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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 Preamendment Class III Devices**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to retain in class III, three preamendment medical devices and to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for the suction antichoke device, the tongs antichoke device, and the implanted neuromuscular stimulator. The agency has summarized its 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. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

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 SMDA (Pub. L. 101–629) added new section 515(i) (21 U.S.C. 360e(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 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.

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 document 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 as referenced in the May 6, 1994, notice.

In the **Federal Register** of July 30, 1998 (63 FR 40673), FDA published a proposed rule (hereinafter referred to as the July 1998 proposed rule), to retain in class III, the suction antichoke device (§ 874.5350 (21 CFR 874.5350)), the tongs antichoke device (§ 874.5370 (21 CFR 874.5370)), and the implanted neuromuscular stimulator device (§ 882.5860 (21 CFR 882.5860)), and to require the filing of a PMA or PDP for these three preamendment class III devices. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the July 1998 proposed rule the agency's findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring these devices to have an approved PMA or a declared PDP and the benefit to the public from use of the device.

The preamble to the July 1998 proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings, and under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the devices was required to be submitted by

August 13, 1998. The comment period closed October 28, 1998. The agency did not receive any comments^o or petitions requesting a change in the classification of these devices. my/ep

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the July 1998 proposed rule. As required by section 515(b)(2)(A) of the act, FDA published its 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 device.

These findings are based on the reports and recommendations of the advisory committees (the panels) for these devices, the Ear Nose and Throat Devices Panel and the Neurological Devices Panel, for the classification of the devices along with any additional information FDA discovered. Additional information can be found in the proposed and final rules classifying these devices in the **Federal Register** of January 22, 1982 (47 FR 3280) and November 6, 1986 (51 FR 40378) for the ear, nose and throat devices; and of November 28, 1978 (43 FR 55640) and September 4, 1979 (44 FR 51726) for the neurological device, respectively.

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the July 30, 1998, proposed rule and issuing this final rule to require premarket approval of the generic type of devices by revising §§ 874.5350(c), 874.5370(c), and 882.5860(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before (*insert date 90 days after date of publication in the **Federal Register***), for any of these class III preamendment devices that were in commercial distribution before May 28, 1976, or that have been found by FDA to be substantially equivalent to such a device on or before (*insert date 90 days after date of publication in the **Federal Register***). An approved PMA or a declared completed PDP is required to be in effect for any such devices on or before 180 days after FDA

files the application. Any other class III preamendment device subject to this rule that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for any of these class III preamendment devices is not filed on or before the 90th day past the effective date of this regulation, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of these class III preamendment devices. Further, FDA concludes that investigational class III preamendment devices are significant risk devices as defined in § 812.3(m) and advises that, as of the effective date of §§ 874.5350(c), 874.5370(c), and 882.5860(c), the requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of these class III preamendment devices. For any of these class III preamendment devices that is not subject to a timely filed PMA or PDP, an IDE must be in effect under § 812.20 on or before 90 days after the effective date of this regulation or distribution of the device must cease. FDA advises all persons presently sponsoring a clinical investigation involving any of these class III preamendment devices to submit an IDE application to FDA no later than 60 days after the effective date of this final rule to avoid the interruption of ongoing investigations.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 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.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule does not contain information collection provisions. 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, 21 CFR parts 874 and 882 are 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 a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before *(insert date 90 days after date of publication in the **Federal Register**)* for any suction antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before *(insert date 90 days after date of publication of the **Federal Register**)*, 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 a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before *(insert date 90 days after date of publication in the **Federal Register**)* for any tongs antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before *(insert date 90 days after date of publication of the **Federal Register**)*, 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:

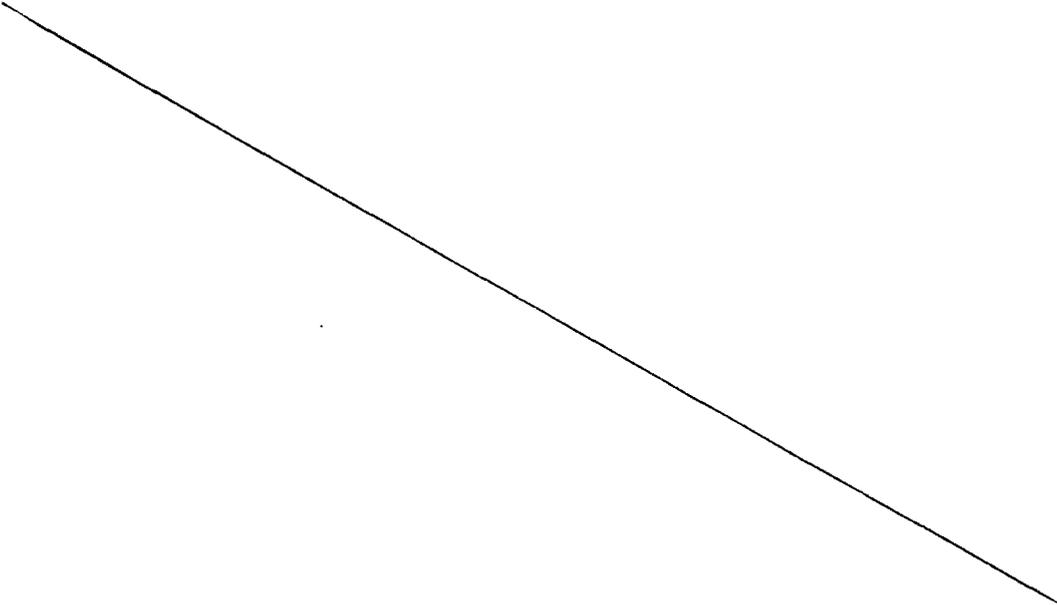
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

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

§ 882.5860 Implanted neuromuscular stimulator.

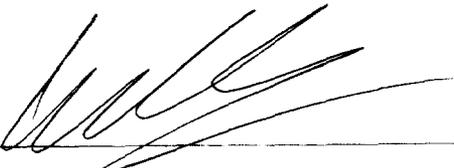
* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before *(insert date 90 days after date of publication in the Federal Register)* for any implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976, or that has, on or before *(insert date 90 days after date of publication in the Federal Register)*, been found to be substantially equivalent to an implanted neuromuscular

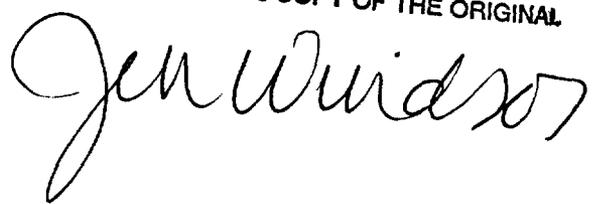


stimulator that was in commercial distribution before May 28, 1976. Any other implanted neuromuscular stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: April 7, 1999
April 7, 1999



William K. Hubbard
Acting Deputy Commissioner for
Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL


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