FOR FURTHER INFORMATION CONTACT: Marshall P. Jones, Chief, Office of Management Authority, at the address above, telephone (202) 343–4968.

SUPPLEMENTARY INFORMATION: During the past few months, proposals for temporary exhibition loans of giant pandas (*Ailuropoda melanoleuca*) have become an increasingly controversial issue. The giant panda is subject to strict U.S. and international protection by its listing as an endangered species under the U.S. Endangered Species Act (Act), and its inclusion on Appendix I to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (Convention). The Fish and Wildlife Service (Service) has the responsibility to regulate panda loans to institutions in the United States by deciding whether to grant import permits required by the Act and the Convention. The Service believes that its existing regulations and guidelines under the Act and the Convention have been sufficient for panda import permit decisions made to date (two in 1988, three in 1987, and one in 1984).

However, the Service has received reports that as many as 30 additional institutions may now be negotiating with the People's Republic of China to arrange panda loans, posing new, cumulative threats to the wild and captive populations of the species. Several international conservation organizations have recommended that such loans must be curtailed, and expert opinion increasingly suggests that future loans, if not strictly controlled, may be harmful to the species. Since a large percentage of the institutions which may seek loans are from the United States, the Service must carefully evaluate this new information to ensure that its permitting actions do not result in such harmful effects. Therefore on June 6, 1988, the Director of the Service suspended further review and processing of new panda loan permit applications until additional information is evaluated and cumulative effects analyzed. This **Federal Register** notice announces the June 6, 1988, suspension and describes the evaluation process to be completed by the Service.

Before any import permit can be granted, it must be reviewed in terms of the applicable requirements of the Convention and the Act. Issuance of an import permit under the Convention requires prior findings that: (1) The import would not be for primarily commercial purposes; (2) the import would not be for purposes detrimental to the survival of the species; and (3) the permit applicant could suitably house and care for the animals. Issuance of a permit under the Act requires prior determinations that, among other things: (1) The import would be for scientific purposes or to enhance the propagation or survival of the species, in a manner consistent with the purposes and policies of the Act; and (2) approval of the import would not be likely to jeopardize the continued existence of the species. These requirements are further implemented by application requirements and issuance criteria found in 50 CFR 17.21, 17.22, 23.14 and 23.15.

Prior to making any further decisions on panda imports, the Service is evaluating all available information on the potential effects of further loans on the wild and captive populations of giant pandas, including the cumulative impacts of the anticipated increasing number of loan requests. The Service has also initiated a review of its current policies and guidelines as they relate to future determinations on panda permit applications for temporary exhibition purposes.

Accordingly, the Service is suspending the review and processing of any further permit applications for panda imports for temporary exhibition loans until the evaluations described above are completed. The Service intends to complete the review and develop any new policies or guidelines as quickly as possible. Interested organizations and members of the public are invited to comment on the applicability of the Act and Convention requirements listed above to temporary giant panda exhibitions, as well as any other issues which the Service should consider in undertaking this review. A proposed policy will also be published for public review as soon as it is available.

Author: This notice was prepared by Marshall P. Jones, Chief, Office of Management Authority, U.S. Fish and Wildlife Service, Washington, DC 20240 (202) 343–4968 or FTS 343–4968).

Authority: The authority for this action is the Endangered Species Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (a treaty to which the U.S. is a party).

Dated: June 20, 1988

Frank Dunkle,

Director, Fish and Wildlife Service.

[FR Doc. 88–14345 Filed 6–23–88; 8:45 am]

BILLING CODE 4310–55–M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 122
Friday, June 24, 1988

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

FEDERAL MARITIME COMMISSION

TIME AND DATE: 10:00 a.m., June 29, 1988.

PLACE: Hearing Room One, 1100 L Street, NW., Washington, DC 20573-0001.

STATUS: Part of the meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portion Open to the Public

1. P5-87—Truck Detention Charges at West Coast Ports—Petition Filed by the Waterfront Rail Truckers Union, and P1-88—Truck Detention Charges at California Ports—Petition Filed by the California Trucking Association—Consideration of Comments.

Portions Closed to the Public

1. Totem Ocean Trailer Express, Inc., 7.5 Percent General Rate Increase in its Alaska Trade Tariff FMC-F No. 4.
2. Puerto Rico Maritime Shipping Authority—Five Percent General Rate Increase in its Puerto Rico/Virgin Islands Tariff FMC-F No. 8.
3. Aloha Pacific Cruises—Certificate (Performance).
4. Docket No. 87-13—Pate Stevedore Company of Mobile, *et al.* v. The Alabama State Docks Department, *et al.*, and Docket No. 87-17—Atlantic & Gulf Stevedores of Alabama and Alabama Insurance Guaranty Association v. The Alabama State Docks Department and Aetna Casualty & Surety Company—Consideration of the Record.
5. Docket No. 87-14—Banfi Products Corporation—Possible Violations of section 16, Initial Paragraph, Shipping Act, 1916 and section 10(a)(1) of the Shipping Act of 1984—Motion to Amend Order of Investigation.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, *Secretary*, (202) 523-5725.

Joseph C. Polking,

Secretary.

[FR Doc. 88-1440 Filed 6-22-88; 3:29 pm]

BILLING CODE 6730-01-M

NEIGHBORHOOD REINVESTMENT CORPORATION

Board Meeting

TIME AND DATE: 7:30 a.m., Monday, June 27, 1988.

PLACE: Federal Reserve System 20th & Constitution NW., Martin Building, Terrace Level, Blue Room, Washington, DC. 20551.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Bonnie Nance Frazier, Director of Communications, 376-2623.

AGENCY: Continuation of Agenda Items Carried Forward From Meeting of June 21, 1988.

Carol J. McCabe,

Secretary.

[FR Doc. 88-14441 Filed 6-22-88; 3:30 pm]

BILLING CODE 7570-01-M

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of June 27, 1988.

An open meeting will be held on Thursday, June 30, 1988, at 10:00 a.m., followed by a closed meeting.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Grundfest, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the open meeting scheduled for Thursday, June 30, 1988, at 10:00 a.m., will be:

Consideration of whether to publish a release proposing two alternatives to provide for automatic effectiveness of post-effective amendments filed to provide required financial statements, financial information and textual information related to significant acquisitions by limited partnerships. For further information, please contact Sarah A. Miller at (202) 272-2589.

The subject matter of the closed meeting scheduled for Thursday, June 30, 1988, following the 10:00 a.m. open meeting, will be:

Formal order of investigation.
Settlement of administrative proceedings of an enforcement nature.
Institution of administrative proceedings of an enforcement nature.
Institution of injunctive actions.
Litigation matter.
Opinion.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Alden Adkins at (202) 272-2014.

Jonathan G. Katz,

Secretary.

June 21, 1988.

[FR Doc. 88-14434 Filed 6-22-88; 3:29 pm]

BILLING CODE 8010-01-M

LEGAL SERVICES CORPORATION, BOARD OF DIRECTORS MEETING

TIME AND DATE: The open meeting of the Board of Directors will commence at 6:00 p.m. on Friday, July 1, 1988, and continue until all official business is completed. An Executive Session will be held immediately following the open meeting, if appropriate.

PLACE: Loews L'Enfant Plaza Hotel, Ballroom B, 480 L'Enfant Plaza SW., Washington, DC 20024.

STATUS OF MEETING: Open [A portion of the meeting is to be closed to discuss personnel and litigation matters under The Government in the Sunshine Act [5 U.S.C. 552b(c) (2), (6), (9) and (10)] and 45 CFR 1622.5 (a), (e), (g) and (h)].

MATTERS TO BE CONSIDERED:

Board of Directors Meeting (Open)

1. Approval of Agenda
2. Performance Review of the President of the Corporation and Possible Action on Such Review
3. Discussion and Action on New Personnel Discussion and Public Comment follow each item.

Executive Session (Closed)

1. Personnel Litigation Matters
2. New Personnel Reviews

CONTACT PERSON FOR MORE INFORMATION: Maureen R. Bozell, Executive Office, (202) 863-1839.

Date issued: June 22, 1988.

Maureen R. Bozell,

Secretary.

[FR Doc. 88-14452 Filed 6-22-88; 5:03 pm]

BILLING CODE 7050-01-M

Corrections

Federal Register
Vol. 53, No. 122
Friday, June 24, 1988

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

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL 3378-8]

Approval and Promulgation of Implementation Plans; Ohio

Correction

In rule document 88-10626 beginning on page 18087 in the issue of Friday, May 20, 1988, make the following correction:

§ 52.1881 [Corrected]

On page 18091, in the third column, in § 52.1881(a)(8), in the first line, "Washington" should read "Montgomery".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Privacy Act of 1974; Revision of System Notice 09-30-0050

Correction

In notice document 88-13319 beginning on page 22225 in the issue of Tuesday, June 14, 1988, make the following correction:

The heading to the document should read as set forth above. The system of records was not deleted. Only routine use 2 was deleted by the document.

BILLING CODE 1505-01-D

MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1200

Board Organization

Correction

In rule document 88-13611 beginning on page 22465 in the issue of Thursday, June 16, 1988, make the following correction:

§ 1200.10 [Corrected]

On page 22465, in the third column, in § 1200.10(g), in the fourth line, "action the" should read "action by the".

BILLING CODE 1505-01-D

Federal Register

Friday
June 24, 1988

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 878

General and Plastic Surgery Devices; General Provisions and Classifications of 51 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 78N-2646]

General and Plastic Surgery Devices; General Provisions and Classifications of 51 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 51 general and plastic surgery devices. In the preamble to this rule, FDA is responding to comments received on the proposed regulations classifying these devices. This action is the last of the umbrella classification rules for devices of a type on the market before enactment of the Medical Device Amendments of 1976.

EFFECTIVE DATE: July 25, 1988.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Palmer, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Background

In the **Federal Register** of January 19, 1982 (47 FR 2810-2853), FDA published a proposed rule containing general provisions applicable to the classification of general and plastic surgery devices and individual proposed regulations to classify 54 general and plastic surgery devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). In this final rule, FDA is classifying 51 devices, with 23 in class I, 1 device in class I or class II (depending upon the specific characteristics of the device), 18 devices in class II, and 9 devices in class III. FDA has classified several devices differently than had been proposed and has made other changes in the final rule. First, 3 of the 9 class III devices are transitional devices that the statute classified into class III and that, therefore, were not subject to proposed classification rules. Second, one proposed generic type of device is being split into two generic types of devices. Third, FDA plans to issue new proposals for three devices. Fourth, to allow time for FDA to review additional data on safety of certain AC-powered devices, FDA is postponing final classifications of four devices. Fifth, FDA is classifying into class I the eye pad as a general and plastic surgery device, although the proposed regulation for the device was published in the proposals on ophthalmic devices (Docket No. 78N-3265). Sixth, FDA has withdrawn the proposed regulation for one device.

Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant eight general and plastic surgery devices an exemption from the requirement of premarket notification.

Classification of medical devices in commercial distribution is required by section 513 (21 U.S.C. 360c) of 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 that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before December 31, 1990, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the proposed rule described the development of the general provisions and the proposed regulations to classify general and plastic surgery devices and the activities of the General and Plastic Surgery Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of general and plastic surgery devices. FDA provided a period of 160 days for interested persons to submit written comments on these proposed regulations. The comments received are discussed below.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II. Under the amendments, FDA is using the regulatory controls of class I to regulate a device classified into class II until a performance standard is established under section 514 of the act (21 U.S.C. 360d) for the class II device.

In that notice, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices:

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

b. The recommendations of FDA's advisory committees.

c. The impact of an FDA guideline or recommendation.

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

e. The impact of voluntary standards.

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

g. The effect of dissemination of information and education efforts.

h. The sufficiency of voluntary corrective actions.

i. Valid scientific evidence developed since classification.

j. The existence of a petition for reclassification.

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

C. Devices Not Being Classified at This Time

1. After publishing the proposed regulation to classify the aorto-saphenous vein ostia marker into class II, the agency determined that the device is included, as an accessory, in a generic type of cardiovascular device that the agency had already classified into class II: § 870.3460 *Vascular graft prosthesis of 6 millimeters and greater diameter* (February 5, 1980; 45 FR 7938). The agency has published in the **Federal Register** a separate notice withdrawing this proposed regulation (November 6, 1986; 51 FR 40396). FDA has placed the administrative record for the proposed regulation in the administrative record for the vascular graft prosthesis of 6 millimeters and greater diameter (Docket No. 78N–1484).

