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Client Alert

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FDA Issues Guidance on Medical Device Product Codes

The Food and Drug Administration (FDA) announced on Thursday, April 11, 2013, the availability of a guidance document entitled "Medical Device Classification Product Codes." The guidance, which supersedes the previous device product code guidance document issued in 2012, is intended to describe how classification products codes are used at FDA to regulate, track, and identify medical devices, including those regulated by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and unclassified devices.[1]

Since the passage of the 1976 Medical Device Amendments, FDA's Classification Regulation Panels have been the basis for CDRH's Classification Product Code structure and organization (21 C.F.R. parts 862 through 892). These 16 Panels have largely formed CDRH's internal organizational structure as well. Rulemaking is required in order to add to or modify the Panels. But, rulemaking has resulted in few additions or modifications to the Panels since 1976.

In order to respond to the evolution of device technology, classification product codes were created to identify and track current medical devices accurately and to allow for tracking and easy reference of predicate device types. CDRH assigns devices classification product codes, which are a combination of three letters (*e.g.*, "KGX" and "NEC"). Each code is associated with a device type and product classification. When a device is assigned a code, the device becomes associated with the code's product attributes and the other products that CDRH has assigned to the code. While the code delineates technology and indication subgroups within a regulation, it can also differentiate between levels of evidence required for different subgroups, and allow for tracking devices for adverse event reporting or compliance actions. Classification product codes are also used throughout the total product life cycle as they connect all medical device databases.

Product Code Evolution

1. Product codes are required in both 510(k) and Premarket Approval (PMA) submissions. If the applicant is submitting a 510(k), this product code is based on a predicate device identified by the applicant, even if the predicate's product code has become obsolete. If it appears as though there are no suitable classification product codes for the device, the applicant can contact the appropriate review

1 77 Fed. Reg. 125 (Jan. 3, 2012).

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division and submit a Request for Classification (513(g)) application for devices that are Class I exempt or Class II exempt.[2]

2. FDA uses this code to initially assign the submission to a review branch or division, as well as a review panel.
3. FDA reviews the code for accuracy. If FDA determines the proposed code is incorrect, or a more appropriate product code should be used FDA will change the code and notify the applicant. FDA partly bases this decision on any established classification regulations as described in 21C.F.R. Part 860, though devices which do not fall under any classification regulation are also assigned product codes. If FDA determines the device's technology does not raise new safety and effectiveness questions, and the device's intended use and indications for use are the same as listed in an existing code in FDA's database,[3] the existing code will be assigned to the device. Otherwise, a new product code is assigned.
4. FDA's official determination of the code is included in the 510(k) clearance or PMA letter. Companies should include this code when listing the device in the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM).

Product Code Variations

If the device is reclassified (e.g., from Class III to Class II), the product code may not necessarily change. However, product codes may change under the following circumstances:

- As new product codes are created due to new technology and old ones become obsolete, FDA may reassign a device to a new code;
- If a product code is assigned in an Investigational Device Exemption (IDE), this code may differ from that of the final clearance or approval;
- New indications for use are developed; and
- A device's technology raises new questions of safety and effectiveness.

The guidance also mentions that multiple product codes can be assigned to 510(k) devices, but the primary code to be used in all postmarket correspondence should be the product code that corresponds with the highest regulatory class, or if codes' regulatory class is the same, the product code corresponding to the most relevant technology.

Import Entry Process

Device importers must also submit a product code to FDA. If the product code is unknown, importers can

2 If a device is submitted under the humanitarian device exemption (HDE), the Office of Orphan Products determines whether the device is exempt prior to CDRH's review of the submission. Thus, FDA does not determine whether it is eligible for this exemption based on the product code.

3 The Classification Product Code database is available at the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm.

use the Office of Regulatory Affairs' (ORA) Product Code Builder[4] to formulate a product code, though it is a seven digit code, rather than the three letter combination found in the FDA product code database. As new product codes are created by CDRH and old ones modified, the Product Code Builder is updated. The classification product code helps the FDA import entry reviewer determine what information should be verified to ensure the medical device meets all regulatory requirements. Classification product codes are also used by FDA to designate products for Import Alerts.

Adverse Events and Recalls

Classification product codes are a key element of adverse event reporting. Although not clearly requested in the 3500A mandatory reporting form (MedWatch Form), the guidance recommends that product codes be used in reporting adverse events in medical device reports (MDRs), recalls, corrections, and removals. Classification product codes are also an important in reporting recalls, corrections, and removals. They are used to ensure correct device identification to assign responsibility within FDA for classification and oversight of the recall, correction, or removal.

Guidance Status

Consistent with the FDA's good guidance practices regulation,[5] the FDA's guidance does not create or confer any rights to anyone and does not operate to bind the FDA. Companies are free to use an alternative approach so long as the approach satisfies the requirements of the applicable statutes and regulations. But, because this guidance does represent agency action to educate the regulated industry and FDA staff on how, when, and why to use classification product codes, it should be reviewed carefully by companies developing medical devices.

A copy of the guidance document is available here.[6]

4 The Office of Regulatory Affairs' (ORA) Product Code Builder is available at the following website: http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM.
5 21 C.F.R. § 10.115.
6 The guidance is available at the following website: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm.