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

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

You may submit written comments and suggestions at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Submit electronic comments to **http://www.regulations.gov (http://www.regulations.gov)**. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register. Comments may not be acted upon by the Agency until the document is next revised or updated.

INO Therapeutics LLC
Exhibit 2034
Praxair Distrib., Inc. v. INO Therapeutics LLC
Case IPR2015-00891

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

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discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Since the passage of the May 28, 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act (FD&C Act), the Classification Regulation Panels (21 CFR Parts 862-892) have been the basis for the Center for Devices and Radiological Health's (CDRH's) Classification Product Code structure and organization. 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 of and easy reference to predicate device types. Classification product codes are used by FDA to obtain quality and reliable data, and perform analyses that are often reported to Congress, the Government Accountability Office (GAO), the general public, the media, and industry. Classification product codes are also used throughout the total product life cycle (TPLC) as they connect all medical device databases.

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). This document is limited to medical devices as defined in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act and does not discuss classification product codes used to regulate non-medical electronic radiation emitting products.

The scope of this document includes devices described in the existing classifications under 21 CFR Parts 862-892. It also describes how the product code builder developed by FDA's Office of Regulatory Affairs is used for devices that are licensed under the Public Health Service Act (PHS Act), and currently do not have product codes generated under classification regulation panels. It also covers unclassified devices and devices not yet classified.[1]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

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Definition

Classification product codes are a method of internally classifying and tracking medical devices. CDRH and a subset of CBER regulated medical device product codes consist of a 3 letter combination which 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.

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Use of Classification Product Codes in Premarket Review

1. General Uses of Classification Product Codes for Premarket Submissions

A. Classification product codes help to delineate technology and indication subgroups within a regulation. They can also serve to categorize unclassified or Class III (PMA) devices. Some of these subgroups may require different levels of evidence to support marketing clearance or approval, or specific warnings in the labeling. Classification product codes are also useful to identify devices for subsequent changes such as reclassification. If a device is reclassified (e.g., from Class III to Class II) the classification product code may stay the same or a new classification product code may be created.

B. Classification product codes are used for internal tracking purposes, such as adverse event monitoring or compliance actions. Product codes may be created and assigned for these purposes.

C. Classification product codes are assigned and maintained by the Agency. The submitter of the premarket submission selects a product code based on the identified predicate device(s). The proposed product code is reviewed by FDA staff for accuracy. If the proposed product code is incorrect, or a more appropriate product code should be used, the reviewer will change the product code and notify the applicant. In the case of adverse event reporting, when an incorrect product code is used or a new tracking product code is created, the Agency will assign the most accurate product code to the adverse event report.

D. Proposed classification product codes cited in premarket submissions are used in the initial assignment to the appropriate review branch/division. They are also used to determine the review panel for the device.

E. As new classification product codes are created, a device may be re-assigned into a new product code. If this occurs, FDA will send a corrected substantially equivalent or approval letter to the manufacturer of the marketed device to notify them of the new classification

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product code.

F. Guidance documents often define their scope by referencing the classification product codes to which they apply.

2. Premarket Notification [510(k)] Devices

A. Classification – Product codes are assigned within established classification regulations as described in 21 CFR Part 860. They are also assigned to unclassified devices and not-classified devices. An unclassified device is a pre-amendments device for which a classification regulation has not been promulgated. Until the unclassified device type has been formally classified and a regulation established, marketing of new devices within this type will require submission of a 510(k) premarket notification to CDRH or CBER. Once classified, these devices may require submission of a PMA, a 510(k), or be exempt from any premarket submission. A not-classified device is a post-amendments device for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application.

B. Predicate Devices –To demonstrate substantial equivalence and therefore obtain clearance of a 510(k) submission, a comparison to a predicate device is provided. Selecting a predicate device with the same classification product code as the proposed device is usually most appropriate.

C. Assignment – The reviewer will assign a classification product code based on the regulation (if relevant) or the device intended use, indications for use or technology. The most common method of assignment is to use an existing product code from the product code database. A device will be assigned an existing classification product code when it has the same intended use, indications for use, and relies on technology that does not raise new safety and effectiveness questions. However, if the proposed device differs significantly from the predicate device with respect to technology, intended use or indications for use or is found not substantially equivalent (NSE), a new product code should be assigned. The 510(k) summary will include all classification product codes considered relevant. The 510(k) clearance letter will specify one primary product code for the device and may include subsequent product codes that address additional features or functions of the device. The primary classification product code should correspond with the regulation and class applicable to the device and should be used in all postmarket correspondence as needed. The accurate use of this product code in all actions including premarket submissions, adverse event reporting and compliance actions is important to ensure accurate communication with the Agency and to avoid potential negative impacts such as delays in delivery or shipment. Multiple subsequent product codes can be used even if they fall under a different regulation and class. If multiple product codes are

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