generic type of device includes the pulley, strap, head halter, and pelvic belt.

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

§ 890.5940 Chilling unit.

(a) *Identification.* A chilling unit is a refrigerative device intended for medical purposes to chill and maintain cold packs at a reduced temperature.

(b) *Classification.* Class II (performance standards).

§ 890.5950 Powered heating unit.

(a) *Identification.* A powered heating unit is a device intended for medical purposes that consists of an encased cabinet containing hot water and that is intended to heat and maintain hot packs at an elevated temperature.

(b) *Classification.* Class II (performance standards).

§ 890.5975 Therapeutic vibrator.

(a) *Identification.* A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(b) *Classification.* Class II (performance standards).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule in accordance with section 3(g)(1) of Executive Order 12291, 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 to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain

subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket 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 are not major rules.

Effective date. This regulation is effective December 23, 1983.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)))

Dated: November 14, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31321 Filed 11-22-83; 8:45 am]

BILLING CODE 4160-01-M

federal register

Wednesday
November 23, 1983

Part IV

Department of Health and Human Services

National Institutes of Health

Recombinant DNA Research; Actions Under the Guidelines

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Recombinant DNA Research; Actions Under the Guidelines

AGENCY: National Institutes of Health, PHS, HHS.

ACTION: Notice of Actions under NIH Guidelines for Research Involving Recombinant DNA Molecules.

SUMMARY: This notice sets forth actions taken by the Director, National Institute of Allergy and infectious Diseases (NIAID), by authority of the Director, NIH, under the June 1983 NIH Guidelines for Research Involving Recombinant DNA Molecules (48 FR 24556).

EFFECTIVE DATE: November 23, 1983.

FOR FURTHER INFORMATION CONTACT: Additional information can be obtained from Dr. William J. Gartland, Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20205, (301) 496-6051.

SUPPLEMENTARY INFORMATION: Two major actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules are being promulgated today. These proposed actions were published for comment in the **Federal Register** of August 16, 1983 (48 FR 37198), and reviewed and recommended for approval by the Recombinant DNA Advisory Committee (RAC) at its meeting on September 19, 1983. In accordance with Section IV-C-1-b of the NIH Guidelines, these actions have been found to comply with the Guidelines and to present no significant risk to health or the environment.

Part I of this announcement provides background information on the actions.

Part II provides a summary of the actions and additional announcements of the Director, NIAID.

I. Decisions on Actions Under Guidelines

A. Inclusion of S. Mutans in Sublist F of Appendix A

Dr. Francis Macrina of the Medical College of Virginia of the Virginia Commonwealth University requested the *Streptococcus mutans* be included in Sublist F of Appendix A of the NIH Guidelines for Research Involving Recombinant DNA Molecules. Dr. Macrina argued that *S. mutans* should be included in this sublist for the following reasons:

1. A broad host range streptococcal plasmid, pAMβ1 (conferring erythromycin resistance), is conjugatively transmissible to *S. mutans*. Strains of *S. mutans* inheriting this plasmid are able to transmit it via conjugal transfer.

2. The report of non-plasmid associated conjugal transfer of tetracycline resistance from *S. mutans* to other strains of *S. mutans* and to *S. faecalis*, support the claim of natural genetic transfer from *S. mutans* to other streptococci.

3. A tetracycline resistance determinant from a naturally-resistant *S. mutans* clinical isolate shares sequence homology to the Tn916 (Tc^r) conjugative transposon originating in *S. faecalis*.

4. Naturally transformable strains of *S. mutans* are readily transformed with plasmid or chromosomal DNA from other *mutans* as well as *sanguis* strains.

5. *S. mutans* is far less virulent than two of the current members of Sublist F, *S. pneumoniae* and *S. pyogenes*.

The proposal was published in the August 16, 1983 **Federal Register** (48 FR 37199). No comments were received.

