

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 874 and 882****[Docket No. 98N-0405]****Medical Devices; Retention in Class III and Effective Date of Requirement for Premarket Approval for Three Preamendments Class III Devices****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to retain in class III, three preamendments class III medical devices, and is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for these devices. FDA believes that the suction antichoke device, the tongs antichoke device, and the implanted neuromuscular stimulator device should remain in class III because insufficient information exists to determine that special controls would provide reasonable assurance of their safety and effectiveness, and/or these devices present a potential unreasonable risk of illness or injury. The agency is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of any of the devices based on new information.

DATES: Written comments by October 28, 1998; request for a change in classification by August 14, 1998. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Written comments or requests for a change in classification to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184.

SUPPLEMENTARY INFORMATION:**I. Background**

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final

classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see 21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. Section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the

act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that "the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval." (H. Rept. 94-853, 94th Cong., 2d sess. 42 (1976).)

The SMDA added new section 515(i) to the act (21 U.S.C. 360e(i)). This section requires FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMA's and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Indeed, proceeding directly to rulemaking under section 515(b) of the act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMA's have not been

required either be reclassified to class I or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy set forth FDA's plans for implementing the provisions of section 515(i) of the act for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups:

1. Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used or are in very limited use. FDA's strategy is to call for PMA's for all Group 1 devices in an omnibus 515(b) rulemaking action. In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA implemented this strategy by proposing to require the filing of a PMA or a notice of completion of a PDP for 43 class III preamendments devices. Subsequently, in the **Federal Register** of September 27, 1996 (61 FR 50704), FDA called for the filing of a PMA or a notice of completion of a PDP for 41 preamendments class III devices. Due to public comment, the agency is reconsidering its position on the two remaining devices subject to the September 7, 1995, proposal.

2. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. In the **Federal Register** of August 14, 1995 (60 FR 41986), and of June 13, 1997 (62 FR 32355), FDA issued an order under section 515(i) of the act requiring manufacturers to submit safety and effectiveness information on these Group 2 devices so that FDA can make a determination as to whether the devices should be reclassified.

3. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA intends to issue proposed rules to require the submission of PMA's for the 15 high priority devices in this group in accordance with the schedule set forth in the strategy document. In the **Federal Register** of August 14, 1995 (60 FR 41984), and of June 13, 1997 (62 FR 32352), FDA issued an order under section 515(i) of the act for the 27 remaining Group 3 devices requiring manufacturers to submit safety and effectiveness information so that FDA can make a determination as to whether the devices should be reclassified or retained in class III. This proposed rule

would further implement the strategy by retaining the three devices in class III (referred to previously) and requiring manufacturers of such devices to submit PMA's or completed PDP's for the devices.

II. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, the agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that " * * * the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d) (21 CFR 812.2(d)), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2 (c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days, after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications

should be submitted to FDA at least 30 days before the end of the 90-day period after the final rule to avoid interrupting investigations.

III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with any additional information that FDA discovered. Additional information can be found in the proposed and final rules published in the **Federal Register** classifying these devices: On January 22, 1982 (47 FR 3280), and November 6, 1986 (51 FR 40378), for ear, nose, and throat devices (part 874 (21 CFR part 874)); and on November 28, 1978 (43 FR 55640), and September 4, 1979 (44 FR 51726), for neurological devices (part 882 (21 CFR part 882)).

IV. Devices Subject to This Proposal

A. Suction antichoke device (§ 874.5350)

1. Identification

A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.

2. Summary of Data

The Ear, Nose, and Throat Devices Classification Panel (the panel) recommended that the suction antichoke device intended to be used in an emergency situation to remove foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient be classified into class III based on an unpublished study that showed unsuccessful performance of the device. FDA agreed and continues to agree with the panel's recommendation. FDA also notes that the agency received no 515(i) submissions of safety and effectiveness information on the device and that although there was one premarket notification for the device in 1979, the device appears to have fallen into disuse. The agency also realizes that the Heimlich Maneuver is now recognized as the best way to assist a choking victim.

3. Risks to Health

Failure of the device to perform as intended could result in asphyxiation of the patient. The effectiveness of the suction feature of this device for the removal of foreign objects from an obstructed airway is questionable. Certain designs of the device have been shown to be ineffective.

B. Tongs antichoke device (§ 874.5370)

1. Identification

A tongs antichoke device is a device intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

2. Summary of data

The Ear, Nose, and Throat Devices Classification Panel (the panel) recommended that the tongs antichoke device intended to remove foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient be classified into class III based on an unpublished study that showed that the device may grasp an anatomical structure of the body rather than the obstructing foreign object and that the foreign object would not be extracted. FDA agreed and continues to agree with the panel's recommendation. FDA also notes that the agency received no 515(i) submissions of safety and effectiveness information on the device, and that the device appears to have fallen into disuse. There are no premarket notification submissions for the device. The agency also realizes that the Heimlich Maneuver is now recognized as the best way to assist a choking victim.

