

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0649]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Pacemaker Pulse Generator; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: External Pacemaker Pulse Generator." This draft guidance document describes a means by which external pacemaker pulse generators may comply with the requirement of special controls for class II devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 17, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: External Pacemaker Pulse Generator" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number

found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elias Mallis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4622, Silver Spring, MD 20993-0002, 301-796-6216.

I. Background

This draft guidance document was developed as a special control guidance to support the reclassification of external pacemaker pulse generators into class II (special controls). This draft guidance document will serve as the special control for external pacemaker pulse generators. Section 513(f)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides that the Agency may initiate the reclassification of a device. This classification will be a reclassification of the device. FDA must publish a notice in the **Federal Register** announcing this reclassification. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify this device type from class III into class II (special controls), under section 513(e) of the FD&C Act (21 U.S.C. 360c(e)).

FDA is issuing this guidance document as a level 1 draft guidance document. FDA will consider any comments that are received within 90 days of the issuance of this notice to determine whether to revise the guidance document.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this draft guidance document, when finalized, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of external pacemaker pulse generator classified under § 870.3600 (21 CFR 870.3600). If classified as a class II device under § 870.3600, an external pacemaker pulse generator will need to comply with the requirement for special controls; manufacturers will need to address the issues requiring special controls as identified in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using

the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Class II Special Controls Guidance Document: External Pacemaker Pulse Generator," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1769 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 807, subpart E are currently approved under OMB control number 0910-0120; the collections of information in 21 CFR 56.115 are currently approved under OMB control number 0910-0130; the collections of information in 21 CFR part 812 are currently approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 801 are currently approved under OMB control number 0910-0485.

V. 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.

Dated: October 11, 2011.

Nancy K. Stade,

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

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