

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FDA'S CLEARANCE OF MEDICAL
DEVICES THROUGH THE 510(K)
PROCESS**



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**EXECUTIVE SUMMARY: FDA'S CLEARANCE OF MEDICAL DEVICES
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WHY WE DID THIS STUDY

The Food and Drug Administration's (FDA) premarket notification (i.e., 510(k)) process is a faster and less stringent method to obtain clearance to market medical devices than the Premarket Approval (PMA) process. FDA is required to classify devices by the level of control needed to provide reasonable assurance of device safety and effectiveness (i.e., Class I, II, or III). Most Class III devices must be approved through the PMA process, although some continue to be cleared through the 510(k) process using regulatory categories of devices ("Class III preamendment device types"). The Safe Medical Devices Act of 1990 requires FDA to either reclassify Class III preamendment device types as Class II or I or keep them as Class III and require a PMA review.

HOW WE DID THIS STUDY

We determined whether FDA finished classifying the Class III preamendment device types used to clear devices through the 510(k) process, the number of Class III devices cleared using the 510(k) process, and the number of times each Class III preamendment device type was used to clear those devices through the 510(k) process from April 9, 2009, to July 9, 2012. We reviewed documents in files submitted to us electronically by FDA for Class III and Class II devices cleared through the 510(k) process in 2010. We did not determine whether FDA's clearance of the devices was appropriate.

WHAT WE FOUND

FDA has not finished classifying all types of Class III devices cleared through the 510(k) process, as required by Congress in 1990. As a result, FDA continues to clear some Class III devices through the 510(k) process. Additionally, FDA did not consistently document the review of Class III and Class II devices cleared through the 510(k) process in 2010, according to our review of the files provided electronically by FDA. Further, FDA did not provide complete administrative files during our data collection, thereby demonstrating deficiencies in its filing system.

WHAT WE RECOMMEND

FDA agreed with both of our recommendations to: (1) in accordance with the law, finish classifying all types of Class III preamendment devices used to clear devices through the 510(k) process and (2) improve its maintenance of administrative files for devices and continue to implement new policies on how to compile an administrative file.

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OBJECTIVES

1. To determine whether the Food and Drug Administration (FDA) has finished classifying the remaining types of Class III preamendment devices that are currently used to review devices through the Premarket Notification (i.e., 510(k)) process.¹
2. To determine whether FDA consistently documented the review of devices cleared through the 510(k) process in 2010.

BACKGROUND

The 510(k) process is a faster and less stringent method to obtain FDA clearance to market devices than the Premarket Approval (PMA) process. The Medical Device Amendments of 1976 (MDA) to the FFDCFA established three regulatory classes for types of medical devices, on the basis of the level of control needed to ensure the safety and effectiveness of the device (i.e., Classes I, II, and III).^{2,3} In recent years, there has been congressional and media interest in the 510(k) process, and consumer groups have criticized that process and FDA's use of it to review certain Class III devices.

Medical Device Approvals and Clearances

A medical device is defined as “an instrument, apparatus, implement...or other similar or related article, including any component, part, or accessory, which is...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease...”⁴ Devices vary in complexity and application, ranging from simple tongue depressors to complex pacemakers. FDA's Center for

¹ The 510(k) process is based on section 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 360(k)). The applicable regulations can be found at 21 CFR Part 807, Subpart E.

² P.L. 94-295 (May 28, 1976). The device classes are described at section 513(a)(1) of the FFDCFA (21 U.S.C. § 360c(a)(1)). After the enactment of the MDA, any new device (referred to as a “postamendment device”) that is not substantially equivalent to a predicate device (a device already being legally marketed) is automatically classified as a Class III device. The sponsor must either submit a PMA application or petition FDA to reclassify the device as Class I or II. Section 513(f)(1) (21 U.S.C. § 360c(f)(1)).

³ Devices are classified using types of devices in 21 CFR Parts 862-892.

⁴ A medical device, as distinguished from a drug, “does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” Section 201(h) of the FFDCFA (21 U.S.C. § 321(h)).

Devices and Radiological Health (CDRH) is, in part, responsible for the premarket review of devices.⁵

The Premarket Approval process. The PMA review is the most stringent process for obtaining FDA approval to market a device and is required by statute for devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury.⁶ For a device to receive approval via the PMA process, the device manufacturer (i.e., sponsor) must submit sufficient scientific evidence to demonstrate a reasonable assurance that it is safe and effective for its intended use.⁷ Typically, FDA requires sponsors to submit results of nonclinical laboratory studies and clinical investigations involving human subjects.⁸

After a sponsor submits a PMA application, FDA performs a preliminary review to determine whether the application is sufficiently complete for scientists with subject matter expertise (reviewers) to begin a substantive review.⁹ FDA's substantive review includes inspections of manufacturing facilities, audits of clinical study data, and reviews of safety and effectiveness data and patient labeling information.¹⁰

The Premarket Notification process. The 510(k) process is a faster and less stringent method for sponsors to obtain FDA clearance to market a device, and FDA is required by statute to review specific devices through the 510(k) process. For a device to receive clearance via the 510(k) process, sponsors do not have to submit scientific evidence demonstrating that the device is safe and effective for its intended use, as is required under the PMA process. Instead, sponsors must submit information demonstrating a device's substantial equivalence to a device already being legally marketed (i.e., the predicate device).¹¹

⁵ FDA encompasses seven centers. CDRH has primary responsibility for reviewing device submissions through the 510(k) process. CDRH reviewed all devices cleared through the 510(k) process in 2010.

⁶ Sections 515(a) and 513(a)(1)(C) of the FFDCA (21 U.S.C. §§ 360e(a) and 360c(a)(1)(C)).

⁷ Section 515(c) of the FFDCA (21 U.S.C. § 360e(c)) and 21 CFR § 814.20.

⁸ 21 CFR § 814.20.

⁹ 21 CFR § 814.42(a).

¹⁰ FDA, *Premarket Approval: PMA Review Process*, June 8, 2011. Accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm> on August 13, 2012.

¹¹ "A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or class I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process." 21 CFR § 807.92(a)(3).

