4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2011-N-0650]

Cardiovascular Devices; Withdrawal of Proposed Rule of Reclassification of External Pacemaker Pulse Generator Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the Federal Register of October 17, 2011. In that document, FDA proposed to reclassify the external pacemaker pulse generator (EPPG) devices, a preamendments class III device into class II (special controls). In response to the requirements under the Food and Drug Administration Safety and Innovation Act (FDASIA) and new information received during a panel meeting, FDA is withdrawing the proposed rule and issuing a proposed administrative order to reclassify EPPGs.

DATES: The proposed rule is withdrawn on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1652, Silver Spring, MD 20993, 301-796-6351.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

On October 17, 2011, FDA published in the Federal Register (76 FR 64223) a proposed rule proposing the reclassification of external pacemaker pulse generator (EPPG) devices from class III to class II with special controls. FDA identified special controls that the Agency believed would provide reasonable assurance of safety and effectiveness for the device type. FDA considered EPPGs in accordance with the reserved criteria and determined that the device type does require premarket notification.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (Public Law 112-144) amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e)) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting on the classification of this device. On September 11, 2013, a meeting of the Circulatory System Devices Panel (the Panel) was held to discuss whether EPPG devices should be reclassified or remain in class III (Ref. 1). There was Panel consensus that EPPG devices did not fit the regulatory definition of a class III device. Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of safety and effectiveness, the Panel recommended class II (special controls) for EPPG when intended for cardiac rate control or prophylactic arrhythmia prevention.

II. Withdrawal of the Proposed Rule

FDA provided an opportunity for interested parties to comment on the proposed rule for EPPG (76 FR 64223). FDA received three comments to the docket in response to the 2011 proposed rule. These comments were received and have been considered during the presentations to the Panel and in developing the proposed order. In response to these comments

and findings at the Panel meeting, FDA is withdrawing the proposed rule for these devices and is issuing a proposed administrative order.

III. Proposed Reclassification

Elsewhere in this issue of the Federal Register, FDA is proposing in an order to reclassify EPPG devices, currently a preamendments class III device, into class II (special controls). FDA continues to review the merits of the submissions for requests for reclassification that meet the requirements under 21 CFR 860.123, submitted in response to the proposed rule.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. The panel transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm.

Dated: September 8, 2014

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21816 Filed 09/12/2014 at 8:45 am; Publication Date: 09/15/2014]