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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 890

[Docket No. 98N-0009]

Medical Devices; Revocation of Exemptions from Premarket Notification for Certain Cardiovascular and Physical Medicine Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal in part.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing in part its proposed rule that published in the **Federal Register** of November 12, 1998 (63 FR 63222), to revoke the exemptions from the requirement off premarket notification of a cardiovascular device (cardiopulmonary bypass accessory equipment) and a physical medicine device (electrode cable). Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to exempt other devices from the requirement of premarket notification.

DATES: The proposed rule that published at 63 FR 63222, November 12, 1998, is withdrawn in part for §§ 870.4200 and 890.1175 as of *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1 190.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (FDAMA) into law (Public Law 105-1 15). Section 206 of FDAMA, in part, added a new section 510(I) to the Federal Food, Drug, and Cosmetic Act (the act). Under section 206 of FDAMA, new section 510(I) of the act became effective on

February 19, 1998. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. FDA refers to devices that FDA believes meet these criteria as "reserved." FDA has evaluated all class I devices to determine which device types should be subject to premarket notification requirements.

In the **Federal Register** of February 2, 1998 (63 FR 5387), FDA published a list of devices it considered reserved and that require premarket notification and a list of devices it believed met the exemption criteria in FDAMA. FDA invited comments on the February 2, 1998, notice.

FDA had proposed two rules that relate to the classification and premarket notification status of cardiopulmonary bypass accessory equipment (21 CFR 870.4200) and electrode cables (21 CFR 890.1175). In the November 12, 1998, proposed rule after reviewing the comments submitted on the February 2, 1998, notice, FDA proposed to designate which devices require premarket notification, and which are exempt, subject to limitations, under notice and comment rulemaking proceedings under new section 510(l) of the act. At that time, FDA also proposed to revoke existing exemptions for certain devices from premarket notification, including those for cardiopulmonary bypass accessory equipment and the electrode cable.

In the **Federal Register** of August 9, 1999 (64 FR 43114), FDA published a proposed rule to reclassify three devices into class II in order to make them subject to the performance standard for electrode lead wires and patient cables, including cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient and the electrode cable. Because FDA believes that compliance with the performance standard for electrode lead wires and patient cables will provide adequate assurance of the safety and effectiveness of these devices, the proposal provides that these devices would be exempt from the premarket notification requirements.

Under the August 9, 1999, proposed rule, cardiopulmonary bypass accessory equipment that does not involve an electrical connection to the patient would remain in class I and would be

exempt from the premarket notification requirements. FDA expects to finalize the August 9, 1999, proposed rule in the very near future. If the rule is finalized, the devices will be exempt from the premarket notification requirements and all such devices will be subject to the performance standard for electrode lead wires and patient cables, when the rule becomes effective for those devices on May 9, 2000.

If FDA were to finalize the November 12, 1998, proposed rule to revoke the existing premarket notification exemptions for cardiopulmonary bypass accessory equipment and the electrode cable, the manufacturers of these devices would have to comply with the premarket notification requirements only during the interim period until the proposed rule to make these devices class II exempt is finalized. FDA believes that there is no reason to require premarket notification for these devices during the short interval between these two final rules. Therefore, FDA is withdrawing in part its proposed rule to revoke the exemption from the premarket notification requirements for the cardiopulmonary bypass accessory equipment and the electrode cable.