FDA determines that a device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate device. FDA may also determine that a device is substantially equivalent to a predicate if it has the same intended use but different technological characteristics as the predicate and the information submitted to FDA does not raise questions of safety and effectiveness that are different from those raised by the predicate device.^{12, 13}

An FDA scientist with subject matter expertise analyzes data in the sponsor's submissions to determine whether a device is substantially equivalent to its predicate device. Once this reviewer reaches a final decision, CDRH managers (i.e., the Branch Chief and Division Director) review the file, including the reviewer's final decision. If the managers agree with the reviewer's final decision, FDA sends a letter specifying the decision to the sponsor. If the managers disagree with the reviewer's final decision, CDRH may initiate its procedures for resolving scientific disputes.^{14, 15} Of all devices under review through the 510(k) process in 2010, FDA cleared 71 percent (2,714 of 3,825) of them.^{16, 17}

Medical Devices, Types of Devices, and Regulatory Classification

Medical devices are categorized into types that generally describe their function and characteristics. The device type determines for each what

¹² FDA, *Medical Devices: Premarket Notification (510k)*. Accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> on August 28, 2012. A device cannot be found substantially equivalent to the predicate device if the predicate device has been removed from the market at the initiative of FDA or has been determined by a judicial order to be misbranded or adulterated. 21 CFR § 807.100(b).

¹³ In December 2011, FDA issued new draft guidance on evaluating substantial equivalence. FDA, *Draft Guidance for Industry and Food and Drug Administration Staff, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] (12/27/2011)*. This draft guidance was not in effect during our review.

¹⁴ FDA, *FDA Staff Manual Guides*, SMG 9010.1 Volume IV, Agency Program Directives, General or Multidiscipline Dispute Resolution, Scientific Dispute Resolution at FDA (eff. January 13, 2009); *CDRH SOP for Resolution of Internal Differences of Opinion in Regulatory Decision-Making* (September 4, 2012).

¹⁵ CDRH's policies and procedures for addressing scientific disputes were the subject of another OIG evaluation, *Scientific Disagreements Regarding Medical Device Regulatory Decisions*, OEI-01-10-00470, June 2012.

¹⁶ The remaining 29 percent of devices were not cleared through the 510(k) process. For example, these devices were determined to be not substantially equivalent, had been withdrawn by the sponsor, or had been exempted from premarket review. 2010 510(k) clearance data provided by CDRH on August 25, 2011.

¹⁷ When reporting the number of individual devices cleared by FDA through the 510(k) process, we included all 510(k) applications, including, for example, those that may have been submitted for clearance for changes to a device already being marketed (i.e., a Special 510(k) review).

the review process will be (e.g., PMA, 510(k)) or whether the device will be exempt from review. Hereinafter, the term “device” is describes a unique device, and the terms “type of device” and “device type” describe a regulatory category of devices.¹⁸

FDA classifies devices according to the level of control needed to provide reasonable assurance of the safety and effectiveness of the device (i.e., Classes I, II, and III). Types of Class III devices include those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury.^{19, 20} Generally, Class III devices must be approved via the PMA process.²¹ Table 1 contains the regulatory class, examples of types of devices in each class, and the premarket review process associated with each class.

Table 1: Medical Device Regulatory Classes, Examples of Types of Devices, and Premarket Review Process		
Class	Examples of Types of Device	Premarket Review Process
I	Tongue depressors, stethoscopes	Most are exempt from premarket review.* Nonexempt devices must be cleared through the 510(k) process rather than the PMA process.
II	Syringes, electrocardiographs	Some are exempt from premarket review.* Nonexempt devices must be cleared through the 510(k) process rather than the PMA process.
III	Implantable pacemakers, atrial defibrillators	In most cases, premarket approval is required. In limited circumstances, FDA clears Class III devices through the 510(k) process. (FDA’s clearance of Class III devices through the less stringent 510(k) process is discussed below.)

* Manufacturers of exempt devices must register and list the devices with FDA.

Source: OIG review of FDA Web site, *Medical Devices: Device Classification*. Accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> on April 27, 2012.

¹⁸ Throughout this report, we state that FDA “uses” Class III preamendment device types to clear devices through the 510(k) process. By this, we mean that a device within a Class III preamendment device type undergoes a 510(k) review.

¹⁹ Section 513(a)(1)(C) (21 U.S.C. § 360c(a)(1)(C)). Class I and Class II devices are defined at sections 513(a)(1)(A) and (B) (21 U.S.C. §§ 360c(a)(1)(A) and (B)), respectively.

²⁰ Devices with components from more than one type of device are classified at the higher class. FDA, *Guidance for Industry and Food and Drug Administration Staff - Medical Device Classification Product Codes* (issued on April 11, 2013). Accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm> on July 25, 2013.

²¹ There are exceptions, such as devices that are substantially equivalent to a preamendment predicate device (21 CFR Part 814, Subpart A); devices that have an approved humanitarian device exemption (21 CFR Part 814, Subpart H); and devices that have an approved investigational device exemption (21 CFR Part 812).

Of the 2,714 devices that FDA cleared through the 510(k) process in 2010:

- 9 percent (241) were Class I,
- 89 percent (2,414) were Class II, and
- 2 percent (59) were Class III.

Classification of Preamendment Medical Device Types

Preamendment devices are those that were in commercial distribution before May 28, 1976, the date the MDA were signed into law.²² The MDA required FDA to classify all types of devices as one of the three established regulatory classes (i.e., Class I, II, or III) and to issue regulations requiring PMA review for all devices classified as Class III.²³ The MDA authorized FDA to convene classification panels to classify all the preamendment device types.²⁴ The law required that FDA, once these device types were classified, take a number of steps for every Class III preamendment device type, including publishing a notice of proposed rulemaking; allowing comments on the proposed rule; providing an opportunity to request reclassification of the device type on the basis of new information; initiating a proceeding to reclassify the device type; and then, if the device type was determined to be Class III, publishing a final regulation requiring submission of a PMA application.²⁵

By the late 1980s, FDA had not finished classifying all Class III preamendment device types.²⁶ Until FDA finishes classifying (i.e., reclassifying as Class I or Class II or requiring a PMA review) these Class III preamendment device types, all devices that relied on predicate devices in Class III preamendment device types are required to be reviewed through the 510(k) process.²⁷

In the Safe Medical Devices Act of 1990, Congress mandated that FDA before December 1, 1995: (1) require all manufacturers of preamendment

²² FDA uses the term “preamendment device” to describe devices marketed before May 28, 1976, and devices substantially equivalent to them that have been marketed since May 28, 1976. See, e.g., 59 Fed. Reg. 23731 (May 6, 1994).