The RAC reviewed this proposal at its September 19, 1983, meeting. It was judged that the data supplied by Dr. Macrina showed that *S. mutans* exchanges DNA by known physiological processes with the other organisms already listed in Sublist F of Appendix A of the Guidelines. The RAC recommended that *S. mutans* be included in Sublist F of Appendix A by a vote of 14 in favor, 0 opposed, and 0 abstentions.

I accept this recommendation, and *S. mutans* has been added to Sublist F, Appendix A. Sublist E of Appendix A will remain as previously published as *S. lactis* is included in Sublist E, but not Sublist F.

B. Modification of Appendix L

The RAC Working Group on Revision of the Guidelines at its January 21, 1983, meeting recommended that Guidelines for field experimentation involving plants modified by recombinant DNA techniques be developed for consideration at the April 11, 1983, RAC meeting.

The Guidelines in force at that time required RAC review and NIH approval as well as IBC approval for the "deliberate release into the environment of any organism containing recombinant DNA." The proposal developed by the working group would have changed this so that provided experiments met certain criteria, growing of plants containing recombinant DNA in the field would have been able to proceed without RAC review and NIH approval. IBC approval would have been required as would notification to ORDA.

The RAC considered the proposal at its April 11, 1983, meeting and discussed it extensively. RAC made several modifications in the specific criteria and modified the procedural aspects of the proposal. The RAC recommended that the modified language be incorporated into a new appendix (Appendix L) which would require review and approval of experiments both by the Institutional Biosafety Committee (IBC) and also by the Plant Working Group of the RAC.

The exact language of Appendix L was subsequently developed by NIH Staff based on the recommendations made at the RAC meeting. The United States Department of Agriculture (USDA) Recombinant DNA Committee then reviewed the RAC recommendation, including the proposed wording for Appendix L, and endorsed their adoption.

The NIH accepted the proposed language and incorporated it into the Guidelines as Appendix L (48 FR 24548 and 24580). Subsequently, Dr. Sue Tolin, the liaison member of the Department of Agriculture to the RAC, in consultation with other members of the RAC Plant Working Group, proposed amendments to Appendix L-II-C which gives some of the criteria allowing review by the RAC Plant Working Group without the requirement for full RAC review. Appendix L-II-C currently reads as follows:

> Appendix L-II-C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences sausing disease have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to fiv) above. The DNA may be introduced by any suitable method.

Dr. Tolin proposed that Appendix L-II-C be modified to read as follows:

> Appendix L-II-C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences resulting in production of disease symptons have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method. If sequences resulting in production of disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequences before such plants, derivatives, or seed from them can be used in field tests.

The proposal was published in the August 16, 1983, **Federal Register** (48 FR 37199) for comment. No comments were received.

The RAC discussed this proposed modification at its September 19, 1983, meeting. Dr. Tolin noted that, under the June 1, 1983, **Federal Register** language, the Plant Working Group review might have to be conducted using the strictest definition of the word "disease." This may preclude the approval of some plasmid and virus-derived nucleic acids as vectors, since their replication might be construed as a disease process even though no symptoms develop in the plants. Dr. Tolin stated that it is her belief that if all other stipulations of Appendix L are satisfied, this minor change will result in no greater probability of risk of introducing plants containing recombinant DNA into the environment.

Dr. Tolin said sequences causing disease symptoms might be necessary to introduce the recombinant DNA into the plant. There are, however, methods for removing these sequences before the plants are tested in the field. Data showing elimination of these sequences would be evaluated by the Plant Working Group.

The RAC recommended the proposed modification by a vote of 13 in favor, 0 opposed, and 0 abstentions.

I accept this modification and Appendix L–II–C is modified to reflect this change.

