

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.

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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).

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 part 812 (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 that 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. 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 3 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 (the September 1995 proposal). 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 of these 43 preamendments class III devices. (Due to public comment, the agency is reconsidering its position on the two remaining devices subject to the September 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 further implements the strategy for three high priority Group 3 class III devices.

II. Dates New Requirements Apply

In accordance with 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), 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 original reports and recommendations of the Physical Medicine Device Classification Panel (the panel), an advisory committee for the classification of these devices, along with any additional information that FDA has discovered. Additional information can be found in the proposed and final rules classifying these devices into class III, published in the **Federal Register** of August 28, 1979 (44 FR 50458), and the **Federal Register** of November 23, 1983 (48 FR 53032), respectively.

IV. Devices Subject to This Proposal

A. Microwave Diathermy (21 CFR 890.5275(b))

1. Identification

A microwave diathermy device for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures, is a device that applies to the body electromagnetic energy in the microwave frequency bands of 915 megahertz to 2,450 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues. Use of this device does not include use for the treatment of malignancies.

2. Summary of Data

The panel recommended that the device intended for applying therapeutic deep heat be classified into class II based on the potential hazards associated with use of the device, on the panel members' knowledge of and clinical experience with the device, and pertinent literature. FDA agreed with

this recommendation for the above intended use. FDA also was aware that the device was being used for additional purposes for which it had not been shown to be safe and effective.

Accordingly, FDA believed the device should also be classified with respect to all other intended uses. For all other intended uses other than applying deep therapeutic heat for treatment of select medical conditions, the agency still believes that this device presents a potential unreasonable risk of injury without a proven benefit to the patient because substantial clinical information does not exist to support any other claims.

The agency notes that neither the classification panel nor the agency was aware of any preamendments use of the device for treatment of malignancies. Therefore, when classifying this device, the agency specifically excluded treatment of malignancies from the device identification. Accordingly, a PMA or completed PDP is required before this device may be marketed for the treatment of malignancies, irrespective of the date the new requirements apply for all other uses.

3. Risks to Health

- Adverse tissue response that can result in possible cataract formation in the eye and central nervous system injury.

- Electrical shock from excessive leakage current from improper grounding or a device malfunction.

- Burns from contact of uncovered parts of the body at the device output terminal or with inadequately insulated cables and electrodes.

B. Ultrasonic Diathermy (21 CFR 890.5300(b))

1. Identification

An ultrasound diathermy device for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures, is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues. Use of this device does not include use for the treatment of malignancies.

2. Summary of Data

The panel recommended that the device intended for applying therapeutic deep heat be classified into class II based on the potential hazards associated with use of the device, on the panel members' knowledge of and

clinical experience with the device, and pertinent literature. FDA agreed with this recommendation for the above intended use. FDA also was aware that the device was being used for additional purposes for which it had not been shown to be safe and effective.

Accordingly, FDA believed the device should also be classified with respect to all other intended uses. For all other intended uses other than applying deep therapeutic heat for treatment of select medical conditions, the agency still believes that this device presents a potential unreasonable risk of injury without a proven benefit to the patient because substantial clinical information does not exist to support any other claims.

The agency notes that neither the classification panel nor the agency was aware of any preamendments use of the device for treatment of malignancies. Therefore, when classifying this device, the agency specifically excluded treatment of malignancies from the device identification. Accordingly, a PMA or completed PDP is required before this device may be marketed for the treatment of malignancies, irrespective of the date the new requirements apply for all other uses.

3. Risks to Health

- Electrical shock due to faulty design or malfunction.
- Burns from high density current.
- Inappropriate therapy from inaccurate measurement of applied energy.
- Cavitation (cellular destruction) from inadequately uniform field distribution or a lack of sufficient external pressure on the device applied to the skin.

C. *Ultrasound and Muscle Stimulator* (21 CFR 890.5860(b))

1. Identification

An ultrasound and muscle stimulator for uses other than treatment of select medical conditions such as relief of pain, muscle spasms, and joint contractures, is a device that applies to the body ultrasonic energy at a frequency beyond 20 kilohertz bands and applies to the body electrical currents and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues and the stimulation or relaxation of muscles. Use of this device does not include use for the treatment of malignancies.

2. Summary of Data

The panel recommended that the device intended to repeatedly contract

muscles by passing an electric current through electrodes contacting the body be classified into class II based on the panel members' knowledge of and clinical experience with the device, and pertinent literature. FDA agreed with this recommendation for the above intended use. FDA also was aware that the device was being used for additional purposes for which it had not been shown to be safe and effective.

Accordingly, FDA believed the device should also be classified with respect to all other intended uses. For all other intended uses other than applying deep therapeutic heat for treatment of select medical conditions, the agency still believes that device presents a potential unreasonable risk of injury without a proven benefit to the patient because substantial clinical information does not exist to support any other claims.

The agency notes that neither the classification panel nor the agency was aware of any preamendments use of the device for treatment of malignancies. Therefore, when classifying this device, the agency specifically excluded treatment of malignancies from the device identification. Accordingly, a PMA or completed PDP is required before this device may be marketed for the treatment of malignancies, irrespective of the date the new requirements apply for all other uses.

3. Risks to Health

- Electrical shock due to faulty design or malfunction.
- Cardiac arrest from excessive electrical current passing through the heart.
- Inappropriate therapy from inaccurate measurement function.

V. PMA Requirements

A PMA for any of 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 above, 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 the following: (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 the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), Food and Drug Administration, 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 the following: (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 the Center for Devices and Radiological Health, Office of Device Evaluation (HFZ-400), Food and Drug Administration, 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 of the regulations.

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), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121) 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 Commissioner 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 Part 890

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 part 890 be amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

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

2. Section 890.5275 is amended by revising paragraph (c) to read as follows:

§ 890.5275 Microwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section 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) for any microwave diathermy described in paragraph (b) of this section 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), been found to be substantially equivalent to a microwave diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other microwave diathermy described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

3. Section 890.5300 is amended by revising paragraph (c) to read as follows:

§ 890.5300 Ultrasonic diathermy.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section 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) for any ultrasonic diathermy described in paragraph (b) of this section 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), been found to be substantially equivalent to an ultrasound diathermy described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound diathermy described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

4. Section 890.5860 is amended by revising paragraph (c) to read as follows:

§ 890.5860 Ultrasound and muscle stimulator.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section 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) for any ultrasound and muscle stimulator described in paragraph (b) of this section 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), been found to be substantially equivalent to an ultrasound and muscle stimulator described in paragraph (b) of this section that was in commercial distribution before May 28, 1976. Any other ultrasound and muscle stimulator described in paragraph (b) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 21, 1998.

Elizabeth D. Jacobson,

Deputy Director for Science, Center for Devices and Radiological Health.

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