The New 510(k) Paradigm

Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications

Final Guidance

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Prepared by the
Center for Devices and Radiological Health

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Comments and suggestions may be submitted at any time for Agency consideration to Heather Rosecrans, Office of Device Evaluation, 10903 New Hampshire Avenue, Silver Spring, MD 20993. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact the Premarket Notification (510(k)) Section at 301-796-5640.

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Preface

As part of the Center for Devices and Radiological Health's (CDRH) organizational transformation initiative, the 510(k) Process Reengineering Team examined the existing process through which regulated industry demonstrates substantial equivalence of medical devices in premarket notifications (510(k)s). On June 13, 1997, the Food and Drug Administration (FDA) released a draft proposal entitled, "A New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" for comment on the Internet. The proposal was the subject of two videoconferences which were co-sponsored by FDA and the Food and Drug Law Institute (FDLI) and was also discussed at several trade and industry association meetings. On September 19, 1997, the Agency published a Notice of Availability of the proposal in the Federal Register (62 FR 49247) to formally solicit comments from interested parties.

During this same period of time, the United States Congress was in the process of drafting the FDA Modernization Act of 1997 (the FDAMA)(Pub. L. 105-115), which amended the device provisions of the Federal Food, Drug, and Cosmetic Act (the Act). During its deliberations over the new law, several of the concepts in the New 510(k) Paradigm were discussed by members of Congress. On November 21, 1997, the President of the United States signed into law the FDAMA, which incorporated many of the changes proposed in the New Paradigm as well as many others that were envisioned in the Center's reengineering efforts. As a direct result of the enactment of this new law and the comments that were received during the period of public review, the 510(k) Process Reengineering Team developed this final guidance document.

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Introduction

This document provides guidance to the regulated industry and reviewers on two alternative approaches that may be used, under appropriate circumstances, to demonstrate substantial equivalence. It establishes procedures regarding the use of consensus standards in the premarket review process (section 514 of the Act, as amended by section 204 of the FDAMA) and reflects other changes to the 510(k) Program that have resulted from enactment of the new law, such as increased reliance on postmarket controls to expedite premarket review (section 513 of the Act, as amended by section 205 of the FDAMA). In addition, it incorporates concepts that have arisen out of the Center's organizational transformation initiative, including a new emphasis on the use of guidance documents and special controls. The alternative approaches described in this guidance document should streamline the 510(k) preparation and review processes, thus conserving industry and Agency resources while still protecting the public health.

Background

Under section 510(k) of the Act, a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. Section 513(i) of the Act states that FDA may issue an order of substantial equivalence only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. Under 21 CFR 807.87, FDA established the content requirements for premarket notifications to be submitted by device manufacturers in support of the substantial equivalence decision. FDA has, however, discretion in the type of information it deems necessary to meet those content requirements. For example, to allocate review resources more effectively to the highest risk devices, FDA developed a tiering system based on the complexity and the level of risk posed by medical devices. Under this system, the substantial equivalence determination for low risk devices is based primarily on descriptive information and a labeling review, while the decision for higher risk devices relies on performance data.

In a further effort to manage FDA's workload and allocate resources most appropriately, the Agency exempted Class I devices for which it determined that premarket notification requirements were not necessary to provide reasonable assurance of safety and effectiveness.

Between the passage of the Medical Device Amendments of 1976 and the FDAMA, FDA exempted 574 generic types of Class I devices from the requirement of premarket notification. As a result of the FDAMA, all Class I devices are exempt from the requirement of premarket notification, unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury ("reserved" criteria). Therefore, only those Class I devices that meet the reserved criteria remain subject to the premarket notification requirement. (See 63 FR 5387, February 2, 1998, for a listing of Class I "reserved" devices.)

The FDAMA also gave FDA the authority to directly exempt certain Class II devices rather than first down-classifying them to Class I before they become eligible for exemption. On January 21, 1998, FDA published a listing of Class II devices that no longer require premarket notification. (See 63 FR 3142.) In the future, additional Class II devices may become exempt from the premarket notification requirement as FDA considers additional devices for exemption.

The last phase of the Agency's effort to evaluate which devices should be subject to 510(k) review involves the preamendments Class III devices. Preamendments Class III devices for which general controls or special controls are sufficient to ensure safety and effectiveness will eventually be down-classified to either Class I (510(k) exempt or reserved) or to Class II, respectively. Those preamendments Class III devices that are not appropriate for reclassification will remain in that class and be subject to either premarket approval (PMA) or product development protocol (PDP) requirements. It is anticipated that, as a result of this reclassification effort, the premarket notification process will be primarily reserved for Class II devices and a few "reserved" Class I devices. Until a preamendments Class III device type becomes subject to a regulation requiring premarket approval, however, the device type will remain subject to the premarket notification requirement.

The New 510(k) Paradigm

To streamline the evaluation of premarket notifications for the reserved Class I devices, Class II devices subject to premarket notification, and preamendments Class III devices for which FDA has not yet called for PMAs, the Agency has developed "The New 510(k) Paradigm." Attachment 1 outlines the New Paradigm, which presents device manufacturers with two new optional approaches for obtaining marketing clearance for devices subject to 510(k) requirements. While the New Paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Act, it also presents the "Special 510(k): Device Modification" option, which utilizes certain aspects of the Quality System Regulation, and the "Abbreviated 510(k)" option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review. Use of either alternative, however, does not affect FDA's ability to obtain any information authorized by the statute or regulations.

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