DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0650]

Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the external pacemaker pulse generator preamendments class III device into class II (special controls). FDA is proposing this reclassification on its own initiative based on new information. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: Submit either electronic or written comments by January 17, 2012. Please see section XIII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0650 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1538, Silver Spring, MD 20993, 301–796–6216.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), FDAMA (Pub. L. 105–115), MDUFMA (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting 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 FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (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 automatically classified by section 513(f) of the FD&C 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 FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* supra, 366 F.2d at 181*; Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch,* supra, 422 F.2d at 951.) Whether data before the Agency are past or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

FDAMA added a new section 510(m) to the FD&C Act. New section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

In the preamble to the proposed rule (44 FR 13284, March 9, 1979 and 44 FR 13372, March 9, 1979), the Cardiovascular Devices Panel recommended that external pacemaker pulse generators be classified into class III because the device provided temporary life-support and that certain kinds of failures could cause this device to emit inappropriate electrical signals, which could cause cardiac irregularities and death. The panel indicated that general controls alone would not be sufficient and that there was not enough information to establish a performance standard. Consequently, the panel believed that premarket approval was necessary to assure the safety and effectiveness of the device. In 1980, FDA classified external pacemaker pulse generators into class III after receiving no comments on the proposed rule. In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for external pacemaker pulse generator devices (52 FR 17732, May 11, 1987).

In 2009, FDA published an order for the submission of information on external pacemaker pulse generators by August 7, 2009 (74 FR 16214, April 9, 2009). In response to that order, FDA received reclassification petitions from three device manufacturers who all recommended that external pacemaker pulse generators be reclassified to class II. The manufacturers stated that safety and effectiveness of these devices may be assured by design and maintenance (special controls), consideration of risks involved with the device, and an independent verification that appropriate standard operating procedures are in place and being followed.

III. Device Description

An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

IV. Proposed Reclassification

FDA is proposing that the device subject to this proposal be reclassified from class III to class II. FDA believes that the identified special controls would provide reasonable assurance of safety and effectiveness. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the devices, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. FDA has considered external pacemaker pulse generators in accordance with the reserved criteria and determined that the device does require premarket notification. The Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided for under section 510(m) of the FD&C Act.

V. Risks to Health

After considering the information from the reports and recommendations of the advisory committees (panels) for the classification of these devices along with information submitted in response to the 515(i) order and any additional information that FDA has encountered, FDA has evaluated the risks to health associated with the use of external pacemaker pulse generators and determined that the following risks to health are associated with its use:

1. Failure to pace—A failure of the electronic circuitry can cause failure to pace the patient's heart;

2. Improper pacing leading to high rate—Electric failure, electromagnetic interference, or improper programming can cause sustained high rate pacing, which can lead to arrhythmias such as pulseless ventricular tachycardia;

3. Improper pacing leading to unwanted stimulation—Pacing during vulnerable periods of the cardiac cycle or at higher than programmer amplitude can induce cardiac arrhythmias; and

4. Micro/macro shocks—Uncontrolled leakage currents or patient auxiliary currents can cause an electric shock resulting in an arrhythmia or cardiac tissue damage.

VI. Summary of Reasons for Reclassification

FDA believes that external pacemaker pulse generators should be reclassified into class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device. In addition, there is now adequate effectiveness information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

Since 1980 when FDA classified external pacemaker pulse generators into class III, sufficient evidence has been developed to support a reclassification to class II with special controls. The effectiveness and acceptability of pacing for the treatment of various cardiac arrhythmias has been demonstrated in extensive clinical studies and is summarized in the American College of Cardiology/American Heart Association Guidelines for implantable cardiac pulse generators. Several key performance standards have been developed and used to support marketing applications over the years, which address various aspects of design and performance and have been determined to be sufficient in the establishment of requirements for market entry.

VIII. Proposed Special Controls—Related Documents

FDA believes that the special controls described in the guidance document ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator'' are sufficient to mitigate the risks to health described in section V of

this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that, when finalized, would serve as a special control, if FDA reclassifies this device. If adopted, following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket notification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

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, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule will not introduce new requirements for manufacturers of external pacemaker pulse generators, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

This rule proposes to reclassify external pacemaker pulse generator devices into class II with special controls from its current classification as preamendment class III. Manufacturers of new or modified external pacemaker pulse generators would continue to be subject to premarket notification requirements as they have already been marketed through premarket notification procedures. The rule would require compliance with the proposed special controls, in addition to general controls. As described in the special controls guidance document, however, the standards for labeling, safety, and performance testing for these devices reflect current FDA requirements for marketing clearance.

The information and data requirements for 510(k) submissions remain unchanged. Thus, there would be no additional manufacturer costs associated with this proposed rule. While reclassification is unlikely to result in any procedural changes in how the affected devices are reviewed, the proposed rule will ensure that manufacturers understand the requirements by clarifying FDA's expectations for premarket submissions in the special controls guidance document.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to FDA's Registration and Listing database, there are seven establishments that currently market external pacemaker pulse generator devices. Because this proposed rule would impose no additional regulatory burdens, the Agency proposes to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.

XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain state requirements ''different from or in addition to'' certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k); *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic, Inc.* 128 S. Ct. 999 (2008)). If this proposed rule is made final, the special controls established by the final rule would create ''requirements'' for specific medical devices under 21 U.S.C. 360(k), even though product sponsors have some flexibility in how they meet those requirements (Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–742 (9th Cir. 1997)).

XII. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XIII. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final rule.

XIV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Gregoratos G., Cheitlin, M.D., Conill A., *et al.,* ''ACC/AHA Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: Executive Summary—A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Pacemaker Implantation),'' *Circulation* 1998; 97; 1325–35.

2. Class II Special Controls Guidance Document: External Pacemaker Pulse Generator.

List of Subjects in 21 CFR Part 870

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 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

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

2. Section 870.3600 is amended by revising paragraph (b) and removing paragraph (c) to read as follows:

§ 870.3600 External pacemaker pulse generator.

* * * * *

(b) *Classification.* Class II. The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator.''

Dated: October 11, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–26625 Filed 10–13–11; 8:45 am]

BILLING CODE 4160–01–P