2. FDA proposed that the following three devices be classified into class 1: nonabsorbable gauze, surgical sponge, and wound dressing for external use (Docket No. 78N–2666); hydrophilic beads for wound exudate absorption (Docket No. 78N–2669); and the porcine burn dressing (Docket No. 78N–2670). The agency has now decided to issue new proposals to classify these devices in a future issue of the **Federal Register**.

3. FDA is postponing final classification of four general and plastic surgery devices pending agency review of additional data concerning electrical safety: the surgical microscope and its accessories (Docket No. 78N–2691); AC-powered, battery powered, and pneumatically powered surgical instrument motors and their accessories and attachments (Docket No. 78N–2698); the air or AC-powered operating table and its accessories and the air or AC-powered operating chair and its accessories (Docket No. 78N–2705); and ultraviolet lamps for tanning (Docket No. 78N–2687). (See comment 26 below for a discussion of how FDA has clarified its identification of ultraviolet lamps by treating those intended for tanning in a different regulation than ultraviolet lamps intended for use in activating a drug in the treatment of dermatological disorders.) FDA is considering issuance of a proposal to classify these four devices into class I.

D. Changes in Classifications in Final Regulations

Based upon consideration of the comments received and additional information before the agency, FDA has placed several devices that are listed below in different classes from those proposed. FDA's reasons for adopting classifications for these devices that differ from the proposals are provided in this preamble under the heading "J. Summaries of Comments and FDA's Responses to Comments."

Device	Proposed class	Final class
§ 878.4040 Surgical apparel.	II	II Surgical gowns and masks. I Surgical apparel other than gowns and masks.
§ 878.4200 Introduction/drainage catheter and accessories.	II	I.
§ 878.4350 Cryosurgical unit and accessories.	II, III	II.
§ 878.4460 Surgeon's glove.	II	I.
§ 878.5650 Topical oxygen chamber for extremities.	II	III.

FDA believes that it is unnecessary to issue new proposed regulations concerning these decisions. The purpose of publishing a proposed regulation and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposal or upon reconsideration, the agency may determine that its proposed classification is incorrect. 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 regulations for general and plastic surgery devices (see 47 FR 2810; January 19, 1982). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of 21 Part CFR 860.

E. Changes in the Name of the General and Plastic Surgery Device Advisory Committee

FDA has periodically restructured its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the General and Plastic Surgery Devices Panel (the Panel) (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to general and plastic surgery devices as did its predecessors, the General and Plastic Surgery Device Classification Panel (1976–78) and the Surgical and Rehabilitation Devices Panel (1978–84).

F. Classification Regulations Published to Date

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

Panel name	Publication date in FEDERAL REGISTER
Circulatory Devices Panel.	March 9, 1979, 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel.	February 2, 1982, 47 FR 4802–4929 (proposals); May 1, 1987, 52 FR 16102–16138 (final regulations).
Hematology and Pathology Devices Panel.	September 11, 1979, 44 FR 53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations).
General Hospital and Personal Use Devices Panel.	August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations).
Gastroenterology-Urology Devices Panel.	January 23, 1981, 46 FR 7562–7641 (proposals); November 23, 1983, 48 FR 53012–53029 (final regulations).
Immunology Devices Panel.	April 22, 1980, 45 FR 27204–27359 (proposals); November 9, 1982, 47 FR 50814–50840 (final regulations).
Microbiology Devices Panel.	Do.
Obstetrics-Gynecology Devices Panel.	April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations).
Radiologic Devices Panel.	January 29, 1982, 47 FR 4406–4451 (proposals); January 20, 1988, 53 FR 1554–1571 (final regulations).
Ophthalmic Devices Panel.	January 26, 1982, 47 FR 3694–3749 (proposals); September 2, 1987, 52 FR 33346–33363 (final regulations).
Ear, Nose, and Throat Devices Panel.	January 22, 1982, 47 FR 3280–3325 (proposals); November 6, 1986, 51 FR 40378 (final regulations).
Dental Devices Panel.	December 30, 1980, 45 FR 85962–86168 (proposals); August 12, 1987, 52 FR 30082–30106 (final regulations).

Panel name	Publication date in FEDERAL REGISTER
Anesthesiology and Respiratory Therapy Devices Panel.	November 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Devices Panel.	November 23, 1978, 43 FR 54640-55732 (proposals); September 4, 1979, 44 FR 51726-51778 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices).	August 28, 1979, 44 FR 50458-50537 (proposals); November 23, 1983, 48 FR 53032-53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices).	July 2, 1982, 47 FR 29052-29140 (proposals); September 4, 1987, 52 FR 33686-33711 (final regulations).
General and Plastic Surgery Devices Panel.	January 19, 1982, 47 FR 2810-2853 (proposals); (*Insert date of publication in the* **Federal Register** (final regulations).

G. Minor Changes or Clarifications

Occasionally the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Additionally, the agency is adding § 878.3 to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a new paragraph (c) in the classification regulation for each device classified into class III to declare, where applicable, the effective date for premarket approval requirements for the device.

H. Transitional Devices

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

Liquid silicone for injection is an investigational transitional general and plastic surgery device that is not in commerical distribution. Accordingly, although this device is classified by statute as a class III device, FDA will not publish a final classification regulation describing the device's statutory classification into class III unless the agency approves an application for premarket approval for this device.

FDA is including in this final rule sections codifying the statutory classification into class III of the following three commercially distributed, transitional general and plastic surgery devices; these devices were the subject of a **Federal Register** notice (December 16, 1977; 42 FR 63472) on their former status as new drugs: absorbable powder for lubricating a surgeon's glove (§ 878.4480), the absorbable hemostatic agent and dressing (§ 878.4490), and polytetrafluoroethylene injectable (§ 878.4520).

FDA will deal with the classification of absorbable and nonabsorbable sutures in a future **Federal Register** document. These sutures are transitional devices that have been classified into class III by section 520(l) of the act. However, at this time, the agency is considering petitions under section 520(l) of the act seeking reclassification of certain of these sutures. Moreover, FDA has already reclassified stainless steel sutures from class III into class II, in response to a petition that had been submitted by Alto Corporation, Farmingdale, New Jersey. In the future, FDA plans to issue a rule codifying the reclassification of stainless steel sutures, as well as any other reclassifications that may be accomplished in response to the petitions now under review.

I. List of General and Plastic Surgery Devices

The list below shows for each general and plastic surgery device the section of the Code of Federal Regulations at which the classification of that device is being codified (or will be codified), the docket number of the corresponding proposed classification regulation (where applicable), the final classification of the device, and an identification (yes or no) of whether comments were received on the proposed regulation. If no comments were received, FDA is adopting the proposed regulation without a change in classification. The list also identifies the eight generic types of class I general and plastic surgery devices that are subjects of a proposed rule, published elsewhere in this issue of the **Federal Register**, to grant an exemption, with limitations, from the requirement of premarket notification. The names of the eight devices are identified with footnote "1" (§§ 878.1800, 878.3250, 878.3910, 878.3925, 878.4160, 878.4800, 878.4950, and 878.5900).

The list includes the four generic types of general and plastic surgery devices for which classification is being postponed. For each of these devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "3," and no classification is provided (§§ 878.4635, 878.4700, 878.4820, and 878.4960).

The list includes the eye pad (Docket No. 78N-3265), which was the subject of a proposed regulation published with those on ophthalmic devices. FDA is classifying this device with general and plastic surgery devices (§ 878.4440). A summary of the comments received on the proposed regulation for the eye pad is in paragraph 34, under "J. Summaries of Comments on Classifications and FDA's Responses to Comments."

Section	Device	Docket No.	Class	Comments
	Subpart B—Diagnostic Devices			
878.1800	Speculum and accessories [1]	78N-2647	I	No.
	Subpart D—Prosthetic Devices			
878.3250	External facial fracture fixation appliance [1]	78N-2649	I	No.
878.3300	Surgical mesh	78N-2650	II	Yes.
878.3500	Polytetrafluoroethylene with carbon fibers composite implant material	78N-2651	II	Yes.
878.3530	Silicone inflatable breast prosthesis	78N-2653	III	Yes.
878.3540	Silicone gel-filled breast prosthesis	78N-2654	III	Yes.
878.3550	Chin prosthesis	78N-2655	II	Yes.
878.3590	Ear prosthesis	78N-2656	II	Yes.

Section	Device	Docket No.	Class	Comments
878.3610	Esophageal prosthesis	78N-2657	III	No.
878.3680	Nose prosthesis	78N-2658	II	Yes.
878.3720	Tracheal prosthesis	78N-2659	III	No.
878.3750	External prosthesis adhesive	78N-2660	I	No.
878.3800	External aesthetic restoration prosthesis	78N-2661	I	No.
878.3900	Inflatable extremity splint	78N-2662	I	No.
878.3910	Noninflatable extremity splint [1]	78N-2663	I	No.
878.3925	Plastic surgery kit and accessories [1]	78N-2664	I	No.
	Subpart E—Surgical Devices			
878.4040	Surgical apparel	78N-2665	I, II	Yes.
878.4100	Organ bag	78N-2667	I	Yes.
878.4160	Surgical camera and accessories [1]	78N-2671	I	No.
878.4200	Introduction/drainage catheter and accessories	78N-2672	I	Yes.
878.4300	Implantable clip	78N-2674	II	Yes.
878.4320	Removable skin clip	78N-2675	I	No.
878.4350	Cryosurgical unit and accessories	78N-2676	II	Yes.
878.4370	Surgical drape and drape accessories	78N-2677	II	Yes.
878.4380	Drape adhesive	78N-2678	I	Yes.
878.4400	Electrosurgical cutting and coagulation device and accessories	78N-2679	II	Yes.
878.4460	Surgeon's glove	78N-2682	I	Yes.
878.4470	Surgeon's gloving cream	78N-2683	I	No.
878.4480	Absorbable powder for lubricating a surgeon's glove [2]		III	
878.4490	Absorbable hemostatic agent and dressing [2]		III	
878.4520	Polytetrafluoroethylene injectable [2]		III	
878.4580	Surgical lamp	78N-2686	II	Yes.
878.4630	Ultraviolet lamp for dermatologic disorders	78N-2687	II	Yes.
(878.4635)	Ultraviolet lamp for tanning [3]	78N-2687		Yes.
878.4660	Skin marker	78N-2689	I	No.
878.4680	Nonpowered, single patient, portable suction apparatus	78N-2690	I	No.
(878.4700)	Surgical microscope and accessories [3]	78N-2691		Yes.
878.4730	Surgical skin degreaser or adhesive tape solvent	78N-2692	I	Yes.
878.4750	Implantable staple	78N-2693	II	Yes.
878.4760	Removable skin staple	78N-2694	I	Yes.
878.4780	Powered suction pump	78N-2695	II	Yes.
878.4800	Manual surgical instrument for general use [1]	78N-2696	I	No.
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology.	78N-2697	II	Yes.
(878.4820)	AC-powered, battery-powered and pneumatically powered surgical instrument motors and accessories attachments [3].	78N-2698		Yes.
878.4930	Suture retention device	78N-2703	I	No.
878.4950	Manual operating table and accessories and manual operating chair and accessories [1].	78N-2704	I	No.
(878.4960)	Air or AC-powered operating table and accessories and air or AC-powered operating chair and accessories [3].	78N-2705		Yes.
	Subpart F—Therapeutic Devices			
878.5070	Air-handling apparatus for a surgical operating room	78N-2709	II	Yes.
878.5350	Needle-type epilator	78N-2711	II	Yes.
878.5360	Tweezer-type epilator	78N-2712	III	No.
878.5650	Topical oxygen chamber for extremities	78N-2714	III	Yes.
878.5900	Nonpneumatic tourniquet [1]	78N-2716	I	No.
878.5910	Pneumatic tourniquet	78N-2717	II	Yes.

[1] Subject of a proposed rule to grant an exemption from premarket notification published elsewhere in this issue of the FEDERAL REGISTER.
[2] Not proposed; statutory classification.
[3] Classification postponed.

