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Dated: April 5, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 868, 884, and 890

**[Docket No. 98N–0564]**

## Medical Devices; 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 three class III preamendment devices in class III and to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following devices: The lung water monitor, the powered vaginal muscle stimulator, and the stair-climbing wheelchair. 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.

**DATES:** This rule is effective April 13, 2000.

**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

In the **Federal Register** of August 18, 1998 (63 FR 44177), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)), of a PMA or a notice of completion of a PDP for three preamendment class III devices. In accordance with section 515(b)(A)(2) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the premarket approval requirements of the act, and the benefits to the public from use of the devices. The proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. 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. If anyone wanted to submit a petition requesting a change in the classification of the three devices, they were required to submit it by September 2, 1998. The comment period closed November 16, 1998.

FDA received no comments on the proposed rule. FDA received one citizen petition requesting a change in the classification of the stair-climbing wheelchair from class III to class II. FDA reviewed the petition and determined that there was not sufficient information to establish special controls to reasonably assure the safety and effectiveness of the device. FDA informed the petitioner in a letter dated May 10, 1999, that if additional information was submitted under section 513(e) of the act (21 U.S.C. 360c(e)) within 30 days to support the reclassification of the device, FDA would review the information. FDA also stated that if the petitioner did not submit additional information within 30 days to show that sufficient information is available to establish special controls to reasonably assure the safety and effectiveness of the device, FDA would deem the reclassification petition withdrawn. FDA has not received any new information from the petitioner and has deemed the reclassification petition withdrawn.

### II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings it published in the proposed rule. As required by section 515(b) 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 devices.

These findings are based on the reports and recommendations of the advisory committees (the panels) for these devices, the Anesthesiology and Respiratory Devices Panel, the Obstetrical and Gynecological Devices Panel, and the Orthopedic and Rehabilitation Devices Panel for the classification of the devices along with any additional information that FDA discovered. Additional information can be found in the proposed and final rules classifying these devices published in the **Federal Register** of November 2, 1979 (44 FR 63292), and July 16, 1982 (47 FR 31130), for the lung water monitor; April 3, 1979 (44 FR 19894), and February 26, 1980 (45 FR 12682), for the powered vaginal muscle stimulator; and August 28, 1979 (44 FR 50458), and November 23, 1983 (48 FR 53032), for the stair-climbing wheelchair.

### III. The Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and issuing this final rule to require premarket approval of these generic types of devices for class III preamendment devices by revising parts 868, 884, and 890 (21 CFR parts 868, 884, and 890).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before July 12, 2000, 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 July 12, 2000. 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 (21 CFR part 812) are met.

**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 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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.

On August 14, 1996 (60 FR 41984), FDA issued an order under section 515(i) of the act requiring manufacturers of these three devices (among others) to submit information concerning the safety and effectiveness of the devices. Manufacturers were required to comply with this order, if they wished to market the device. FDA received no submissions in response to this order for these three devices. Although one manufacturer submitted a reclassification petition for the stair-climbing wheelchair in response to the proposed rule, the manufacturer did not respond to requests for additional information. FDA believes that the manufacturer is no longer interested in marketing this device because there is limited demand for it. Therefore, 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 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 868, 884, and 890**

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 868, 884, and 890 are amended as follows:

## PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

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

2. Section 868.2450 is amended by revising paragraph (c) to read as follows:

**§ 868.2450 Lung water monitor.**

* * * * *

(c) *Date PMA or notice of completion of a 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 July 12, 2000, for any lung water monitor that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a lung water monitor that was in commercial distribution before May 28, 1976. Any other lung water monitor device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

## PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

3. The authority citation for 21 CFR part 884 continues to read as follows:

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

4. Section 884.5940 is amended by revising paragraph (c) to read as follows:

**§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.**

* * * * *

(c) *Date PMA or notice of completion of a 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 July 12, 2000, for any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a powered vaginal muscle stimulator that was in commercial distribution before May 28, 1976. Any other powered vaginal muscle stimulator for therapeutic use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

## PART 890—PHYSICAL MEDICINE DEVICES

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

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

6. Section 890.3890 is amended by revising paragraph (c) to read as follows:

**§ 890.3890 Stair-climbing wheelchair.**

* * * * *

(c) *Date PMA or notice of completion of a 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 July 12, 2000, for any stair-climbing wheelchair that was in commercial distribution before May 28, 1976, or that has, on or before July 12, 2000, been found to be substantially equivalent to a stair-climbing wheelchair that was in commercial distribution before May 28, 1976. Any other stair-climbing wheelchair shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: April 3, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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