II. Summary of Actions

A. Inclusion of S. Mutans in Sublist F of Appendix A

Sublist F of Appendix A is modified to read:

"Sublist F

"1. *Streptococcus sanguis*
"2. *Streptococcus pneumoniae*
"3. *Streptococcus faecalis*
"4. *Streptococcus pyogenes*
"5. *Streptococcus mutans*"

B. Modification of Appendix L—Release Into the Environment of Certain Plants

Appendix L–II–C of Appendix L is modified to read as follows:

Appendix L–II–C. The vector consists of DNA: (i) From exempt host-vector systems (Appendix C); (ii) from plants of the same or closely related species; (iii) from nonpathogenic prokaryotes or nonpathogenic lower eukaryotic plants; (iv) from plant pathogens only if sequences resulting in production of disease symptoms have been deleted; or (v) chimeric vectors constructed from sequences defined in (i) to (iv) above. The DNA may be introduced by any suitable method. If sequences resulting in production of disease symptoms are retained for purposes of introducing the DNA into the plant, greenhouse-grown plants must be shown to be free of such sequences before such plants, derivatives, or seed from them can be used in field tests.

Additional Announcement of the Director, NIAID

In connection with the incorporation of Appendix K into the Guidelines on June 1, 1983, it was stated in the note in 48 FR 24551 that Section III–B–5 of the Guidelines was to be changed to delete reference to 45 FR 24968 and to add instead a reference to Appendix K. However, due to an error, this change was not made when the Guidelines were published (48 FR 24559). To correct this error, Section III–B–5 of the Guidelines is now modified to read as follows:

III–B–5. *Experiments Involving More Than 10 Liters of Culture.* The appropriate containment will be decided by the IBC. Where appropriate, Appendix K, *Physical Containment for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules*, should be used.

Dated: November 15, 1983.

Richard M. Krause,

Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health.

Note.—OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance*. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every federal research program in which DNA recombinant molecule techniques could be used, it has been determined to be not cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every federal program would be included as many federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

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federal register

Wednesday
November 23, 1983

Part V

Office of Management and Budget

Budget Deferrals

OFFICE OF MANAGEMENT AND BUDGET

Budget Deferrals

To the Congress of the United States:

In accordance with the Impoundment Control Act of 1974, I herewith propose one rescission of $30,000,000 in contract authority for the Department of the Interior and two new deferrals of budget authority totaling $72,164,000 for the Department of Energy.

The details of the proposed rescission and the deferrals are contained in the attached reports.

Ronald Reagan,

The White House, November 17, 1983.

BILLING CODE 3110-01-M

CONTENTS OF SPECIAL MESSAGE
(In thousands of dollars)

Deferral #	Item	Budget Authority
	Department of Energy:	
D84-21	Fossil energy research and development.....	58,364
D84-22	Alternate fuels production.....	-13,800
	Department of the Interior	
D84-23	National Park Service, land acquisition and state assistance (contract authority).....	30,000
	Total, deferrals.....	102,164

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SUMMARY OF SPECIAL MESSAGES
FOR FY 1984
(In thousands of dollars)

	Rescissions	Deferrals
Second special message		
New items.....	---	102,164
Revisions to previous special messages.....	---	---
Effects of second special message.....	---	102,164
Amounts from previous special messages that are changed by this message (change noted above).....	---	---
Subtotal, rescissions and deferrals.....	---	102,164
Amounts from previous special messages that are not changed by this message.....	---	1,924,697
Total amount proposed to date in all special messages.....	---	2,026,861

Deferral No: D-84-21

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of Energy

Bureau: Energy Programs

Appropriation title & symbol: Fossil Energy, Research and Development 89X0213 1/

New budget authority (P.L. _____) $ 0

Other budgetary resources 80,972,028

Total budgetary resources 80,972,028

Amount to be deferred:
Part of year $ 46,326,000
Entire year 12,038,000

OMB identification code: 89-0213-0-1-271

Legal authority (in addition to sec. 1013):
☐ Antideficiency Act
☐ Other _____

Trust program: ☐ Yes ☒ No

Type of account or fund:
☐ Annual
☐ Multiple-year _____ (expiration date)
☒ No-year

Type of budget authority:
☒ Appropriation
☐ Contract authority
☐ Other _____

Justification: This account provides for research and development activities relating to coal, petroleum, and natural gas. This deferral includes $46.3 million that was deferred pending enactment of the FY 1984 Department of the Interior Appropriations Bill. This Bill would reprogram these funds for appropriate fossil energy research and development activities in FY 1984. This deferral also includes $12.0 million in prior year unobligated balances that are available as a result of the completion of various fossil energy related construction projects. These funds will be used in FY 1985.