J. Summaries of Comments and FDA's Responses to Comments

FDA is responding below to nine general comments (paragraphs 1 through 9) which did not identify specific devices and 25 comments (paragraphs 10 through 34) on specific devices. When a comment applies to more than one device, the agency is summarizing the comment, listing the devices involved, and responding to the comment.

1. One comment stated that several years ago the agency issued a notice to explain the transitional provisions of the devices amendments (December 16, 1977; 43 FR 63472). The comment stated that 14 transitional devices listed in that notice were not included in the proposed regulations to classify general and plastic surgery devices. The comment stated that FDA also should classify these 14 transitional devices.

FDA believes that it should codify the statutory classifications of certain of those transitional devices that are general and plastic surgery devices and is doing so in this rule.

2. A comment stated that a number of the Class III transitional devices requiring premarket approval were part of the DESI review for human drugs (Drug Efficacy Study Implementation: 37 FR 26623; December 14, 1972) and found to be safe and effective with minor labeling changes. The comment stated that, had these devices remained drugs, marketing of them would be permitted under an abbreviated new drug application. Thus, the comment contended that the regulatory burden has been increased for these products without justification.

The agency advises that reclassification procedures are available for devices, including transitional devices (see 21 CFR Part 860), that these procedures are designed to minimize burdens on petitioners, and that the agency encourages the submission of reclassification petitions for these transitional devices.

3. A comment stated that FDA referred a number of transitional devices to the Panel for classification recommendations, e.g., absorbable dusting powder and absorbable hemostatic agents, but no mention is made of the Panel's recommendations for these products in the general and plastic surgery device classification proposals. Because the agency referred these devices to the Panel for its recommendations and has received them, the comment stated that the agency is required to publish these recommendations.

Transitional devices are classified by section 520(l) of the act, not under the procedures in section 513 (c) and (d) for other preamendments devices. There is no statutory requirement to refer transitional devices to the Panel or to publish the Panel's recommendations for transitional devices. These recommendations are available upon request. The agency advises, however, as noted above, that it encourages reclassification petitions for these transitional devices.

4. A comment said that, according to the regulations, the "* * * evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury * * *." Under this criterion, the comment asserted that a manufacturer is required to show an absence of risk. The comment noted that this is an impossible standard, particularly since FDA will, in evaluating safety, consider such data as "* * * isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions."

FDA believes that the language cited by the comment is out of context and does not reflect the total content of the regulations involved (21 CFR 860.7 (c)(2) and (d)(1)). The complete language of 21 CFR 860.7(d)(1) follows:

> There is reasonable assurance that a device is safe when it has been determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

FDA believes that the criteria it uses to determine the safety of a device, found in section 513(a)(2) of the act and 21 CFR 860.7, are required by law and are reasonable. Further, FDA believes that any risk of injury or illness is unreasonable when no evidence is available of probable benefit to the health of those persons for whose use the device is intended. This conclusion is supported by the legislative history of the Medical Device Amendments of 1976 (Pub. L. 94–295). In its report, the House Committee on Interstate and Foreign Commerce explained the meaning of "potential unreasonable risk" as follows:

> The phrase "presents a potential unreasonable risk of illness or injury" has two significant features. First, the requirement that a risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against benefits from use. Second, the risk need only be a potential one. The risk may be one demonstrated by reported injuries or it may simply be foreseeable. The fact that a device is being marketed without sufficient testing is an adequate basis for the Secretary's conclusion that the device presents a potential unreasonable risk to health. (H.R. Rept. No. 94–853, 94th Cong. 2d Sess. 36 (1976)).

5. A comment said that the FDA classifies a device into class II it is a formal determination by FDA that without a performance standard there is not reasonable assurance that the device is safe and effective.

As discussed above, however, the statute contemplates that FDA will set priorities for the establishment of performance standards, and until a standard is set for a class II device, it is allowed to be marketed subject only to general controls of the act. FDA has published in the **Federal Register** a notice announcing its policy for setting priorities for initiating proceedings to establish performance standards for devices classified into class II (October 23, 1985; 50 FR 43060). See "B. FDA's Priorities for Establishing Performance Standards" earlier in this preamble.

6. Several general comments stated that FDA proposed to classify too many general and plastic surgery devices in class II and requested that more devices be in class I.

FDA agrees that certain of the devices that it proposed to classify in class II should be in class I. These devices are identified earlier in this preamble under "D. Changes in Classifications in Final Regulations." FDA's reasons for making these changes are provided below in paragraphs 15, 17, 19, 24, and 32. FDA's reasons for classifying the remaining general and plastic surgery devices into class II as proposed are provided below in FDA's responses to comments on each device, and in the preamble to the proposal.

7. A comment stated that (1) a standard for tissue compatibility of implantable materials would preclude the use of new implant materials, because the standard would identify only materials that have been shown to be compatible; and (2) the tissue compatibility of new materials could be addressed more expeditiously through section 510(k) procedures (premarket notification), rather than through development of standards.

FDA disagrees with the comment. FDA would apply any performance standard for tissue biocompatibility for implant materials both to preamendments devices and (through premarket notification procedures) any devices found to be substantially equivalent to such devices. FDA evaluates the safety and effectiveness of a new implant material as part of its evaluation of a device. Performance standards for preamendments devices made of designated materials would not prevent FDA's evaluation and approval of devices made from new postamendments materials. The comment suggested use of premarket notification procedures as a vehicle for FDA to allow marketing of new materials. The premarket notification procedures under section 510(k) of the act are not intended to establish the valid scientific evidence (defined in 21 CFR 860.7) necessary to demonstrate the safety and effectiveness of new, not substantially equivalent implant materials. Accordingly, before marketing a new postamendments implant material, manufacturers must submit to FDA an application for premarket approval under section 515 of the act and receive FDA approval of the application or seek to have the material reclassified.

8. A comment asserted that, where the only risks to health presented by a device are electrical hazards, nonsterility, or bioincompatibility, FDA should classify the device into class I. The comment suggested that FDA should classify into class I all of the remaining devices, unless information establishes that (1) the risks identified in the proposal are of sufficient magnitude to justify the promulgation of a standard under section 514 of the act and (2) such a standard is a suitable means for controlling those identified risks.

FDA disagrees with the comment. FDA believes that, in accordance with section 513(a)(1)(B) of the act, the agency is required to classify a device into class II when it determines that the controls of class I are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

when there is sufficient information to establish a performance standard to provide such assurance. FDA believes that for certain devices performance standards for biocompatibility, electrical safety, sterility, or other factors sometimes are necessary to provide reasonable assurance of the safety and effectiveness of such devices. Also, FDA believes that certain devices should be classified into class III, according to the statutory criteria.

9. A comment asserted that the documents on which the Panel's recommendations were based were not made available to the public prior to the meetings at which the classification recommendations were made. As a result, the comment said that public involvement, including submission of information by manufacturers, was severely limited.

FDA agrees that the documents upon which the Panel's recommendations were based were not generally available before the Panel meetings, but disagrees that this procedure was deficient. During its classification deliberations, the Panel held public meetings, and the public was given numerous opportunities to make presentations and arguments to the Panel. In any event, when FDA published the proposed regulations classifying general and plastic surgery devices, the agency provided an extremely generous comment period of 160 days in which any member of the public could comment on any of the documents on which FDA relied.

10. Comments stated that the specific materials used in a device should not be identified in the classification name or the codified identification of the devices listed below, because such specificity within a classification regulation may be viewed as a de facto performance standard imposed without benefit of the procedures listed under section 514 of the act. The comment said that designation of specific materials in classification names and identification assures that, as new materials are introduced, the classification regulations will have to be revised.

Section	Device	Proposed class
878.3500	Polytetrafluoroethylene with carbon fibers composite implant material.	II.
878.3550	Chin prosthesis	II.
878.3590	Ear prosthesis	II.
878.3680	Nose prosthesis	II.
878.4730	Surgical skin degreaser or adhesive tape solvent.	I.

FDA disagrees with the comments' assertion that identification of specific materials in the names or the identifications of devices would be the imposition of a de facto performance standard. Regardless of whether FDA identifies a specific material in the name or the identification of a device, FDA would still have to follow applicable statutory procedures to establish binding requirements for the device.

In the final regulations, the agency has eliminated, where possible, the mention of a specific material in the name of a generic type of device or its identification. It is sometimes necessary, however, to name specific materials to provide an adequate description of the device. It is true that, when FDA has identified a specific material in the name or identification of a device, the agency may need to revise the regulation later if new but substantially equivalent materials have entered the marketplace. FDA cautions that a device made of a new postamendments material is subject to premarket notification under section 510(k) of the act, and may be subject to premarket approval under section 515 of the act, even though the device seems to be described in a classification regulation. (See § 878.3(b) of these regulations.)

11. Comments requested that the devices listed below be classified into class III instead of class II, because no standards have been established for the devices under section 514 of the act. The comments said that evidence of biocompatibility may not have been shown for some of the materials used in the devices listed below that are intended to be implanted.

Section	Device	Proposed class
878.3300	Surgical mesh	II.
878.3500	Polytetrafluoro-ethylene with carbon fibers composite implant material.	II.
878.3550	Chin prosthesis	II.
878.3590	Ear prosthesis	II.
878.3680	Nose prosthesis	II.
878.4300	Implantable clip	II.
878.4750	Implantable staple	II.

Although the devices listed above are intended to be implanted, FDA has determined that requirements of premarket approval are unnecessary to control the risks to health presented by the devices, including the risk of bioincompatibility and the other risks FDA identified in the proposed regulations for these devices. FDA believes that the biocompatibility of the materials now being used in these devices has been established through their successful use for a number of years. However, FDA agrees that clarification of the indentifications of the latter two devices is needed to clarify that these devices do not include new absorbable materials for which biocompatibility may not have been established. Therefore, in the final rule FDA has added the following sentence in each device's identification (§§ 878.4300 and 878.4750): "It is not absorbable."

Under section 510(k) of the act and Subpart E of 21 CFR Part 807, a person must submit to FDA a premarket notification before he or she begins commercial distribution in interstate commerce of a new or significantly changed device. FDA believes that a change in a material used in a device intended to be implanted is a significant change in a device that could affect its safety and effectiveness. FDA believes that the requirement of premarket notification will assure that FDA is aware of new or significantly changed materials intended for use in the devices listed above. FDA will require that new or significantly changed materials be subject to requirements of premarket approval to provide reasonable assurance that these materials are biocompatible and otherwise safe and effective.

Clinical experience with the devices listed above has established the persons for whose use the devices are intended and the proper conditions of use. FDA has determined that the probable benefit to health from proper use of these devices outweighs and likelihood of illness or injury resulting from their use. FDA believes that informative labeling and compliance with general controls will reduce the risks to health presented by the devices listed above. However, FDA believes that the general controls of class I by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices. FDA believes that establishment of performance standards will provide reasonable assurance of the safety and effectiveness of these devices and sufficient evidence is available to establish such standards. (See the discussion earlier in this preamble, "B. FDA's Priorities for Establishing Performance Standards"). Accordingly, FDA is adopting the proposed regulations classifying the devices listed above into class II as proposed with clarifying changes.

12. Section 878.3300; Surgical mesh; proposed class II.

Two comments said that the device is made from well-established materials and that general controls would provide reasonable assurance of the continuing reliability of the device. The comments

requested that the device be classified into class I instead of class II, based on safe and effective clinical use over the years.

FDA disagrees with the comments. FDA is classifying the device into class II to control the risks to health of infection and foreign body reaction which may result in implant rejection. Surgical mesh is intended to be implanted in the human body. Section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) requires that FDA classify all implants into class III unless the agency determines that, for a particular implant, premarket approval is unnecessary to provide reasonable assurance of its safety and effectiveness. FDA believes that surgical mesh has not been implanted in a sufficient number of patients by a sufficient number of medical practitioners to provide adequate evidence on the long-term biocompatibility of these devices. Consequently, FDA believes that insufficient evidence of safety and effectiveness is available at this time to support classifying surgical mesh into class I.

13. Section 878.3530; Inflatable breast prosthesis, proposed class III, Section 878.3540; Silicone gel-filled breast prosthesis; proposed Class III.

13a. Comments on the two proposed regulations above requested that FDA classify each of the devices into class II as recommended by the Panel on July 23, 1976.