²³ Section 2 of P.L. 94-295, adding sections 513 and 515 of the FFDCA (21 U.S.C. §§ 360c and 360e).

²⁴ FDA, *PMA Historical Background*. Accessed at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm046769.htm> on August 28, 2012.

²⁵ Section 2 of P.L. 94-295, adding section 515(b) of the FFDCA (21 U.S.C. § 360e(b)).

²⁶ Government Accountability Office (GAO) (09-190), p. 11, *FDA Should Take Steps to Ensure that High-Risk Device Types are Approved through the Most Stringent Premarket Review Process*. Issued January 2009. Accessed at <http://www.gao.gov/new.items/d09190.pdf> on January 4, 2011.

²⁷ Section 513(f)(1)(A) of the FFDCA (21 U.S.C. § 360c(f)(1)(A)); 21 CFR § 807.92(a)(3).

devices that were classified as Class III with no PMA requirement to submit a summary of information to FDA, including adverse safety or effectiveness information, and (2) reexamine the remaining types of Class III preamendment devices to determine whether they should be reclassified as Class I or II or remain as Class III. If device types remained as Class III, FDA was required to establish, within 12 months, a schedule for the Class III devices to undergo PMA review.^{28, 29}

A May 1994 Federal Register notice described FDA's plan for implementing the Safe Medical Devices Act of 1990.³⁰ FDA planned to propose regulations to finish classifying all the remaining types of Class III preamendment devices. As of 1994, FDA had not finished classifying 117 Class III preamendment device types.³¹ Between 1994 and 2009, FDA finished classifying 91 of these types.³² However, as of 2009, FDA had not finished classifying the remaining 26 types. On April 9, 2009, FDA issued a Federal Register notice requiring sponsors to submit additional safety information to FDA by August 7, 2009, for 25 types of Class III preamendment devices.³³ One additional type of Class III preamendment device was addressed separately in the Federal Register.³⁴

On April 9, 2009, FDA began the 515 Program Initiative to finish classifying the 26 remaining types of Class III preamendment devices.^{35, 36}

²⁸ Section 4 of P.L. 101-629 (November, 28, 1990), adding section 515(i) of the FFDCA (21 U.S.C. § 360e(i)).

²⁹ FDA, *PMA Approvals*. Accessed at <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/pmaapprovals/default.htm> on August 28, 2012. Sponsors of Class III preamendment devices are not required to submit PMA applications until 30 months after the promulgation of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of PMA applications, whichever period is later. FDA may allow more than 90 days after the promulgation of a final rule for submission of a PMA application. See section 501(f)(2)(B) of the FFDCA (21 U.S.C. § 351(f)(2)(B)).

³⁰ 59 Fed. Reg. 23731 (May 6, 1994).

³¹ GAO (09-190), p. 43, *FDA Should Take Steps to Ensure that High-Risk Device Types are Approved through the Most Stringent Pre-market Review Process*. Issued January 2009. Accessed at <http://www.gao.gov/new.items/d09190.pdf> on January 4, 2011.

³² FDA, *515 Program Initiative*. Accessed at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm> on August 28, 2012.

³³ 74 Fed. Reg. 16214 (April 9, 2009).

³⁴ 76 Fed. Reg. 22805 (April 25, 2011).

³⁵ FDA, *515 Program Initiative*. Accessed at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm> on January 11, 2011. This guidance has been revised by FDA to reflect changes made by the Food and Drug Administration Safety and Innovation Act (FDASIA), discussed below.

³⁶ The 515 Program Initiative is based on section 515 of the FFDCA (21 U.S.C. § 360e), which requires Class III devices to undergo PMA review to be legally marketed.

For types of devices that will remain Class III, FDA will call for PMA applications for all devices within the device type.

The 515 Program Initiative had five steps.

- Step 1: FDA collects existing scientific information (e.g., safety of the devices) in the public domain and/or from scientific experts in the medical community.
- Step 2: FDA assesses the risks and benefits of the types of devices, as well as the clarity of knowledge of the medical device type subject to the reclassification.
- Step 3: FDA issues a proposed rule to classify the type of device into Class I, II, or III.
- Step 4: FDA receives and reviews comments submitted by the public regarding the proposed classification.
- Step 5: FDA issues a final rule, which notifies the public and stakeholders of the classification of the type of device as either Class I, II, or III.

Once FDA requires PMA review for devices within a Class III preamendment device type, all sponsors of those previously cleared devices, as well as sponsors of those devices determined to be substantially equivalent to a preamendment device in that type, must submit PMA applications. For each of these devices, FDA must approve the PMA application for the sponsor to continue marketing the device; however, if the application is filed in a timely manner, the device may continue to be marketed while the application is under review.³⁷ Each device type may include hundreds of unique devices, each of which would be subject to a PMA review. For example, in the pedicle screw spinal system device type, which is one of the remaining 26 Class III preamendment device types, FDA cleared 157 individual Class III devices between April 9, 2009, and July 9, 2012.

On July 9, 2012, FDASIA established a new process for finishing the classification of types of Class III preamendment devices.³⁸ Before a Class III preamendment device type can have a finished classification, FDA will now be required to issue an administrative order following publication of a proposed order, convene a device classification panel meeting, and consider public comments. The statute specifies that the new process applies to reclassifying or requiring PMA review for types of Class III

³⁷ Sections 515(b)(1) and 501(f) of the FFDCA (21 U.S.C. §§ 360e(b)(1) and 351(f)).