Estimated Program Effect: None.

Outlay Effect: This deferral action will shift $12 million in outlays from FY 1984 to FY 1985.

1/ This account was the subject of a similar deferral in FY 1983 (D83-81). This account has been merged with the Fossil energy construction account.

Deferral No: D84-22

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of Energy	New budget authority (P.L. ____) $ 0
Bureau: Energy Programs	Other budgetary resources 14,500,000
Appropriation title & symbol: Alternate Fuels Production 89X5180 1/	Total budgetary resources 14,500,000
	Amount to be deferred: Part of year $ 13,000,000
	Entire year 800,000
OMB identification code: 89-5180-0-2-271	Legal authority (in addition to sec. 1013): ☐ Antideficiency Act
Grant program: ☐ Yes ☒ No	☐ Other ____
Type of account or fund: ☐ Annual ☐ Multiple-year ____ (expiration date) ☒ No-year	Type of budget authority: ☒ Appropriation ☐ Contract authority ☐ Other ____

Justification: This program provides for the development and production of alternative fuels. This deferral includes $13.0 million that was deferred pending enactment of the 1984 Department of the Interior Appropriations Bill. This Bill would reprogram these funds for appropriate alternate fuels production projects in FY 1984. This deferral also includes $800 thousand in FY 1983 unobligated balances made available from completed alternative fuels projects that will be used in FY 1985.

Estimated Program Effect: None.

Outlay Effect: This deferral action will shift $800 thousand in outlays from FY 1984 to FY 1985.

1/ This account was the subject of a similar deferral in FY 1983 (D83-77).

[FR Doc. 83-31525 Filed 11-22-83; 8:45 am]
BILLING CODE 3110-01-C

Deferral No: D84-21

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

Agency: Department of the Interior	New budget authority [16 U.S.C. 460L-10a] $ 30,000,000
Bureau: National Park Service	Other budgetary resources 128,000,000
Appropriation title & symbol: Land Acquisition and State Assistance 1/ 14X5035	Total budgetary resources 158,000,000
	Amount to be deferred: Part of year 30,000,000
	Entire year ____
OMB identification code: 14-5035-0-2-303	Legal authority (in addition to sec. 1013): ☐ Antideficiency Act
Grant program: ☒ Yes ☐ No 2/	☐ Other ____
Type of account or fund: ☒ Annual 2/ ☐ Multiple-year ____ (expiration date) ☐ No-year	Type of budget authority: ☒ Appropriation ☒ Contract authority (annual) 2/ ☐ Other ____

Justification: This appropriation provides (1) funds to acquire land for inclusion in the National Park system, and (2) grants to States for outdoor recreation purposes.

Under existing law [16 U.S.C. 460L-10a], $30 million in contract authority is made available each fiscal year for use as an anti-cost escalation measure in purchasing authorized Federal recreation land. This authority was last used in 1969 and 1970, and there are no plans to use it in the future. The contract authority lapsed in fiscal years 1971-1981 and was rescinded by Congressional action for fiscal years 1982 (P.L. 97-257) and 1983 (P.L. 98-63). The $30 million in FY 1984 contract authority has been deferred pending final FY 1985 Budget decisions to be submitted by the President to Congress this January.

Estimated Program Effect: None.

Outlay Effect: None.

1/ This account was subject to a similar deferral in FY 1983 (D83-11).
2/ The deferred funding is non-grant contract authority with a one-year availability.