FDA believes that the devices need to be classified into class III. On Janaury 26 and 27, 1983, the Panel met to review and consider all comments that were submitted to FDA on the two proposed regulations above, including those comments submitted by the American Society of Plastic and Reconstructive Surgeons (ASPRS) and breast prosthesis manufacturers. The Panel also reviewed additional manufacturing data which has been requested by FDA from all manufacturers of breast prostheses. At the portion of the meeting that was open to the public, FDA presented to the Panel an overview of its reasons for issuing the proposed regulations. Members of ASPRS and representatives of Dow Corning Corp. Also made presentations. The Panel also met in closed session to review confidential documents on silicone, including data furnished by Dow Corning Corp. During the meeting of January 26 and 27, 1983, the Panel unanimously recommended that FDA classify both of the breast prosthesis devices into class III as proposed. FDA agrees with this recommendation.

13b. Comments stated that the following information can be used to develop performance standards for the two breast prosthesis devices above that would provide reasonable assurance of the safety and effectiveness of these devices: information contained in the references that were attached to the comments and discussed during the meeting of the Panel of January 26 and 27, 1983; the collective knowledge, experience, and expertise of implant manufacturers, ASPRS, and FDA; and the current standard for implantable breast prostheses adopted by the American Society of Testing and Materials (ASTM), ASTM–F703–81. The comments requested that the devices be in class II instead of class III.

FDA believes that, for the reasons discussed in the preamble to the proposed rule and in this preamble, insufficient information exists to establish performance standards that would provide reasonable assurance of the safety and effectiveness of the two breast prosthesis devices.

13c. Comments stated that some of the risks of health identified in the proposed regulations for breast prostheses are not device related but are expected consequences of surgery. The comments said that such risks would not be significantly reduced by requiring premarket approval for the devices.

FDA agrees in part and disagrees in part with the comments. FDA agrees that some of the risks to health cited in the two proposals may not result from the breast prostheses, but rather from surgical technique or other factors. Risks such as infections, hematoma, or tissue or skin necrosis may be associated with many surgical procedures. However, other risks identified in the proposed regulations are directly related to the devices. Though it may be argued that deflation of the inflatable breast prostheses or leakage of silicone gel from the silicone gel-filled breast prostheses may, in some instances, result from damage to the devices due to a surgeon's error in wielding a sharp needle or instrument, the argument does not account for all occurrences of deflation, or all implant shell failures, nor for silicone migration from an intact implant. FDA also disagrees with the argument that the risks of surgery to implant the devices are not device related risks. Especially because implantation of a breast prosthesis device is discretionary surgery, consideration of the total risks to health from implantation of such a device must include the usual risks of the surgery involved, and of risks of surgical error that are enhanced by the properties of the device itself.

13d. A comment asserted that, because of changes in manufacturing techniques, valve failure and fold-flaw failure no longer are involved with experiences of deflation of the inflatable breast prosthesis.

FDA does not have, nor did the comment submit, valid scientific evidence showing that valve failure and fold-flaw failure no longer are significant factors in experiences of deflation of the device.

13e. Comments argued that the risk of injury to patients due to fibrous capsule contracture following implantation of the devices above is not a potential unreasonable risk because (1) contracture is not a complication but rather a normal event in all wound healing; (2) though all patients have some degree of breast contracture, the phenomenon cannot be considered a complication if it does not produce patient dissatisfaction; (3) changes in surgical technique and post-surgical therapy have reduced the incidence of clinically detectable fibrous capsular contracture to less than 5 to 10 percent of patients; (4) the reported contracture incidence in as many as 74 percent of patients is due to many factors, including nonquantitative diagnosis and poor sampling of patient population (i.e., satisfied patients do not return for followup); and (5) the biology of contracture has been explained more completely during the past decade.

FDA believes that the risk of fibrous capsule contracture is a potential unreasonable risk of illness or injury under the terms of the statute. FDA does not have, nor did the comment contain, valid scientific evidence showing that the rate of occurrence of fibrous capsule contracture following implantation of breast prostheses has been reduced to such an extent that a classification other than class III is possible.

13f. A comment on the proposed regulation for the inflatable breast prosthesis stated that the identification should be changed to show that the device can be inflated to the desired size before implantation, as well as after implantation.

FDA agrees that the inflatable breast prosthesis can be inflated either before or after implantation. Accordingly, FDA is clarifying the identification of this generic type of device.

13g. A comment on the proposed regulation on the silicone gel-filled breast prosthesis stated that the agency did not evaluate the data and information on the safety, effectiveness, and use of the polyurethane coated

silicone gel-filled breast prosthesis before publishing the proposed regulation. The comment stated that this version of the generic type of device is unique. The device has a tripartite thin-walled septum in the interior and a polyurethane coated outer shell. The comment said that three potential unreasonable risks of injury that FDA cited in the proposed regulation for the device are not pertinent to this particular version of the silicone gel-filled breast prosthesis. To support its claim, the comment contained documentation and references. The comment requested that this version of the device be classified into class II.

FDA agrees in part and disagrees in part with the comment. It is true that, when the proposed regulation was being prepared, the agency did not specifically consider the safety and effectiveness of the polyurethane coated version of the silicone breast prosthesis. However, FDA believes that the identification of the silicone gel-filled breast prosthesis that was proposed is sufficiently broad as to include the polyurethane coated version of the device. FDA is making clarifying changes in the identification of the generic type of device in response to the comment. Further, FDA disagrees with the comment's claims that sufficient information and data are available on this version of the silicone gel-filled breast prosthesis to support its classification into class II. FDA does not have, nor did the comment contain, valid scientific evidence showing that the polyurethane coating over the silicone shell eliminates fibrous capsule contracture or prevents migration of the silicone gel from the interior of the implant to body tissues after implantation. Such evidence may be submitted as part of the application for premarket approval of the device, when FDA issues a regulation under section 515(b) of the act (21 U.S.C. 360e(b)) calling for premarket approval applications for breast prostheses.

13h. One comment on the proposed regulation on the silicone breast prosthesis stated that the proposed identification of the device does not adequately distinguish between the various versions of these devices and that the identification should be amended to include the double-lumen silicone gel-filled breast prosthesis and the polyurethane coated silicone gel-filled breast prosthesis.

FDA agrees with the comment. FDA is clarifying the identification of the generic type of device in the final rule.

13i. Comments stated that the risk of illness or injury due to possible long-term toxic effects of the silicone polymer used in breast prostheses is not a potential unreasonable risk because: (1) over a million patients have undergone augmentation mammaplasty with silicone breast implants and there is no evidence of toxicity; (2) for about 20 years, numerous other medical devices made from silicone polymer have demonstrated excellent clinical performance; (3) numerous published studies attest to the safety and lack of toxicity of silicone, including a number of reports that have concluded that there is no correlation between the presence of a silicone prosthesis and findings of cancer in patients; and (4) if small quantities of silicone migrate from a breast prosthesis into the body tissues of a patient, no harm would result.

FDA recognizes that both of these devices, as well as other prostheses made of similar materials and having similar construction, have been used for many years. However, FDA has examined recent scientific data concerning silicone implants and the migration of silicone in the body (Refs. 20 through 27) that support the agency's proposed classification. Some of these data reveal occurrence of allergic reactions (Ref. 20), silicone lymphadenoma (Refs. 21, 22, and 23), morbidity due to silicone (Refs. 24 and 25), and silicone migration (Refs. 26 and 27). Breast prostheses of both types present a potential unreasonable risk of illness or injury to the patient. The silicone used in the prostheses may migrate in the body of the patient, as described above, with unknown long-term effects. Furthermore, the devices are implants, and FDA is required by section 360c(d) of the act (21 U.S.C. 360c(d)) to classify implants into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. For these devices, the agency has determined that premarket approval is necessary because FDA believes that the devices present a potential unreasonable risk of illness or injury to patients if data showing that the devices are safe and effective are not available. In addition, the devices are purported or represented to be for a use (reconstructive surgery) that is of substantial importance in preventing impairment of human health, even though implantation of a breast prosthesis is discretionary surgery. The agency has determined that premarket approval is necessary for both of the devices because general controls and performance standards are insufficent to provide reasonable assurance of the safety and effectiveness of the devices. FDA also believes that insufficient information is available to establish performance standards to provide reasonable assurance of the safety and effectiveness of the devices. Because use of the devices is discretionary, use of the devices must be balanced against the long-term unknown effects of possible silicone migration in the body. Accordingly, FDA is classifying the two devices above into class III as proposed with minor clarifying changes. Also, FDA is clarifying the name of the inflatable breast prosthesis.

14. Section 878.3550; Chin prosthesis; proposed class II.

One comment indicated that one type of chin prosthesis, the silicone rubber gel-filled chin prosthesis, was not included in FDA's proposed identification of the generic type of device. The comment requested that the agency modify the identification section of the regulation to read as follows: A chin prosthesis is an implanted silicone rubber solid prosthesis or a silicone rubber gel-filled prosthesis.

FDA disagrees with the comment. The silicone rubber gel-filled chin prosthesis identified by the comment is a different preamendments device that, due to inadvertence, has not yet been considered by the Panel for classification. FDA will refer to the Panel for its classification recommendation the silicone rubber gel-filled chin prosthesis. After receiving the Panel's classification recommendation, in a future issue of the **Federal Register**, FDA will publish a proposed regulation classifying the device. For the reasons given in the proposal, FDA believes that the silicone rubber solid chin prosthesis should be classified into class II. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

15. Section 878.4040; Surgical apparel; proposed class II.

15a. Comments stated that surgical suits and dresses, commonly known as scrub suits, are intended to replace the street clothes of operating room personnel, but are not intended to be part of the sterile field. The comments said that surgical gowns that are intended to be part of the sterile field are worn over scrub suits to protect the wearer and the patient from bacterial contamination. The comments questioned including scrub suits as a category of medical devices. One comment suggested that scrub suits be placed in class I with exemption from most requirements of the CGMP regulations.

FDA agrees with the comments that questioned the inclusion of scrub suits as medical devices. FDA has decided not to classify surgical suits and dresses,

commonly known as scrub suits, as medical devices. FDA is changing the identification of surgical apparel to exclude surgical suits and dresses. Accordingly, FDA is not responding to the comments that scrub suits should be classified into class I.

15b. A comment suggested that FDA classify surgical gowns, surgical caps, and surgical shoe covers in class I. Comments stated that surgical caps and surgical hoods generally are made of nonflammable materials and are intended to prevent contamination from shedding hair, but are not intended as a microbial barrier. Thus, the comments suggested that such devices be either classified into class I or not considered medical devices. Comments suggested that surgical caps and surgical hoods be exempt from most requirements of the CGMP regulations. Comments requested that operating room shoe covers be placed in class I, because there is no record of hazard to safety or health from shoe covers. The comments argued that the potential risks of slippage and fire or explosion from nonconductive shoe covers is practically nonexistent, because (1) materials used have improved, (2) users are aware of, and are controlling, the buildup of static electricity, (3) nonconductive shoe covers are used, and (4) flammable anesthetics are no longer used in most hospitals. The comments argued that class I is adequate to control any anticipated risks to health caused by these devices. One comment urged exemption of shoe covers from the CGMP requirements.

FDA agrees that surgical caps, surgical hoods, and surgical shoe covers should be classified into class I. However, FDA believes that surgical gowns and surgical masks should be placed in class II for the reasons provided below in paragraph 15c. FDA disagrees that surgical caps, hoods, and shoe covers should be exempt from most requirements of the CGMP regulations. The agency believes that compliance with CGMP regulations is necessary to assure the quality of surgical apparel by helping to prevent production of surgical apparel having characteristics that could harm patients.