³⁸ P.L. 112-144, section 608(b), amending section 515(b) of the FFDCA (21 U.S.C. § 360e(b)).

preamendment devices, except those for which final rules had been promulgated before the date of enactment, July 9, 2012. FDASIA amends the timeframe for FDA to finish classifying all types of Class III preamendment devices to July 9, 2014, which is 2 years from the date of FDASIA's enactment.³⁹

FDA's Documentation of Medical Device Clearance

FDA creates an administrative file for each PMA or 510(k) application submitted by a sponsor, which includes "all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations."⁴⁰ Further, FDA must include certain documentation in the administrative file for "every significant FDA decision on any matter under the laws administered by the [FDA] Commissioner."⁴¹ Federal regulations state that documentation of the significant decision includes "[a]ppropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents; and [t]he recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter."⁴² Further, Federal regulations state that documents that are prepared by agency employees but are not in the administrative file have "no status or effect" for the purpose of approving or clearing a device.⁴³ The fact that documents are missing does not necessarily indicate that a device was improperly approved or cleared. Finally, Federal regulations require that all written documents in the administrative file be signed and dated by the author.⁴⁴

FDA issued several relevant Standard Operating Procedures (SOPs) during or after our review. On July 19, 2010, FDA issued an SOP entitled *Documentation of Meetings with Sponsors and Applicants*.⁴⁵ On July 1, 2011, FDA issued *Documentation of Informal Conversations and Communications Regarding Premarket Submissions*.⁴⁶ As of January 2012, when we completed data collection for our file review, FDA had not defined, beyond the requirements of 21 CFR § 10.70 and these SOPs, the

³⁹ P.L. 112-144, section 608(b)(1)(C), amending section 515(i)(2) of the FFDCIA (21 U.S.C. § 360e(i)(2)).

⁴⁰ 21 CFR § 10.3(a).

⁴¹ 21 CFR § 10.70(a) and (b).

⁴² 21 CFR § 10.70(b).

⁴³ 21 CFR § 10.70(d).

⁴⁴ 21 CFR § 10.70(c)(2).

⁴⁵ *CDRH ODE/OIVD SOP 2010-001: Documentation of Meetings with Sponsors and Applicants, Version 1*, (effective July 19, 2010).

⁴⁶ *CDRH ODE/OIVD SOP 2011-001: Documentation of Informal Conversations and Communications Regarding Premarket Submissions, Version 1*, (effective July 1, 2011).

specific documents that must be in administrative files. On September 20, 2012, FDA implemented the SOP entitled *Compiling the Administrative File for Premarket Submission Decisions*.⁴⁷ The stated purpose of this SOP is “to establish written procedures for creating the Administrative File for premarket submission decisions by CDRH review staff.” This SOP was not in place during our review period and was not considered in developing our methodology.

According to FDA officials, the administrative files supporting premarket submission decisions for medical devices, including files for devices undergoing 510(k) reviews, generally are compiled by the reviewer in paper format and then uploaded into the agency’s electronic filing system, known as IMAGE. The paper documents may be housed in binders until they are transferred to IMAGE. Once the paper documents are uploaded to IMAGE, they are retained until the paper file is validated against the electronic file and FDA confirms that IMAGE contains the full administrative file. According to FDA, until this validation is complete, CDRH staff can access the paper files, upon request.

Related Work

In 2009, GAO issued a report on FDA’s PMA and 510(k) review processes.⁴⁸ GAO analyzed data on PMA and 510(k) submissions for fiscal years 2003 through 2007 and analyzed the extent to which FDA used the 510(k) process to clear Class III devices. GAO recommended that FDA reclassify each remaining Class III device type as Class I or Class II or require that it remain in Class III and, for those device types remaining in Class III, require approval for marketing through the PMA process. The Department of Health and Human Services concurred with GAO’s recommendations.

METHODOLOGY

Scope

We determined whether FDA finished classifying the remaining types of Class III preamendment devices, determined the number of Class III devices cleared through the 510(k) process, and determined the number of times Class III preamendment device types were used to clear these devices from April 9, 2009, until July 9, 2012. We also determined whether documents that we concluded should reasonably be included in

⁴⁷ *CDRH SOP CDRHOC012: Compiling the Administrative File for Premarket Submission Decisions, Version 1.0*, (effective September 20, 2012).

⁴⁸ GAO (09-190), *FDA Should Take Steps to Ensure that High-Risk Device Types are Approved through the Most Stringent Premarket Review Process*. Issued January 2009. Accessed at <http://www.gao.gov/new.items/d09190.pdf> on January 4, 2011.

the administrative file to clear Class III and II devices through the 510(k) process in 2010 were present. In October and November 2011, we requested that FDA provide us the complete administrative files for 163 devices cleared through the 510(k) process in 2010. FDA provided files to us electronically within 30 days of our request and said that the electronic transmission completely fulfilled our data request.

We did not determine whether FDA's decisions in 2010 to clear devices through the 510(k) process were appropriate.

Data Collection and Analysis

Determining whether FDA finished classifying the 26 remaining types of Class III preamendment devices, determining the number of Class III devices cleared through the 510(k) process, and determining the number of times Class III preamendment device types were used to clear these devices from April 9, 2009, to July 9, 2012. We analyzed relevant statutes, regulations, Federal Register notices, and CDRH responses to survey questions. On the basis of these documents, we determined the status of the 26 types of Class III preamendment devices in FDA's 515 Program Initiative.

We obtained the three-digit product codes identified in FDA's 515 Program Initiative Project Status table.⁴⁹ Then, we searched FDA's 510(k) clearance database using these product codes to determine the number of times that Class III preamendment device types were used to clear devices between April 9, 2009, the date FDA's 515 Program Initiative began, and July 9, 2012, when FDASIA was enacted.⁵⁰ We then determined the number of devices that were cleared using these Class III preamendment device types.

Determining the extent to which FDA administrative files included documents to clear Class III and Class II devices through the 510(k) process in 2010. During our review period, FDA had not defined the specific documents that must be in administrative files; therefore, we based our assessment of what documents we determined should reasonably be included in an administrative file on our review of relevant Federal regulations, preinspection reviews of 510(k) administrative files, and meetings with FDA officials. See Appendix A for the 12 types of documents that we determined should reasonably be included in an administrative file.

⁴⁹ FDA's 515 Program Initiative Project Status table is at <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm>. Accessed on July 25, 2013.

⁵⁰ FDA's online 510(k) clearance database is at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.

We reviewed each electronic file to determine which documents were present. We examined each page of all documents in the file. We also reviewed the files to see whether all written documents were signed and dated. We considered all emails included in the files to be signed and dated. We did not determine whether documents submitted by the sponsor were signed and dated.⁵¹

We did not determine which of these documents constitute “[a]ppropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents” as stated in 21 CFR § 10.70. Rather, we considered all documentation that we found in the files or found referenced in the files to be relevant and pertinent.

We selected a stratified random sample of 163 devices cleared through the 510(k) process in 2010. We reviewed files for 159 of the devices.⁵² The sample consisted of all 59 Class III devices and a sample of 100 of the 2,414 Class II devices. Table 2 shows the number of population and sample devices by stratum.

Table 2: Number of Population and Sample Devices by Stratum

Stratum	Number of Devices Cleared Through the 510(k) Process in 2010	Sample Size
Class II Devices	2,414	100
Class III Devices	59	59
Class II and Class III Devices	2,473	159

Source: OIG Analysis of FDA 510(k) database, 2011.

Limitations

We may not have identified all documents missing from the administrative files that were relevant and pertinent to the 510(k) review. For example, if FDA held a meeting with the sponsor and there was no reference to the meeting in the administrative file, we would not be aware that the meeting occurred and, therefore, did not report the meeting minutes as missing.

⁵¹ We interpreted the requirements at 21 CFR § 10.70(c) to apply only to records generated by FDA.

⁵² FDA provided a list of all devices cleared through the 510(k) process in 2010. We requested a sample of 163 files from this list. However, during the file review, we discovered that one of the devices was a Class I device (i.e., not within the scope of our study). Also, three devices on FDA’s list classified as Class III were actually Class II devices. We decided to exclude these four devices from the sample; therefore, we reviewed a total of 159 files.

Further, to the extent that we did not receive all relevant documents, the omission may have affected our conclusions as to the consistency and completeness of documents maintained in the 510(k) administrative files.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

FDA has not finished classifying all types of Class III preamendment devices, as required by Congress in 1990

When the Safe Medical Devices Act of 1990 was enacted, FDA was required to finish classifying the 117 types of Class III preamendment devices. Between 1994 and 2009, FDA reclassified types of devices as lower classes or retained the Class III classification, thus requiring a PMA review for each device within the device type, for 91 of these device types. From April 9, 2009, when the 515 Program Initiative began, until July 9, 2012, when FDASIA amended the process and extended FDA's deadline, FDA finished classifying 7 of the remaining 26 types of Class III preamendment devices. During this period, FDA cleared 260 Class III devices through the 510(k) process using 12 of the remaining 19 types of devices.

As of July 9, 2012, FDA had not finished classifying 19 types of Class III preamendment devices

From April 9, 2009, when the 515 Program Initiative began, until July 9, 2012, when FDASIA was enacted, FDA collected existing scientific information (e.g., information on the safety of the devices) in the public domain and/or from scientific experts in the medical community for all of the remaining 26 types of Class III preamendment devices. This was the first step of FDA's five-step 515 Program Initiative. During this time, FDA also assessed the risks and benefits of each of the remaining 26 types of preamendment devices, completing step 2 of the 515 Program Initiative. FDA issued rules proposing classification for 13 device types and had received and reviewed comments for 11 device types, completing steps 3 and 4 of the 515 Program Initiative. As of July 9, 2012, FDA issued a rule finishing the classifications for seven types of devices.

Of these seven types of Class III preamendment devices, six remained Class III devices and all devices in that type will now be required to undergo PMA review. The remaining type of Class III preamendment device was reclassified as Class II. As a result, new devices within this type can continue to be cleared through the 510(k) process.

Table 3 shows the step in the 515 Program Initiative that was completed and the number of types of devices in each step from April 9, 2009, until July 9, 2012.

Table 3: Completed Steps in the FDA 515 Program Initiative and Number of Types of Devices per Step, April 9, 2009 – July 9, 2012

FDA 515 Program Step Completed	Number of Types of Devices
Step 1 – Collect existing scientific data	26
Step 2 – Assess device risk and benefits	26
Step 3 – Issue proposed rule	13
Step 4 – Receive and review public comments	11
Step 5 – Issue final rule	7

Source: OIG analysis of FDA 515 Program Initiative status, 2013.

See Appendix B for the type of device, number of times Class III preamendment device types were used to clear Class III devices from April 9, 2009 to July 9, 2012, and 515 Program Initiative steps completed as of July 9, 2012.

FDA staff cited barriers to issuing proposed and final rules as the reason for the 21-year delay in finishing classifying all preamendment device types. For example, under the 515 Program Initiative, FDA cited the time to convene classification panels, the time to complete the rulemaking process, and disagreement on the part of industry and advocates about the best classification for these types of Class III preamendment devices. FDA informed us that as of February 17, 2012, it expected to recommend that at least 10 of the 22 remaining types of Class III preamendment devices remain Class III.

On July 9, 2012, FDASIA established a new process for reclassifying devices. Before types of Class III preamendment devices can have a finished classification, FDA is now required to issue an administrative order following publication of a proposed order, convene a device classification panel meeting, and consider public comments. The statute specifies that the new process applies to reclassifying or requiring a PMA review for types of Class III preamendment devices, except those for which final rules had been promulgated before the date of enactment, July 9, 2012. The long-term effect of this process change has yet to be determined, but FDA has informed us that implementing it has further delayed progress.

From April 9, 2009, to July 9, 2012, FDA cleared 263 Class III devices through the 510(k) process

From April 9, 2009, to July 9, 2012, FDA cleared 263 devices through the 510(k) process that were determined to be substantially equivalent to Class III preamendment devices in the 515 Program Initiative. Of those devices,

FDA cleared 260 devices using 12 types of Class III preamendment devices that have not completed the 515 Program Initiative.⁵³

Three devices were cleared using one type of device that has completed the 515 Program Initiative.⁵⁴ Devices within the remaining 13 types of devices were not used as predicates to clear any new devices through the 510(k) process from April 9, 2009, to July 9, 2012. Twenty-one of the devices cleared through the 510(k) process during our review period used more than one Class III preamendment device type. Thus, Class III preamendment device types were used 284 times to clear 263 individual devices during our review period. See Appendix B for the 26 types of Class III preamendment devices in the 515 Program Initiative, the number of times each device type was used to clear each of the individual 263 devices from April 9, 2009, to July 9, 2012, and the 515 Program Initiative steps completed for each type of device.

