4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Medical Device Classification Product Codes; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Medical Device Classification Product Codes." This document describes how device product codes are used in a variety of FDA program areas to regulate and track medical devices regulated by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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 the Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. See

the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the 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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1401 Rockville Pike, suite 200N,

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301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Since the May 28, 1976, Medical Device Amendments were passed, the Classification Regulation Panels (parts 862 through 892 (21 CFR 862 through 892)) have been the basis for 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. These Panels were established with the 1976 Medical Device Amendments, and rulemaking is required in order to add to or modify the Panels. However, rulemaking has resulted in very few additions or modifications to the Panels and subgroups since 1976.

In order to respond to the evolution of device technology, classification product codes were created 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. CDRH and a subset of CBER-regulated medical device product codes consist of a three-letter combination that associates a device's type with a product classification designated for the application. 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 this 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 CDRH and CBER. This document describes how classification product codes are used 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 nonmedical 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 be applicable to future devices. It also covers unclassified devices and devices not yet classified.

In the Federal Register of January 3, 2012 (77 FR 125), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by May 2, 2012. Five comments were received with multiple recommendations pertaining to the administrative processes and policies regarding medical device classification product codes. In response to these comments, FDA revised the guidance document to clarify the processes and policies as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 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 CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/defaul

t.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. Paperwork Reduction Act of 1995

This guidance 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 803, subpart A through E, have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information under 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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, and will be posted to the docket at http://www.regulations.gov.

Dated: April 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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