15c. Several comments urged that FDA classify all surgical apparel in class II as proposed. Some comments opposed FDA's classifying surgical gowns made from nonwoven fabrics into class I while leaving surgical gowns made from woven fabrics in class II. These comments stressed the importance of performance standards for these kinds of surgical apparel to provide a reliable aseptic barrier and assure the patient's safety. Some comments questioned the classification into class II of disposable, nonwoven surgical apparel and reusable, woven apparel. The comments argued that, in contrast to the nonwoven apparel, reusable woven apparel offers less protection against bacterial strike-through because this apparel is subject to wear and tear from repeated laundering and sterilization. Therefore, comments suggested that, although class II may be appropriate for the reusable, woven apparel, class I is justified for the single use, nonwoven apparel. Published articles were submitted with comments to support the claim of superior protection against bacterial strike-through from use of disposable, nonwoven surgical gowns (Refs. 1, 2, 3, 4, 13, and 15). Some comments stated that FDA has sufficient authority under general controls, CGMP regulations, and premarket notification procedures to assure the safety and effectiveness of surgical apparel. The comments urged that, because of the history of safe use, all surgical apparel be classified in class I. One comment argued that surgical masks, gowns, caps, shoe covers, etc., should not all be covered by the same identification. Specifically, this comment requested class I for surgical masks, because risks of linting, slippage, conductivity, flammability, and microbial contamination of surgical masks are either irrelevant, or can be addressed by proper labeling and CGMP regulations.

FDA agrees with those comments urging that surgical gowns and surgical masks be classified into class II. FDA believes that making surgical gowns from nonwoven fabrics does not, in itself, guarantee protection in all cases against moist bacterial strike-through. The agency believes that performance standards are necessary for surgical gowns and surgical masks because general controls alone are insufficient to control the risks to health presented by such devices, such as microbial contamination or transfer, shedding, and flammability. Performance standards would provide reasonable assurance of the safety and effectiveness of surgical gowns and surgical masks. FDA believes that sufficient information exists to develop performance standards for surgical gowns and surgical masks.

FDA also agrees with the comments urging that class I controls are sufficient to control the risks to health presented by surgical apparel other than surgical gowns and surgical masks, such as surgical caps, hoods, aprons, isolation masks, and operating room shoes and shoe covers. The agency believes that these kinds of surgical apparel are not a part of the sterile field, and that general controls such as the CGMP regulations are sufficient to provide reasonable assurance of the safety and effectiveness of such devices.

Accordingly, FDA is classifying surgical gowns and surgical masks into class II as proposed and classifying surgical apparel other than surgical gowns and surgical masks into class I without exemptions. Thus, FDA is adopting the proposed regulation with changes in the classification and identification of the device.

16. Section 878.4100; Intestine bag; proposed class I.

One comment said that the identification statement is too restrictive and that it should include surgical drapes that come in contact with internal organs or omentum that are used in similar procedures. The comment recommended that the classification include wound edge protector drapes, aperture drapes, u-drapes, vaginal procedures drapes, and irrigation pouch drapes, because all of these devices are made of plastic material similar to the material in the intestine bag.

FDA agrees in part and disagrees in part with the comment. FDA believes that the name of the device should be changed from "intestine bag" to "organ bag" and the identification should be changed to more accurately describe the generic type of device. FDA disagrees that all surgical drapes are manufactured from plastics. Most surgical drapes are made of cellulose. Surgical drapes and plastic organ bags present different risks to health. Cellulose surgical drapes can shed cellulose fibers into the surgical site. Plastic organ bags do not present this hazard. Relatively few surgical patients have organs placed in an organ bag, but virtually all surgical patients are exposed to a surgical drape. Because of these differences, FDA believes that the two groups of devices identified by the comment should be classified separately. Accordingly, in the final rule FDA is adopting the proposed regulation with changes in the name and identification of the device.

17. Section 878.4200; Introduction/drainage catheter and accessories; proposed class II.

Two comments disagreed with the proposed classification and recommended that the device be in class I because the risks to health can be adequately controlled by general controls.

FDA agrees with the comments. FDA believes that the principal risks to health presented by the device, i.e. the

risk of infection or of introduction into the body of a foreign substance, can be as well controlled by general controls as by a performance standard. Furthermore, FDA believes that there is minimal risk to health from adulteration of drugs due to interactions of drugs with the materials used in the introduction/drainage catheter, because this kind of catheter normally is not used to introduce drugs into the body. FDA believes that inertness is the primary physical property that a material must have to be considered suitable for use in an introduction/drainage catheter. FDA believes that general controls are sufficient to control the safety and effectiveness of current materials used in the introduction/drainage catheter and accessories. The agency is classifying the device into class I instead of class II. Accordingly, FDA is adopting the proposed regulation with a change in classification.

18. Section 878.4300; Implantable clip; proposed class II.

Comments suggested that the device be classified into class I because general controls would provide assurance of the safety and effectiveness of the device. Also, these comments point out the long and extensive use of the implantable clip as evidence of its safety and effectiveness.

FDA believes that implantable clips should be classified into class II to control the risks to health of tissue necrosis from excessive pressure from the device, leakage of body fluids due to a failure to maintain connection of tissues that may lead to such complications as infection and hemorrhage, and allergic or toxic reactions to materials that may be used to make the device. Accordingly, FDA is adopting the proposed regulation with a clarifying change. (See preamble paragraph 11).

19. Section 878.4350; Cryosurgical unit and accessories.

FDA proposed to classify liquid nitrogen cryosurgical units and accessories intended for use in urological applications into class III and all other cryosurgical units and accessories intended for other uses into class II.

19a. Comments said that all cryosurgical units and accessories should be classified into class I.

FDA believes that cryosurgical units and accessories cannot be classified into class I because general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the devices. FDA believes that all cryosurgical units and accessories should be classified into class II, for the reasons given in FDA's response to the following comments.

19b. Comments stated that all cryosurgical units and accessories should be classified into class II regardless of their intended use. One comment stated that the design criteria and performance requirements for a liquid nitrogen apparatus intended for urological use are comparable to similar devices used by other medical specialties. Another comment stated that urological cryosurgery is similar to cryosurgical applications in other specialties, in that achievement of the surgical result is largely dependent upon surgical technique and to a lesser extent upon instrument standards such as liquid nitrogen delivery rate, temperature, probe size, etc. One comment cited a study conducted by the Emergency Care Research Institute (ECRI) under an FDA contract (Ref. 31). The study assessed the risks, hazards, and performance characteristics of cryosurgical devices and accessories and concluded that cryosurgical devices have a safe history. The comment also stated that ECRI made recommendations regarding development of performance standards for all cryosurgical units. Two comments stated that sufficient information exists to establish a standard for all cryosurgical devices that will assure their safety and effectiveness. The comments cited the work of the American Society for Testing Materials (ASTM) task force F04.08, which consists of representatives of industry and the medical community. That task force has nearly completed a final draft performance standard. One of these comments submitted additional data and information which had not been considered by the agency before publishing the proposal to classify liquid nitrogen cryosurgical units and accessories intended for use in urological applications into class III.

FDA agrees with these comments. The agency now recognizes that the design criteria and performance requirements of these devices intended for use in urological applications are comparable to similar devices intended for use in other medical specialties and that achieving the desired cryotherapeutic result, regardless of the medical area, is largely dependent upon the training and experience of the user. The agency acknowledges that the risks to health of cryotherapy in urology is generally limited to a small well-defined segment of patient population in whom the use of alternative means of therapy would subject them to additional or possibly greater risks to health than those identified in the proposal. FDA now believes that sufficient information exists to establish a performance standard for liquid nitrogen cryosurgical units and accessories intended for use in urological applications and that a performance standard will provide reasonable assurance of the safety and effectiveness of the device. In the final rule, the agency is classifying liquid nitrogen cryosurgical units and accessories intended for use in urological applications into class II instead of class III as proposed. Accordingly, FDA is adopting the proposed regulation with a change in classification.

20. Section 878.4370; Surgical drape and drape accessories; proposed class II.

20a. Some comments requested that all surgical drapes and drape accessories be classified into class I instead of class II. The comments argued that those devices have a history of safe use and that FDA has sufficient authority under general controls, particularly the CGMP regulations and the premarket notification procedures, to provide reasonable assurance of the safety and effectiveness of the devices. Other comments requested that FDA change the classification of single use surgical drapes made from nonwoven fabrics from class II to class I. The comments argued that disposable, nonwoven drapes are completely controlled by the manufacturer, whereas the reusable, woven drapes are subject to repeated laundering and sterilization. The comments stated that the effectiveness of the reusable drapes as microbial barriers deteriorates after repeated processing. Copies of published articles were submitted with the comments to support the claim that surgical drapes made from nonwoven fabrics are superior to those made from woven fabrics (Refs. 1, 2, 3, 4, 13, and 15).

FDA believes that, to provide a reliable aseptic barrier and to assure the safety of the surgical patient, general controls are insufficient and performance standards are necessary for the devices, whether they are made from woven or nonwoven fabrics. Although reusable drapes made from woven fabrics may not provide an effective microbial barrier after repeating processing, it is the performance of the material, not whether it is woven or nonwoven, that determines its effectiveness as a microbial barrier. Some types of both reusable, woven fabrics and disposable, nonwoven fabrics permit the passage of microorganisms, and are, therefore, not effective as microbial barriers.

20b. Some comments agreed with FDA's proposal to classify surgical drapes and drape accessories into class II. The comments stressed the need for establishment of performance standards to assure that the devices provide an aseptic barrier and assure patients' safety from moist bacterial strike-through. One comment stressed that surgical drapes should be nonflammable.

FDA agrees with the comments. FDA also believes that the surgical drape and drape accessories should be classified into class II to control the risk of shedding of particulate matter from the device or its accessories into surgical incisions causing foreign body reactions, infection, or allergic or toxic reactions and to reduce the risk of burns from ignition of flammable materials.

20c. Comments requested that FDA remove the Kelly pad from the proposed identification of surgical drapes and drape accessories. A comment questioned whether a Kelly pad is a medical device, because it is used externally. The comment suggested that, if FDA believes that a Kelly pad is a medical device, it should be classified in class I, the same category as the proposed classification of nonabsorbable gauze (or sponges), wound dressings for external use, and medical disposable bedding.

FDA is changing the identification of the surgical drapes and drape accessories to exclude the Kelly pad. FDA believes that a Kelly pad is included in a generic type of device already classified into class I with general hospital and personal use devices. (See § 880.6060 *Medical disposable bedding.*)

21. Section 878.4380; Aerosol drape adhesive; proposed class I. A comment requested that the name of the device and its identification be revised to eliminate the word "aerosol" to include nonaerosol drape adhesives.

FDA agrees with the comment. The agency based the proposed regulation on data designed to demonstrate the noninterference of aerosol drape adhesives in the healing process and the absence of acute, systemic, and local toxicity from the device. FDA believes that nonaerosol and aerosol drape adhesives should both be included in the same device classification regulation. Accordingly, FDA is adopting the proposed regulation with changes in the name of the device and its identification.

22. Section 878.4400; Electrosurgical cutting and coagulation device and accessories; proposed class II.

22a. One comment said that a performance standard should be written immediately for the device and that the standard should specify the maximum level of radiofrequency interference emitted by the device so that other electronic devices used in the operating room are protected against harmful radiofrequency interference from the electrosurgical cutting and coagulation device.

The agency agrees that radiofrequency interference from the device is a significant problem in the operating room. FDA also agrees that the device should be classified into class II. FDA disagrees that establishing a performance standard for the device will eliminate harmful radiofrequency interference due to the device. Most of the interference is generated by the passage of current from the active electrode through the tissue to the dispersive electrode. The physical configuration of electrodes and intervening tissue forms a radiating antenna, which is inherent in the device design and operation and about which little can be done. The promulgation of a performance standard may reduce the radiofrequency interference that may radiate from the cables or the power cord.

22b. A comment said that the electrosurgical cutting and coagulation device and accessories should be classified into class I and that development of voluntary standards will assure the safety and effectiveness of the device.

As stated in the proposed regulation, FDA believes that performance standards should be established to control the risks to health presented by this device such as electrical shock and burns, fire and explosion from use near flammable articles or ignition of bowel or bladder gases during surgery, and cataract formation when the device is used near the eye. FDA believes that general controls alone are insufficient to control the risks to health presented by the device and establishment of a performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulation without change.

23. Section 878.4450; Nonabsorbable gauze for internal use; proposed class II.

23a. A comment suggested that the name and identification of the device be changed to read "nonabsorbable material for internal use," to include nonwoven materials in the device identification.

FDA agrees in part and disagrees in part with the comment. FDA disagrees that nonwoven materials be included in this generic type of device. FDA intended to limit the generic type of device to gauze woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, for internal use. In the final regulation, FDA is clarifying the identification of the device.