FDA did not consistently document the review of devices cleared through the 510(k) process in 2010

Most of the files for Class III and Class II devices cleared through the 510(k) process in 2010 contained most of the documents that we concluded should reasonably be included in the administrative files. However, most of the electronic files we reviewed were missing at least one document. Missing documents included reviewers' notes, memorandums describing the basis for FDA's clearance, and minutes of meetings between FDA reviewers and device sponsors. Further, many documents in the files were not signed and dated.

After we finished our review of FDA's files and during FDA's review of a preliminary draft of the report, FDA informed us that not all documents had been loaded into IMAGE at the time we requested our data. Therefore, FDA had not provided us with the complete administrative files we requested. FDA explained that we had been given documents in the electronic files but not paper documents and that some of the electronic files we received had not been validated as complete. To the extent that not all relevant documents were provided to us, the omission may have affected our conclusions as to the consistency and completeness of documents maintained in the 510(k) administrative files. Our review of

⁵³ For 9 of these 12 types of devices, FDA had completed Step 2 of the five-step 515 Program Initiative. For 3 of these 12 types of devices, FDA had completed Step 3 of the 515 Program Initiative.

⁵⁴ After the clearance of these three devices, FDA reclassified the type of device as Class II, so all devices in this type will continue to be cleared through the 510(k) process; this explains why only 260 of the 263 Class III devices were cleared using Class III preamendment device types that FDA has still not finished classifying.

files FDA submitted electronically and FDA's initial indication that it had provided complete information to us did not alert us to the fact that additional paper records may have existed.

Our review of the electronic files showed that FDA did not consistently document the review of devices cleared through the 510(k) process in 2010. As FDA recently stated, “[C]omprehensive and accurate documentation of the deliberative process is essential to subsequent reviewers and supervisors that assume responsibility for the premarket review. Such documentation also ensures that a rational basis exists for agency decisions and promotes transparency and accountability in decision-making.”⁵⁵ FDA also noted the need for procedures “to enable CDRH review staff and managers to appropriately and systematically document the facts, data, science, and deliberative process concerning premarket decisions.”⁵⁶ Our review also revealed vulnerabilities in FDA's management of its administrative files. An adequate process for maintaining administrative files requires transparency regarding the location of documents and the completeness of the files. The lack of such a process could lead to confusion and human error.

⁵⁵ *CDRH SOP CDRHOC012: Compiling the Administrative File for Premarket Submission Decisions, Version 1.0*, (effective September 20, 2012).

⁵⁶ *Ibid.*

CONCLUSION AND RECOMMENDATIONS

The 510(k) process is a faster and less-stringent method to obtain FDA clearance to market a medical device than the PMA process. For example, in the 510(k) process, sponsors must show that a device is substantially equivalent to a predicate device. The PMA process requires that sponsors demonstrate a reasonable assurance of safety and effectiveness for a device's intended use through the submission of sufficient scientific evidence. Predicate devices used to establish substantial equivalence in the 510(k) process include Class III preamendment devices. For these Class III preamendment device types, FDA must either reclassify them as a lower class or require that they remain Class III and call for a PMA review. In recent years, the media and consumer groups have criticized FDA's continued use of the 510(k) process to clear Class III devices.

FDA has not finished classifying all types of Class III preamendment devices, as required by Congress in 1990 and as currently required by FDASIA. As a result, Class III devices continue to be cleared through the 510(k) process. Although FDA has not finished classifying these Class III preamendment device types, some of them may be reclassified as Class II, and devices can continue to be cleared through the 510(k) process with no change to the review process. For example, one of the seven device types that FDA finished classifying during the 515 Program Initiative was reclassified as Class II. However, FDA determined that six of the seven device types will remain Class III device types, and all previously cleared and new devices in that type will undergo PMA review and be required to demonstrate a reasonable assurance of safety and effectiveness.

With the enactment of FDASIA in 2012, Congress repeated its 1990 directive to finish classifying all Class III preamendment device types but changed the classification process by which these device types must be reviewed. FDA should finish classifying all Class III preamendment device types as quickly as possible and no later than July 9, 2014, consistent with FDASIA. This will promote public health by requiring devices already on the market in those Class III device types to receive the more stringent PMA review to reasonably ensure they are safe and effective for their intended use.

Additionally, we found that FDA did not consistently document the review of devices cleared through the 510(k) process in 2010, according to our review of the files provided electronically by FDA. Further, FDA did not provide complete administrative files during our data collection, thereby demonstrating deficiencies in its filing system. We recommend that FDA:

In accordance with the law, finish classifying the remaining 19 types of Class III preamendment devices that include devices still used as predicates in the 510(k) process

Starting with the highest risk device types, which include devices that are used most frequently as predicates to clear Class III devices, FDA should complete the classification process for all types of Class III preamendment devices as soon as possible but no later than July 9, 2014, the deadline established in FDASIA.

Improve its maintenance of administrative files for devices and continue to implement new policies on how to compile an administrative file

FDA should examine its maintenance of administrative files for all cleared devices. FDA should keep all paper documents in a central location and scan them expeditiously to the electronic file. The FDA administrative file should be maintained such that anyone legitimately consulting the file—even those outside CDRH—can easily ascertain whether the file is complete or additional documents exist elsewhere.

