The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

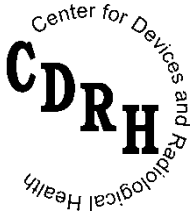
Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

This document supersedes FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.

For questions for the Center for Devices and Radiological Health regarding this document, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.



U.S. Department of Health and Human Services
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room. 1061, (HFA-305), Rockville, MD, 20852. Identify all comments with the docket number FDA-2011-D-0652. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Contains Nonbinding Recommendations

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Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

FDA developed this document to provide guidance to industry and FDA staff about current review practices for premarket notification (510(k)) submissions. The intent of this guidance is to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence. This guidance is not intended to implement significant policy changes to the current 510(k) review process. Rather, the intent of this guidance is to enhance the predictability, consistency, and transparency of the 510(k) program by describing in greater detail the regulatory framework, policies, and practices underlying FDA's 510(k) review.

The draft of this guidance document contained sections addressing FDA's Special and Abbreviated 510(k) programs. FDA intends to finalize those sections separately. Until FDA issues new final recommendations on the Special and Abbreviated 510(k) programs, the recommendations for Special and Abbreviated 510(k)s contained in "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications," dated March 20, 1998, (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm) remain in effect.

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.

II. Background

A. The Medical Device Amendments and Device Classification

The Medical Device Amendments (MDA) (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic (FD&C) Act were enacted on May 28, 1976. The MDA directed FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories: Class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet prior to distributing a device in interstate commerce. According to section 513(a)(1) of the FD&C Act (21 U.S.C. § 360c(a)(1)), the three device classes are defined as follows:

- **Class I**: Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices.[1]

- **Class II**: Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.[2]

- **Class III**: Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval.[3]

Premarket notification is the process by which a new device,[4] i.e., a post-amendments device, is classified into one of these three device classes.[5] A manufacturer who intends to market in the United

[1] General controls apply to all classes of medical devices and provide FDA with the means of regulating devices to assure their safety and effectiveness. General controls include but are not limited to provisions that relate to establishment registration and device listing; premarket notification, although most class I devices are exempt by regulation from this requirement; prohibitions against adulteration and misbranding; records and reports; and good manufacturing practices. Section 513(a)(1)(A) of the FD&C Act (21 U.S.C. § 360c(a)(1)(A)).

[2] The original definition of a class II device in the Medical Device Amendments of 1976 (Pub. L. 94-295) identified performance standards rather than special controls as the mechanism by which FDA could establish reasonable assurance of safety and effectiveness. The Safe Medical Devices Act of 1990 (Pub. L. 101-629) added "special controls," which can include the promulgation of performance standards as well as postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions), and other appropriate actions as FDA deems necessary to provide such assurance. Section 513(a)(1)(B) of the FD&C Act (21 U.S.C. § 360c(a)(1)(B)).

[3] Certain types of devices classified into class III that were in commercial distribution in the United States before May 28, 1976, and those determined to be substantially equivalent to such devices, may be cleared through the 510(k) process until FDA issues an administrative order requiring them to go through the premarket approval process. Section 515(b)(1) of the FD&C Act (21 U.S.C. § 360e(b)(1)). Prior to the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) on July 9, 2012, FDA had to publish regulations to require such devices to go through the premarket approval process. Section 608(b) of FDASIA (126 Stat. 1056) changed the process from rulemaking to administrative order.

[4] For the purpose of this guidance document, a "new device" means a device within the meaning of section 201(h) of the FD&C Act that is not legally marketed. It can be either a completely new device or a modification of a legally marketed device that would require a new 510(k).

[5] By contrast, an unclassified devices, as defined in FDA's Guidance for Industry and Food and Drug Administration Staff, "Medical Device Classification Product Codes"

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