23b. Comments stated that classification of the device into class II would be unduly burdensome on manufacturers, serves no useful purpose, and would not result in a safer, more effective device.

FDA disagrees with the comments. FDA believes that a performance standard is necessary to control the design and construction of the device, to reduce particulate matter contamination, and to assure adequate radiopacity.

23c. Comments stated that the Panel based its recommendations on very old information and that there are few, if any, current problems with the safety of the device.

FDA disagrees with the comments. Reports in the current medical literature (Refs. 5 through 12, 14, 17, 18, and 19) show that fibers shed from nonabsorbable gauze surgical sponges for internal use cause granulomas that are potential risks to health. Thus, FDA believes that the current literature shows that the device presents the same risks to health as the older literature FDA cited in the proposed regulation. FDA believes that complications resulting from use of nonabsorbable gauze for internal use generally are not reported to FDA. Such complications include granulomas and adhesions from shed fibers and adverse reactions from use of bioincompatible materials in the device. FDA believes that establishing a performance standard for the device would control these risks to health and assure the safety and effectiveness of the device.

23d. A comment said that performance standards for nonabsorbable gauze for internal use should address biocompatibility, abrasiveness, strength, wicking rate, shock absorbent properties, and radiopacity.

FDA believes that there is need for performance standards addressing biocompatibility, strength, fiber shedding rate, and radiopacity. Whether performance standards should cover additional characteristics of this device should be determined in the standard-setting proceeding.

23e. A comment said that the label of nonabsorbable gauze for internal use should identify the materials used,

include a warning that the device may shed fibers into a wound, indicate that the material has been tested for acceptable biocompatibility, and describe the length of shelf life and the proper method of sterilization.

FDA acknowledges the comment's concern about the labeling of nonabsorbable gauze for internal use and points out that marketed devices must now comply with requirements under sections 501 and 502 of the act concerning misbranding and adulteration. Also, FDA could develop separate labeling regulations for the device if necessary. FDA is not specifying labeling requirements for the device at this time. When standards are developed for the device, labeling requirements may be addressed in the standard.

23f. One comment alleged that nonabsorbable gauze for internal use is already identified in § 878.4060 *Nonabsorbable gauze, surgical sponge, and wound dressing for external use.* The comment suggested that the generic type of device nonabsorbable gauze for internal use be eliminated.

FDA believes that nonabsorbable gauze for external use presents fewer risks to health. It does not present risks of adhesions or granulomas due to the shedding of cellulose fibers nor does it need to be radiopaque. Because of these differences in degree of risk to health, and because of differences in the intended uses of the devices, FDA believes that the two devices should be classified in separate regulations.

23g. A comment said that experiments in animals that were used to demonstrate foreign body reactions from lint and gauze fragments used excessive amounts of material and do not reflect actual practice in treatment of humans with the device.

FDA believes that the studies in animals to investigate the relationship of fiber and lint to adhesions and granuloma formation used appropriate amounts of material in order to assure a reproducible and significant rate of adhesion and granuloma formation. The medical literature (Refs. 5 through 12, 14, 17, 18, and 19) shows that fibers shed from dressings present risks to health in humans and supports FDA's decision.

23h. A comment stated that if a product is labeled as x-ray detectable, then the misbranding provisions and CGMP requirements of the act are sufficient to ensure that the label claim is met, and further regulation is not needed.

FDA believes that a performance standard for radiopacity is necessary for this device because general controls alone are insufficient to control the risk to health from inadequate radiopacity. A standard for radiopacity would provide a sufficient level of radiopacity in the device to allow a minimum amount of x-ray exposure of the patient to detect the device. Currently, a radiopaque nonabsorbable gauze for internal use device that is labeled as x-ray detectable may contain any level of any substance detectable by x-rays.

23i. A comment stated that additional regulatory standards are not needed for nonabsorbable gauze for internal use because a standard already exists. The comment asserted that any product labeled "absorbent gauze" is misbranded under the act if it does not comply with the current U.S.P. monograph.

The U.S.P. monograph for absorbent gauze does not control all risks to health presented by nonabsorbable gauze for internal use. The current U.S.P. monograph applies to external use and defines the following parameters: Cotton/rayon composition, packaging and storage, labeling, thread count, length, width, weight, absorbency, sterility, ignition residues, fatty matter, and dyes.

23j. A comment stated that (1) disposable surgical sponges for internal use do not present the risks to health cited by the Panel, and (2) the Panel did not address the differences between reusable surgical sponges for internal use and disposable sponges for internal use.

Although it is true that many medical facilities now use disposable nonabsorbable gauze for internal use, FDA believes that this change has had little impact on the risks to health from the device. Several current scientific articles and textbooks for training surgeons, operating room nurses, and operating room technicians describe the hazards from surgical sponges and other cellulose products used in the operating room and provide procedures for reducing these hazards (Refs. 5 through 15, 17, 18, and 19). These documents clearly show that the change from reusable surgical sponges to disposable sponges has not eliminated or reduced the risks to health from nonabsorbable gauze for internal use.

23k. A comment stated that nonabsorbable gauze for internal use has been an essential surgical product for more than 80 years. The comment said that a reasonable evaluation of the risks and benefits would find that the benefits are so great, and the risks so small, that there is an assurance of the safety and effectiveness of the device.

The Panel identified risks to health that are intrinsic to the device that have been documented for over 40 years. Adhesions and granulomas caused by fibers shed from nonabsorbable gauze for internal use are major factors in reoperations. FDA believes that the benefits of surgery can be obtained with a reduction in risks to health, if performance standards are established for nonabsorbable gauze for internal use.

23l. A comment stated that establishing a performance standard will not eliminate the shedding of particulate matter from the device.

FDA agrees with the comment. FDA agrees that establishing a performance standard may not totally eliminate the hazard of fiber shedding from the device. However, FDA believes that establishing a performance standard for the device will reduce the level of fiber shedding and thereby reduce to a reasonable level the risks to health and adhesions and granulomas from fibers from the device shedding into wounds or incisions.

23m. A comment stated that there are no data which identify the minimum level of particulate matter to which a patient can be safely exposed. The comment said that appropriate and meaningful test methods do not currently exist.

FDA agrees that current literature indicates that there is no "safe" level of particulate exposure for gauze for internal use. Although FDA believes that a level of "no particulate shed" cannot be achieved, a performance standard can reduce the number of fibers shed per unit mass and thereby provide reasonable assurance of the safety and effectiveness of the device. FDA believes that meaningful test methods do exist and that several authors have described techniques for accurately counting the number of fibers shed by a gauze sponge (Refs. 6, 13, and 17). These authors have shown that accurate and meaningful test methodologies do exist and can be implemented.

23n. A comment said that the risks of allergic or toxic reactions to the device are hypothetical and unsubstantiated.

FDA disagrees with this comment. The hazards of localized toxic reaction to surgical sponges left in an incision are well established. The practice of sponge counting before closing an incision is an acknowledgment of the magnitude of this hazard. The hazard from sponge particles shed in an incision are also real and thoroughly documented (Refs. 5 through 12, 14, 17, 18, and 19).

Accordingly, FDA is adopting the proposed regulation with clarifying changes.

24. Section 878.4460; Surgeon's glove; proposed class II.

Comments suggested that the surgeon's glove should be classified into class I, because of the history of its safe and effective use. Comments emphasized that not one case of tissue incompatibility in patients has been reported, and that the observed problems have been packaging defects, holes in gloves, and user skin sensitivity reactions. The comments said that these problems can be addressed by general controls, including labeling, and CGMP provisions. The comments suggested that the risk of infection from improper sterilization can be controlled by CGMP requirements and by insistence on validation of the sterilization process. The comments said performance standards are unnecessary for the device. A comment suggested that the term "cross-infection" be removed from the device identification because the preceding word "contamination" includes "cross-infection."

FDA agrees with the comments. FDA now believes that risks of tissue compatibility and sterilization of a surgeon's glove can be controlled by general controls. Accordingly, in the final regulation, FDA is classifying the device in class I, with a clarified identification, rather than class II as was proposed. FDA advises that, in the **Federal Register** of May 11, 1987, it announced the availability of a final guideline on process validation for drugs and devices (52 FR 17638). FDA made the guideline available to assist manufacturers to sterilize devices properly.

25. Section 878.4580; Surgical lamp; proposed class II.

Comments noted that two of the three classification panels that made recommendations on classification of the surgical lamp recommended that the device be in class I. Comments pointed out that numerous codes and guidelines applicable to lighting in health care facilities are available for controlling the devices. Another comment said that many of the risks cited by FDA in the proposed regulation are hypothetical. The comments also suggested that FDA classify the device in class I, because a review of FDA's device experience network reports and manufacturer's complaint files revealed no serious injuries to patients or hospital personnel from surgical lamps.

FDA believes that the data in complaint files of manufacturers or the voluntarily submitted adverse experience reports in FDA's device experience network are not an accurate reflection of the actual levels of adverse experiences with devices. Therefore, FDA's rule that requires manufacturers and importers to report adverse experiences with devices (21 CFR Part 803) has improved the information available to FDA on adverse experiences with devices but it lacks information on experiences that are not reported to manufacturers or importers. FDA believes that a surgical lamp presents risks to health including risks of electrical shock, tissue drying, traumatic injury to patients or medical personnel if the lamp falls, and cuts from a lamp or its diffusers that may fall and break. The fact that there are numerous codes and guidelines for manufacturers on the design of surgical lamps that now are in use in the United States will make it easier to develop a regulatory performance standard for the device. FDA believes that such a standard would provide reasonable assurance of the safety and effectiveness of the device and that sufficient information is available to develop such a standard. Accordingly, FDA is classifying the device into class II as proposed.

26. A comment said that the devices below should be classified into class I unless the risks to health are of sufficient magnitude to justify a performance standard and a performance standard would be an appropriate means of controlling the risks. The comments suggested that the devices listed below be classified into class I instead of class II as proposed.

Section	Device	Class proposed by FDA
878.4630	Dermatologic ultra-violet lamp	II
878.4780	Powered suction pump	II
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	II
878.5070	Air-handling apparatus for a surgical operating room.	II

Dermatologic ultraviolet lamp. In the proposal, the dermatologic ultraviolet lamp, whether intended for the treatment of dermatological disorders or for tanning, was placed in one classification regulation (§ 878.4630). FDA now is splitting the classification of the ultraviolet lamp into two separate classification regulations based on its intended use. When the ultraviolet lamp is intended for tanning purposes, it is to be classified at new § 878.4635 *Ultraviolet lamp for tanning;* however, its classification is being postponed for consideration of electrical safety information to enable FDA to consider issuing a proposal to classify the device into class I. When the ultraviolet lamp is intended for use to photoactivate a drug in the treatment of a dermatological disorder, the ultraviolet lamp is being classified into class II, as proposed, at § 878.4630 of these final classification regulations, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

The performance standard for sunlamp products at 21 CFR 1040.20, issued under the Radiation Control for Health and Safety Act (42 U.S.C. 263b–n) referred to in the proposal, applies to the ultraviolet lamp for tanning. Because this standard covers the risks to health presented by this device other than electrical safety hazards, FDA is postponing the classification of the ultraviolet lamp for tanning pending the agency's review of electrical safety information. Depending upon the results of this review, FDA will consider classifying the ultraviolet lamp for tanning into class I.

FDA believes that a standard is needed under section 514 of the act for the ultraviolet lamp intended to photoactivate a drug for the treatment of dermatological disorders to control the risks to health of burns to skin or eyes from improper shielding or excessive exposure to ultraviolet radiation, accelerated aging of skin from excessive exposure, skin cancer from excessive exposure, and induction of sensitivity reactions in persons with photosensitive skin. See also the discussion of the risks to health presented by the device in the agency's notice of intent to propose rules and develop recommendations published in the **Federal Register** of February 8, 1980 (45 FR 8870). In addition, based on its review of Panel reports, transcripts, and the comments made at Panel meetings concerning the ultraviolet lamp for dermatologic disorders, FDA believes that scientific information supports the use of this device only for photoactivating a drug in the treatment of dermatological disorders, e.g., to photoactivate psoralin in the treatment of psoriasis. Thus, FDA has clarified the identification in § 878.4630 to provide that this device is used to photoactivate a drug for the treatment of dermatological disorders. FDA has also clarified the name of the device.