FDA should also continue to implement its new SOP on how to compile the administrative file for decisions on 510(k) device submissions. This policy could include standard review templates. FDA should also require reviewer training that describes how to document the 510(k) administrative files.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, FDA agreed with both of our recommendations. FDA agreed with the first recommendation to, in accordance with the law, finish classifying the remaining 19 types of Class III preamendment devices that include devices still used as predicates in the 510(k) process. FDA stated that it is taking steps to modify its procedure to comply with the new law. Further, FDA indicated it has made significant progress toward completing the classification of the remaining types of Class III preamendment devices. For example, for 69 percent of the Class III preamendment device types that remained when the 515 Program Initiative began in 2009, FDA indicated that it has issued proposed orders or finished classifying the device types through the rulemaking process as of June 1, 2013.

FDA also agreed with the second recommendation to improve its maintenance of administrative files for devices and continue to implement new policies on how to compile an administrative file. FDA indicated it has significantly improved its policies on how to compile an administrative file. For example, CDRH finalized and implemented an SOP to establish written procedures for creating the administrative file. FDA has also implemented technological changes that have facilitated the introduction of a standard review template.

FDA questioned the relevance of our finding that FDA did not consistently document the review of devices cleared through the 510(k) process in 2010, according to our review of the electronic files provided to us. FDA believes that we included in our review some documents that are not required by regulation or SOP to be in the administrative file and cites two documents specifically. On the basis of our inclusion of these particular documents, FDA questions the relevance of our finding. At the time of our review, we did not have the benefit of FDA's SOP (which had not yet been issued). FDA did not specifically require these two documents, or any other particular documents, to be in the administrative file. Further, most of the files in our review *did* contain the two specific documents that FDA cited. Therefore, the inclusion of these two documents, in particular, had minimal effect on our findings.

FDA also provided technical comments. In response, we made revisions to the report, where appropriate. For the full text of FDA's comments, see Appendix C.

APPENDIX A

Documents That the Office of Inspector General Determined Should Reasonably Be Included in the Administrative Files for Devices Cleared Through the 510(k) Process

On the basis of our review of relevant statutes and regulations, our preinspection review of 10 administrative files, and input from Food and Drug Administration officials during preinspection, we identified documents that we determined reasonably should be included in the file to clear the device through the 510(k) process. We grouped the documents in this manner on the basis of the organization of administrative files and for the purposes of reporting our results. FDA does not formally group the documents in this manner.⁵⁷

A. Documentation of the reviewer's analysis:

1. Reviewer Cover Sheet,
2. Reviewer Memorandum, and
3. Reviewer Decision Flowchart.^{58, 59}

B. All minutes of meetings and correspondence with sponsors and records of consultations with FDA staff:

4. the contents of all phone calls, emails, or other meetings between FDA reviewers and the sponsor; and

⁵⁷ The focus of this review is documents that support the analysis of FDA reviewers. Supervisor decisions and recommendations, as referenced in 21 CFR § 10.70(b)(2), may be included in group 1 or 2, depending on whether they are contained in written Reviewer Memorandums or if they were expressed in meetings or correspondence. The FDA's official Clearance Letter is included in group 3.

⁵⁸ The Reviewer Cover Sheet documents the reviewer's analysis of the device through the 510(k) process. The Reviewer Memorandum contains the reviewer's final summary of the deficiencies identified, additional information submitted by the sponsor to address the deficiencies, and the reviewer's conclusion about whether the additional information addresses the deficiencies. The Reviewer Decision Flowchart documents the logic used to clear the device through the 510(k) process.

⁵⁹ At the time of our review, FDA did not specifically require the Reviewer Decision Flowchart, the Medical Device User Fee Form, or any other documents to be in the administrative file. However, most of the files in our review did contain the Reviewer Decision Flowchart and the Medical Device User Fee Form.

5. the contents of all internal FDA discussions or consultations, or emails regarding device clearance.^{60, 61}
- C. Other standard documents pertinent to the decision to clear the device:
 6. letter from FDA to the sponsor clearing the device through the 510(k) process (i.e., the FDA Clearance Letter);
 7. letter from FDA to the sponsor acknowledging that FDA received the original 510(k) submission (i.e., the FDA Acknowledgement Letter);
 8. letter(s) from FDA to the sponsor confirming FDA's receipt of additional information the sponsor submitted (i.e., Additional Information Confirmation letter);
 9. Medical Device User Fee Form;⁶²
 10. additional information submitted by the sponsor in response to the reviewer's request;
 11. the original 510(k) submission from the sponsor; and
 12. the 510(k) Summary.⁶³

⁶⁰ We manually reviewed each administrative file to determine whether all minutes of meetings and correspondence with sponsors and records of consultations with FDA staff were present. If documents in the administrative file contained a sufficient level of detail, attendees, and dates of meetings, we considered these to be minutes and records.

⁶¹ Opinions of consultants, as referenced in 21 CFR § 10.70, may be included in group 1 or 2, depending on whether they are contained in written Reviewer Memorandums or whether they were expressed in meetings or correspondence.

⁶² The Medical Device User Fee Form documents that the sponsor paid the user fee, if required, to FDA for the 510(k) submission.

⁶³ The 510(k) Summary provides basic information about the device and the sponsor. The 510(k) Summary is posted on FDA's public Web site after a device is cleared.

APPENDIX B

Type of Class III Preamendment Device, Number of Times Each Class III Preamendment Device Type Was Used To Clear 263 Unique Devices Through the 510(k) Process From April 9, 2009, Through July 9, 2012, and 515 Program Initiative Steps Completed as of July 9, 2012						
Type of Class III Device	Times Device Type Used to Clear Devices through the 510(k) Process	Step 1 Complete	Step 2 Complete	Step 3 Complete	Step 4 Complete	Step 5 Complete
Pedicle screw spinal system	157	✓	✓			
Hip joint metal/metal semiconstrained, with an uncemented acetabular component, prosthesis	27	✓	✓			
Automated external defibrillator	24	✓	✓			
Implanted blood access device	20	✓	✓	✓		
Hip joint metal/metal semiconstrained, with cemented acetabular component, prosthesis	16	✓	✓			
Nonroller-type cardiopulmonary bypass blood pump	15	✓	✓			
External cardiac compressor	10	✓	✓			
Intra-aortic balloon and control system	4	✓	✓			
Shortwave diathermy	3	✓	✓	✓		
Iontophoresis device	3	✓	✓			
External counter-pulsating device	1	✓	✓			
Cranial electrotherapy stimulator	1	✓	✓	✓	✓	
Electroconvulsive therapy device	0	✓	✓			
Endosseous dental implant (blade-form dental implants)	0	✓	✓			
Membrane lung for long-term pulmonary support (i.e., ECMO)	0	✓	✓			
Mandibular condyle prosthesis	0	✓	✓			
Transilluminator for breast evaluation	0	✓	✓	✓	✓	
External pacemaker pulse generator	0	✓	✓	✓	✓	
Sorbent hemoperfusion system	0	✓	✓	✓	✓	
Topical oxygen	3	✓	✓	✓	✓	✓
Female condom	0	✓	✓	✓	✓	✓
Implantable pacemaker pulse generator	0	✓	✓	✓	✓	✓
Pacemaker programmers	0	✓	✓	✓	✓	✓
Pacemaker repair or replacement material	0	✓	✓	✓	✓	✓
Cardiovascular permanent pacemaker electrode	0	✓	✓	✓	✓	✓
Ventricular bypass device	0	✓	✓	✓	✓	✓
TOTAL	284*	26	26	13	11	7