3. Risks to health

a. *Asphyxiation.* The use of the generic type of device on a patient with a partial obstruction may force the obstruction further down the airway, causing complete obstruction.

b. *Damage to anatomical structures.* Anatomical structures grasped by the tongs can be torn or ruptured. (Risk is associated primarily with plastic tongs with serrated ends.)

c. *Panic.* Injured and bleeding anatomical structures may result in, or contribute to panic of the patient. (Risk is associated primarily with plastic tongs with serrated ends.)

C. Implanted neuromuscular stimulator (§ 882.5860)

1. Identification

An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulation pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel of the patient's shoe.

2. Summary of data

The Neurology Devices Classification Panel recommended that the device intended to be implanted to improve the gait of a paralyzed patient be classified into class III. The Orthopedics Devices Classification Panel recommended that the device be classified into class II. Both classification panels based their recommendations on their personal knowledge of the device, the potential hazards associated with the device, pertinent literature, and their clinical experience with the device. FDA agreed and continues to agree with the recommendation of the Neurology Devices Classification Panel. The agency noted that only limited clinical data on the device was then available. FDA also notes that there were no 515(i) submissions of safety and effectiveness information on the device and that the device appears to have fallen into disuse. There are no premarket notification submissions for the device.

3. Risks to health

a. *Tissue toxicity.* The materials in the implanted components of the device may cause a toxic or an adverse reaction in the surrounding tissue.

b. *Infection.* There is an increased risk of sepsis associated with the implantation of a foreign object in the body.

c. *Injury to the nerve.* The presence of the electrode or the output current may injure the peroneal or femoral nerve.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1)

Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence obtained from well-controlled clinical studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the device for its intended use. (See 21 CFR 860.7(c)(2).)

Applicants should submit any PMA in accordance with FDA's "Premarket Approval (PMA) Manual." This manual is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850. This manual is also available on the World Wide Web at "http://www.fda.gov/cdrh".

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP should provide: (1) A description of the device; (2) preclinical trial information (if any); (3) clinical trial information (if any); (4) a description of the manufacturing and processing of the devices; (5) the labeling of the device; and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought. Applicants should submit any PDP in accordance with FDA's "PDP Comprehensive Outline with Attachments." This Outline is available upon request from FDA, Center for Devices and Radiological Health, Office of Device Evaluation (HFZ-400), 9200 Corporate Blvd., Rockville, MD 20850. The outline and other PDP information is also available on the World Wide Web at "http://www.fda.gov/cdrh/pdp".

VII. Request for Comments with Data

Interested persons may, on or before October 28, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office

above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of these devices is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by August 14, 1998.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of these devices is submitted, the agency will, by September 28, 1998, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule

is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA believes that there is little or no interest in marketing these devices, the agency certifies that the proposed rule, if issued as a final rule, will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Parts 874 and 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 874 and 882 be amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.5350 is amended by revising paragraph (c) to read as follows:

§ 874.5350 Suction antichoke device.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule based on this proposed rule) for any suction antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule based on this proposed rule), been found to be substantially equivalent to a suction antichoke device that was in commercial distribution before May 28, 1976. Any other suction antichoke

device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

3. Section 874.5370 is amended by revising paragraph (c) to read as follows:

§ 874.5370 Tongs antichoke device.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule based on this proposed rule) for any tongs antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule based on this proposed rule), been found to be substantially equivalent to a tongs antichoke device that was in commercial distribution before May 28, 1976. Any other tongs antichoke device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

4. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 882.5860 is amended by revising paragraph (c) to read as follows:

§ 882.5860 Implanted neuromuscular stimulator.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule based on this proposed rule) for any implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule based on this proposed rule), been found to be substantially equivalent to an implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976. Any other implanted neuromuscular stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 17, 1998.

D.B. Burlington.

Director, Center for Devices and Radiological Health.

[FR Doc. 98-20311 Filed 7-29-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. 98N-0467]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Physical Medicine Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for the following three high priority Group 3 preamendments class III devices: Microwave diathermy for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures; ultrasonic diathermy for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures; and ultrasound and muscle stimulator for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures. The uses of these three devices do not include use for the treatment of malignancies. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of any of these devices based on new information.

DATES: Written comments by October 28, 1998; request for a change in classification by August 14, 1998. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification

to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).