Powered suction pump. FDA believes that a standard is needed to control the risks of infection from airborne microbial contamination and trauma to tissues caused by malfunction of or lack of a vacuum regulator.

Laser surgical instrument for use in general and plastic surgery and in dermatology. FDA believes that a standard is needed under section 514 of the act to control the risks to health that

may occur from unintended exposure to laser light emissions, e.g., damage to the retina of the eye; to prevent exposure of patients to excessive laser radiation resulting in unnecessary tissue damage; and to prevent unnecessary laser radiation of the patient and user. FDA has concluded that the performance standard applicable to laser products at 21 CFR 1040.10 and 1040.11(a) does not address all of the radiation-related risks to health associated with the laser surgical instrument for use in general and plastic surgery and in dermatology.

Air-handling apparatus for a surgical operating room. FDA believes that a standard is needed to control the risk of infection from airborne microbial contamination resulting from design of the device and the filters and from interruption of the pattern of air flow caused by clogged filters or power failure.

For the reasons noted above, FDA believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of these devices and that sufficient information is available to establish performance standards to provide such assurance.

27 Section 878.4730; Surgical skin degreaser or adhesive tape solvent; proposed class I.

Two comments requested that the identification of the generic type of device also include both 1,1,1-trichloroethane and 1,1,1-trichloroethane with mineral spirits.

FDA agrees with the comments. The Panel based its recommendations on its members' personal knowledge of, and clinical experience with, the device and on a review of literature submitted for 1,1,2-trichloro-1,2,2-trifluoroethane. FDA believes that the 1,1,1-trichloroethane and the 1,1,1-trichloroethane with mineral spirits surgical skin degreaser or adhesive tape solvent are substantially equivalent to the device that FDA proposed to classify into class I. FDA is including these types of devices in the generic type of device being classified. Accordingly, FDA is adopting the proposed regulation with changes in the identification of the device.

28. Section 878.4750; Implantable staple; proposed class II. Comments stated that due to many years of safe use of these clips and the absence of any reported medical problems, classification into class I would provide adequate assurance of continued reliability.

FDA disagrees with these comments. FDA believes that the implantable staple should be classified into class II to control the risks to health of tissue necrosis from excessive pressure from the device, leakage of body fluids that may lead to complications such as infection or hemorrhage, and formation of calculi if staples are exposed to urine. Accordingly, FDA is adopting the proposed regulation with a clarifying change. (See preamble paragraph 11.)

29. Section 878.4760; Removable skin staple; proposed class I. A comment agreed that the removable skin staple should be classified into class I. The comment also stated that skin staples fabricated from materials that have not been shown to be biocompatible should be classified into class III.

FDA believes that a removable skin staple should be classified into class I for the reasons given in the proposed regulation. FDA advises that any manufacturer who intends to market a removable skin staple made of a material not used in removable skin staples being commercially distributed before the enactment date of the amendments must submit to FDA a premarket notification submission under section 510(k) of the act and Subpart E of 21 CFR Part 807. If FDA determines that the device subject to the submitted premarket notification is not substantially equivalent to preamendments removable skin staples, the new device is a class III device subject to premarket approval under section 515 of the act. Accordingly, FDA is adopting the proposed regulation without change.

30. Section 878.4810; Laser surgical instrument for use in general and plastic surgery and in dermatology; proposed class II.

A comment agreed with FDA's proposed regulation classifying the carbon dioxide laser and the argon laser into class II and suggested that the generic type of device be classified into class II for all intended uses.

FDA agrees in part and disagrees in part with the comment. FDA agrees that the generic type of device should be in class II, but FDA believes that the safety and effectiveness of the argon laser has not been established for certain intended uses. In the final rule, FDA is identifying separately the carbon dioxide laser and the argon laser, to clearly show that the argon laser is being classified into class II only for use in dermatology. Accordingly, FDA is adopting the proposed regulation with changes in identification.

31. Section 878.5350; High-frequency needle-type epilator; proposed class II.

31a. One comment said that the purpose of electrolysis is to destroy the dermal papilla of a hair, not the follicle as stated in the proposed regulation.

FDA is changing the identification as suggested by the comment.

31b. A comment identified three types of electrolysis devices: Short wave (high-frequency AC-current); galvanic (DC-current); and AC/DC blend machines. The comment stated that short wave AC-machines are used predominantly, the galvanic machines are becoming obsolete, and that AC/DC blend machines are used infrequently. The comment also pointed out that in electrolysis the normal duration for applying current is in the range of 0.02 to 0.04 seconds, far less than the 20-second duration discussed in the proposed regulation.

In the final rule, FDA is changing the name and identification of high-frequency needle-type epilator to identify correctly the different device designs.

31c. FDA received a petition (82P-0216) that requested the agency to ban uncoated electrolysis needles. FDA decided to process the petition as a comment on the proposed regulation for the high-frequency needle-type epilator, which includes electrolysis needles (both coated and uncoated).

FDA disagrees with the comment, because uncoated electrolysis needles have been used for many years in electrolysis and FDA has no evidence, nor was any submitted by the comment, to support the banning of uncoated electrolysis needles. Accordingly, FDA is adopting the proposed regulation with clarifying changes in the name and identification of the generic type of device.

32. Section 878.5650; Topical oxygen chamber for extremities; proposed class II.

A comment suggested that the device be placed in class I instead of class II. The comment argued that the proposed regulation merely identified the risks without discussing the magnitude of the risks and that classifying the device on the basis of perceived risk is unjustifiable. The comment also suggested that the proposal to classify the device into class II is contrary to the philosophy intended in the amendments of classifying a device at the lowest level of regulatory control necessary.

FDA disagrees with the comment. Indeed, FDA believes that, at the time FDA proposed that the topical oxygen chamber for extremities be classified into class II, the agency did not adequately take into account the lack of scientific evidence to support the safety and effectiveness of the device. Accordingly, in the final rule FDA is classifying the topical oxygen chamber for extremities into class III. In a review of the literature on this device (Ref. 28), Dr. Max Cohen, a consultant to the

National Center for Health Care Technology (NCHCT), found little valid scientific evidence to support the safety and effectiveness of use of the topical oxygen chamber for extremities in the treatment of bed sores (decubitus ulcers). Dr. Cohen's review of the literature found no study comparing the results of treating bed sores with the topical oxygen chamber for extremities with the results of treating bed sores by exposing the ulcers to topical air. Thus, Dr. Cohen concluded that valid scientific evidence had not been provided to establish the effectiveness of the device.

Similarly, in an unpublished draft assessment of the value of topical oxygen therapy in the treatment of decubitus ulcers and skin lesions, conducted by the Public Health Service in 1983, the Office of Health Technology Assessment (OHTA) found that studies demonstrate that wounds that are often unresponsive to previous treatment heal following topical oxygen therapy (Ref. 29). However, a number of uncontrolled variables make it difficult to attribute the healing to the use of topical oxygen. According to OHTA, use of topical oxygen in the treatment of pressure sores and other skin lesions does not appear to be a widely accepted practice among members of the medical community.

FDA believes that a potential exists for widespread use of the topical oxygen chamber for extremities in the treatment of skin sores in the elderly and infirm despite the lack of valid scientific evidence of the safety and effectiveness of the device. FDA believes that the device presents a potential unreasonable risk of illness or injury to patients, if there are not adequate data to assure the safety and effectiveness of the device. In addition, the device is purported or represented to be for a use (treatment of decubitus ulcers) that is of substantial importance in preventing impairment of human health. 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 now believes that there is insufficient information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, although FDA proposed that the device be classified into class II, FDA is classifying the device into class III.

33. Section 878.5910; Pneumatic tourniquet; proposed class II.

33a. A comment stated that because various pneumatic units can be used with various types of inflatable cuffs, pneumatic units should be classified separately from the cuffs.

FDA disagrees with the comment. FDA believes that the risks to health presented by a device are the sum of the risks presented by the components of the device. The risks presented by the pressure regulating unit, such as excessive pressure on tissues that may result from faulty pressure regulating controls or inaccurate gauges, are different from the risks presented by the cuff, such as seams or sharp edges that may cause skin trauma. FDA believes that the components of this generic device should be classified in the same regulation.

33b. A comment stated that a draft problem definition study, performed by FDA and sent to manufacturers for comment, identified application technique and preventive maintenance by hospital personnel as the predominant measures necessary to assure the safety and effectiveness of a pneumatic tourniquet. Another comment stated that the proposed classification into class II is incorrect, because the proposed classification does not support the view that the device has unreasonable risks.

FDA disagrees with the comments. During FDA's preparation of the draft study of hazards associated with use of the pneumatic tourniquet, referred to in the comment, FDA reviewed 43 citations in the medical literature on this generic type of device (Ref. 30). The study revealed the following potential hazards from use of the device: excessive inflation pressures, prolonged inflation time, venous congestion, sudden unexpected tourniquet deflation, skin trauma from necrosis or chemical burns, tissue trauma, thermal burns, and post-tourniquet syndrome. Although some of these hazards, such as prolonged inflation time, are user related and may be reduced through improved labeling, other hazards are related to the design and performance of the pressure regulating unit, the connecting tubing, or the cuff. FDA continues to believe that performance standards are necessary for this device, because general controls alone are insufficient to control the risks to health presented by the device. The agency believes that the establishment of a performance standard for the pressure regulating unit of the device may prevent excessive pressure being applied to tissue because of defective pressure controls or an inaccurate pressure gauge, or the hazard of sudden deflation of the cuff. The agency believes that the establishment of a performance standard may prevent the construction of cuffs with seams or sharp edges that may cause tissue trauma as well as failures of the tubing or the cuff that may allow sudden deflation of the cuff. FDA also believes that sufficient information is available to establish performance standards for the device. Accordingly, in the final rule FDA is classifying the generic type of device into class II as proposed, with clarifying changes in the identification of the device.

34. Section 878.4440; Eye pad; proposed class I.

FDA proposed to classify the eye pad with ophthalmic devices. (See Federal Register of January 26, 1982 at 47 FR 3732) (§ 886.4650; Docket No. 78N-3265)). Comments suggested that the identification of the device be broadened to include materials other than gauze and cotton.

FDA agrees with the comments. FDA is changing the identification of the device to include materials other than gauze and cotton that are substantially equivalent. The agency also has decided that the classification of the device should be codified with general and plastic surgery devices (21 CFR Part 878) rather than with ophthalmic devices (21 CFR Part 886). Accordingly, FDA is adopting the proposed regulation for the eye pad. FDA is codifying the classification of the device with general and plastic surgery devices at § 878.4440, with minor clarifying changes. The final classification will retain the docket number assigned to the proposed regulation for the eye pad.

35. Section 878.4800; Manual surgical instrument for general use; proposed class I.

The Panel recommended and FDA proposed that manual surgical instruments for general use be classified into class I with no exemptions. In the proposed rule, FDA included examples of the devices subject to the rule and indicated that other (unnamed) devices would be subject to the rule. No comments were received on this proposed regulation.

FDA now has determined to specifically identify another device subject to the regulation: suturing apparatus for the stomach and intestine. FDA inadvertently omitted the suturing apparatus for the stomach and intestine from the list of example devices provided in the proposed rule. FDA believes that the suturing apparatus for the stomach and intestine was in commercial distribution on the enactment date of the amendments.

Accordingly, FDA is adopting the proposed rule with changes needed to specifically identify the suturing apparatus for the stomach and intestine

as one of the devices subject to the regulation.

K. Exemptions for Class I Devices

Exemptions from CGMP regulations. As stated in the proposals, the agency has determined that exemption of manufacturers of any device 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 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 CGMP regulations, if one has been granted, is still appropriate. Also, for the reasons given in the proposed regulations, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

FDA has prepared guidelines on the procedure 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 the provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). The agency announced the availability of these guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

FDA proposed that an exemption be granted from certain requirements of the CGMP regulations for one general and plastic surgery device, the external aesthetic restoration prosthesis (§ 878.3800). FDA did not receive any comments on the proposal or comments requesting exemptions be granted for other general and plastic surgery devices. In this final rule, FDA is granting manufacturers of the external aesthetic restoration prosthesis an exemption from certain requirements of the CGMP regulations, when the device is intended for use without an adhesive to fasten it to the body. When the device is intended for use with an adhesive to fasten it to the body, the manufacturer must comply with all CGMP requirements.

