4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0916]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Device Classification Product Codes; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Medical Device Classification Product Codes." The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices regulated by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). This document describes how classification product codes are used in a variety of FDA program areas to regulate and track medical 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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Medical Device Classification Product Codes" to the Division of Small Manufacturers,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 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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I. Background

Since the May 28, 1976, Medical Device Amendments were passed, the Classification Regulation Panels (parts 862 through 892 (21 CFR parts 862 through 892)) have been the basis for the CDRH's Classification Product Code structure and organization. These 16 Panels have largely been the driving force for CDRH's internal organizational structure as well. Relying on the Classification Regulation Panels structure, CDRH created classification product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking and easy reference of predicate device types.

Classification product codes are a method of classifying medical devices. Medical device product codes consist of a three-letter combination, which associates a device's type with a product classification. Classification product codes and information associated with these devices, such as names and attributes, are assigned by CDRH to support their regulation.

The purpose of the guidance document is to educate regulated industry and FDA Staff on how, when, and why to use classification product codes for medical devices in a variety of FDA program areas to regulate and track medical devices. This document is limited to medical devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

321(h)) and does not discuss classification products codes used to regulate non-medical electronic radiation emitting products.

The scope of the guidance document includes devices described in the existing classification under parts 862 through 892. It also describes how classification product codes are used for CBER regulated devices, which currently do not fall within this existing classification. This guidance may also be applicable to future devices. It also covers unclassified devices and devices not yet classified.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on medical device classification product codes. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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 or from the CBER Internet site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "Medical Device Classification Product Codes," 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 1774 to identify the guidance you are requesting.

IV. 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. 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: December 28, 2011.

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