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 (21 U.S.C. 360j(f)(2)(A)) for an exemption or variance from the requirement. An exemption granted in response to such a petition applies only to the manufacturer who submitted the petition. 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 a manufacturer's petition (86P-0432) for exemption of its "California Splint" device from the requirement of the CGMP regulations except § 820.180 (general requirements concerning records) and § 820.198 (complaint files). As explained above, that exemption applied only to the petitioner.

FDA has determined that the "California Splint" is one of the devices being classified into class I in this final rule in the generic type of device § 878.3910 *Noninflatable extremity splint* (Docket No. 78N-2663). Consistent with its action on the petition above, in this final rule FDA is exempting from certain sections of the CGMP regulations all manufacturers of the noninflatable extremity splint (§ 878.3910), if the device is not labeled or otherwise represented as sterile.

Exemptions from requirement of premarket notification. FDA recently has developed criteria for granting exemptions from the requirement of premarket notification. In a proposed rule published elsewhere in this issue of the **Federal Register**, FDA is proposing to grant eight class I devices an exemption from the requirement of premarket notification.

L. 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.

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31. "A Study of Safety and Performance Requirements for Cryosurgical Devices," FDA Contract No. 223–77–5037, Task Order No. 2, Emergency Care Research Institute, September 4, 1980.

32. Petition for reclassification of 316L stainless steel sutures (86P–0087) submitted by Alto Corp., Farmingdale, NJ 07727.

33. FDA letter (order) to Alto Corp. of July 30, 1986, that reclassified 316L stainless steel sutures from class III to class II signed by Kshitij Mohan, Director of the Office of Device Evaluation, CDRH.

34. Transcript: General and Plastic Surgery Devices Panel meeting, Washington, DC, March 25, 1986.

35. Minutes: General and Plastic Surgery Devices Panel meeting, Washington, DC, March 25, 1986.

36. General and Plastic Surgery Devices Panel members' individual data sheets concerning reclassification.

M. Environmental Impact

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

N. Economic Impact

The agency has carefully analyzed the economic effects of this final rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the agency has carefully analyzed the impact of this final rule, and has 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, remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter 1 of Title 21 of the Code of Federal Regulations is amended by adding new Part 878 to read as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

Sec.

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878.3250 External facial fracture fixation appliance.

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878.3550 Chin prosthesis.

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878.4300 Implantable clip.

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878.4350 Cryosurgical unit and accessories.

878.4370 Surgical drape and drape accessories.

878.4380 Drape adhesive.

878.4400 Electrosurgical cutting and coagulation device and accessories.

878.4440 Eye pad.

878.4450 Nonabsorbable gauze for internal use.

878.4460 Surgeon's glove.

878.4470 Surgeon's gloving cream.

878.4480 Absorbable powder for lubricating a surgeon's glove.

878.4490 Absorbable hemostatic agent and dressing.

878.4520 Polytetrafluoroethylene injectable.

878.4580 Surgical lamp.

878.4630 Ultraviolet lamp for dermatologic disorders.

878.4660 Skin marker.

878.4680 Nonpowered, single patient, portable suction apparatus.

878.4730 Surgical skin degreaser or adhesive tape solvent.

878.4750 Implantable staple.

878.4760 Removable skin staple.

878.4780 Powered suction pump.

Sec.

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

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a general and plastic surgery 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 one subpart only.

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

§ 878.3 Effective dates of requirement for premarket approval.

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

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

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

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

Subpart B—Diagnostic Devices

§ 878.1800 Speculum and accessories.

(a) *Identification.* A speculum is a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various accessories.

(b) *Classification.* Class I.

Subpart C—Reserved

Subpart D—Prosthetic Devices

§ 878.3250 External facial fracture fixation appliance.

(a) *Identification.* An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship.

(b) *Classification.* Class I.

§ 878.3300 Surgical mesh.

(a) *Identification.* Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery.

(b) *Classification.* Class II.

§ 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

(a) *Identification.* A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient's need.

(b) *Classification.* Class II.

§ 878.3530 Silicone inflatable breast prosthesis.

(a) *Identification.* A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification.* Class III.

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

has been established of the requirement for premarket approval. See § 878.3.

§ 878.3540 Silicone gel-filled breast prosthesis.

(a) *Identification*—(1) *Single-lumen silicone gel-filled breast prosthesis.* A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(2) *Double-lumen silicone gel-filled breast prosthesis.* A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(3) *Polyurethane covered silicone gel-filled breast prosthesis.* A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.3550 Chin prosthesis.

(a) *Identification.* A chin prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the chin.

(b) *Classification.* Class II.

§ 878.3590 Ear prosthesis.

(a) *Identification.* An ear prosthesis is a silicone rubber solid device intended to be implanted to reconstruct the external ear.

(b) *Classification.* Class II.

§ 878.3610 Esophageal prosthesis.

(a) *Identification.* An esophageal prosthesis is a plastic tube or tube-like device that may have mesh reinforcement that is intended to be implanted in, or affixed externally to, the chest and throat to restore the esophagus or provide pharyngoesophageal continuity.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.3680 Nose prosthesis.

(a) *Identification.* A nose prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the nasal dorsum.

(b) *Classification.* Class II.

§ 878.3720 Tracheal prosthesis.

(a) *Identification.* A tracheal prosthesis is a tubular device intended to be implanted to reconstruct the trachea.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.3750 External prosthesis adhesive.

(a) *Identification.* An external prosthesis adhesive is a silicone-type adhesive intended to be used to fasten to the body an external aesthetic restoration prosthesis, such as an artificial nose.

(b) *Classification.* Class I.

§ 878.3800 External aesthetic restoration prosthesis.

(a) *Identification.* An external aesthetic restoration prosthesis is a device intended to be used to construct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.

(b) *Classification.* Class I. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

§ 878.3900 Inflatable extremity splint.

(a) *Identification.* An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

(b) *Classification.* Class I.

§ 878.3910 Noninflatable extremity splint.

(a) *Identification.* A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(b) *Classification.* Class I. 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 exception of § 820.180 of this chapter, with respect to general requirements concerning records, and § 820.198 of this chapter, with respect to complaint files.

§ 878.3925 Plastic surgery kit and accessories.

(a) *Identification.* A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(b) *Classification.* Class I.

Subpart E—Surgical Devices

§ 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification.* Class II for surgical gowns and surgical masks. Class I for surgical apparel other than surgical gowns and surgical masks.

§ 878.4100 Organ bag.

(a) *Identification.* An organ bag is a device that is a flexible plastic bag intended to be used as a temporary receptacle for an organ during surgical procedures to prevent moisture loss.

(b) *Classification.* Class I.

§ 878.4160 Surgical camera and accessories.

(a) *Identification.* A surgical camera and accessories is a device intended to be used to record operative procedures.

(b) *Classification.* Class I.

§ 878.4200 Introduction/drainage catheter and accessories.

(a) *Identification.* An introduction/drainage catheter is a device that is a flexible single or multilumen tube intended to be used to introduce nondrug fluids into body cavities other than blood vessels, drain fluids from body cavities, or evaluate certain physiologic conditions. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters (including dialysis), and other general surgical catheters. An introduction/drainage catheter accessory is intended to aid in the manipulation of or insertion of the device into the body. Examples of accessories include adaptors, connectors, and catheter needles.

(b) *Classification.* Class I.

§ 878.4300 Implantable clip.

(a) *Identification.* An implantable clip is a clip-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification.* Class II.

§ 878.4320 Removable skin clip.

(a) *Identification.* A removable skin clip is a clip-like device intended to connect skin tissues temporarily to aid healing. It is not absorbable.

(b) *Classification.* Class I.

§ 878.4350 Cryosurgical unit and accessories.

(a) *Identification*—(1) *Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories.* A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.

(2) *Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories.* A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.

(3) *Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories.* A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.

(b) *Classification.* Class II.

§ 878.4370 Surgical drape and drape accessories.

(a) *Identification.* A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy.

(b) *Classification.* Class II.

§ 878.4380 Drape adhesive.

(a) *Identification.* A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.

(b) *Classification.* Class I.

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) *Identification.* An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(b) *Classification.* Class II.

§ 878.4440 Eye pad.

(a) *Identification.* An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.

(b) *Classification.* Class I.

§ 878.4450 Nonabsorbable gauze for internal use.

(a) *Identification.* Nonabsorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.

(b) *Classification.* Class II.

§ 878.4460 Surgeon's glove.

(a) *Identification.* A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

(b) *Classification.* Class I.

§ 878.4470 Surgeon's gloving cream.

(a) *Identification.* Surgeon's gloving cream is an ointment intended to be used to lubricate the user's hand before putting on a surgeon's glove.

(b) *Classification.* Class I.

§ 878.4480 Absorbable powder for lubricating a surgeon's glove.

(a) *Identification.* Absorbable powder for lubricating a surgeon's glove is a powder made from corn starch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4490 Absorbable hemostatic agent and dressing.

(a) *Identification.* An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4520 Polytetrafluoroethylene injectable.

(a) *Identification.* Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 878.3.

§ 878.4580 Surgical lamp.

(a) *Identification.* A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) *Classification.* Class II.

§ 878.4630 Ultraviolet lamp for dermatologic disorders.

(a) *Identification.* An ultraviolet lamp for dermatologic disorders is a device (including a fixture) intended to provide ultraviolet radiation of the body to photoactivate a drug in the treatment of a dermatologic disorder if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(b) *Classification.* Class II.

§ 878.4660 Skin marker.

(a) *Identification.* A skin marker is a pen-like device intended to be used to write on the patient's skin, e.g., to outline surgical incision sites or mark anatomical sites for accurate blood pressure measurement.

(b) *Classification.* Class I.

§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) *Identification.* A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

(b) *Classification.* Class I.

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) *Identification.* A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.

(b) *Classification.* Class I.

§ 878.4750 Implantable staple.

(a) *Identification.* An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification.* Class II.

§ 878.4760 Removable skin staple.

(a) *Identification.* A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.

(b) *Classification.* Class I.

§ 878.4780 Powered suction pump.

(a) *Identification.* A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

(b) *Classification.* Class II.

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in Parts 868 through 892.

(b) *Classification.* Class I.

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) *Identification.* (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.

(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

(b) *Classification.* Class II.

§ 878.4930 Suture retention device.

(a) *Identification.* A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, intended to aid wound healing by distributing suture tension over a larger area in the patient.

(b) *Classification.* Class I.

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(a) *Identification.* A manual operating table and accessories and a manual operating chair and accessories are nonpowered devices, usually with movable components, intended to be used to support a patient during diagnostic examinations or surgical procedures.

(b) *Classification.* Class I.

Subpart F—Therapeutic Devices

§ 878.5070 Air-handling apparatus for a surgical operating room.

(a) *Identification.* Air-handling apparatus for a surgical operating room is a device intended to produce a directed, nonturbulent flow of air that has been filtered to remove particulate matter and microorganisms to provide an area free of contaminants to reduce the possibility of infection in the patient.

(b) *Classification.* Class II.

§ 878.5350 Needle-type epilator.

(a) *Identification.* A needle-type epilator is a device intended to destroy the dermal papilla of a hair by applying electric current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the dermal papilla. The electric current may be high-frequency AC current, high-frequency AC combined with DC current, or DC current only.

(b) *Classification.* Class II.

§ 878.5360 Tweezer-type epilator.

(a) *Identification.* A tweezer-type epilator is an electrical device intended for hair removal. The device provides a high-frequency electric current at the tip of a tweezer used for removing hair.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a device intended to surround hermetically a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers or bed sores.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 878.3.

§ 878.5900 Nonpneumatic tourniquet.

(a) *Identification.* A nonpneumatic tourniquet is a device consisting of a strap or tubing intended to be wrapped around a patient's limb and tightened to reduce circulation.

(b) *Classification.* Class I.

§ 878.5910 Pneumatic tourniquet.

(a) *Identification.* A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit,

connecting tubing, and an inflatable cuff. The cuff is intended to be wrapped around a patient's limb and inflated to reduce or totally occlude circulation during surgery.

(b) *Classification.* Class II.

Dated: May 30, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

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