Source: OIG analysis of FDA 515 Program Initiative status and FDA 510(k) online clearance database, 2013.
Class III preamendment device types were used 284 times to clear 263 individual devices from April 9, 2009, through July 9, 2012

APPENDIX C

Agency Comments



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Date: June 21, 2013
To: Inspector General
From: Acting Associate Commissioner for Policy and Planning
Subject: FDA's General Comment to OIG Draft Report on FDA's Clearance of Medical Devices Through the 510(k) Process

FDA is providing the attached general comments to the Office of Inspector General's draft report entitled, *FDA's Clearance of Medical Devices Through the 510(k) Process (OEI-04-10-00480)*.

FDA appreciates the opportunity to review and comment on this draft report before it is published.

/s/

Peter Lurie, MB, MPH

Attachment

FOOD AND DRUG ADMINISTRATION
GENERAL COMMENTS TO OFFICE OF INSPECTOR GENERAL DRAFT REPORT ON
FDA'S CLEARANCE OF MEDICAL DEVICES THROUGH THE 510(K) PROCESS
OEI-04-10-00480

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. Since late 2009, when FDA kicked off the 515 Program Initiative, FDA has made substantial progress in completing the reclassification of or calling for premarket approval applications (PMAs) for the 26 remaining types of Class III preamendment devices. Given the commitment and progress that FDA has demonstrated, the Agency believes that far from delaying the process (see p. 16), we have made considerable progress in addressing the backlog.

OIG Recommendations

The OIG report describes the significant progress that FDA has made toward completing the classification of the 26 remaining types of class III preamendment devices, and recommends that FDA complete its ongoing efforts to finish the classification of Class III preamendment device types¹. FDA agrees and is doing so expeditiously using a five-step process. As of June 1, 2013, FDA has taken significant interim steps toward this goal, as follows:

- FDA has taken at least one of three major regulatory actions for 25 of the 26 (96%) Class III preamendment device types since OIG started this study.²
- Step 1- For 26 of 26 (100%) device types, FDA has collected existing information and assessed the risks and benefits of that device type.
- Step 2- For 20 of 26 (77%) device types, FDA has held a classification panel meeting or finished classifying the device type. In addition, FDA has three more panels scheduled to take place before the end of July 2013.
- Step 3- For 18 of 26 (69%) device types, FDA has issued a proposed order or finished classifying the device type through the rulemaking process. In addition, FDA issued 3 proposed rules that have yet to be reissued as proposed orders, as required by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), enacted on July 9, 2012 (see below).³
- Step 5- For 7 of 26 (27%) device types, FDA has completed both the proposed and final classification stages, either reclassifying the device type or calling for PMAs for the device type.

¹ As used in this document, finish classifying Class III preamendment devices means either requiring premarket approval for the device under section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or reclassifying the device under section 513(e) of the FD&C Act.

² Of the 26 Class III preamendment devices identified in 2009, FDA has proposed reclassification or call for PMAs; held a panel meeting; or has finalized reclassification or call for PMA for all device types except iontophoresis devices (21 CFR 890.5525).

³ Step 4, which involves FDA receiving and considering the comments, is only complete upon reaching step 5 and so is omitted here.

While work remains to be done, FDA is committed to completing this process expeditiously, and continues to move forward through the five-step process.

This progress took place, even in the context of a shifting statutory framework. As identified in the report, section 608 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), enacted on July 9, 2012, modified the classification process by replacing rulemaking with an administrative order process. While the new order process will ultimately streamline reclassifications and calls for PMAs, the change requires FDA to take additional procedural steps to comply with the new order process. Specifically, FDASIA required FDA to issue six proposed orders for device types for which proposed rules had already been issued, but had not yet been finalized. Nonetheless, FDA has moved forward and has already re-proposed three of the six actions as proposed orders.

Further, as the report notes, FDA intends to call for PMAs for only a subset of the remaining Class III preamendment device types, meaning that FDA has preliminarily determined that many of these devices should be reclassified into Class II. For device types that will be reclassified to Class II and thus remain subject to review through the 510(k) program, there will be no change in the premarket review process.

The OIG report also recommends that FDA improve its maintenance of administrative files for devices and continue to implement new policies on how to compile an administrative file. FDA agrees, and in fact, since OIG's data collection, FDA has significantly improved its policies on how to compile an administrative file supporting 510(k) decisions, thereby implementing OIG's recommendation.

As OIG notes, FDA began developing a standard operating procedure⁴ (SOP) for the compilation of an administrative file in August 2011. In September 2012, CDRH finalized and implemented the SOP and required all CDRH staff to be trained on the new SOP by October 31, 2012. The stated purpose of this SOP is "to establish written procedures for creating the Administrative File for premarket submission decisions by CDRH review staff." Further, recent IT changes, including implementation of a standard review template, have helped facilitate the creation, maintenance, and ease of access to documents within administrative premarket files. FDA believes the recent improvements in FDA's administrative file policies, combined with the implementation of the SOP and the associated training, fully address OIG's concerns and implements OIG's second recommendation.

For administrative files that OIG cited as missing certain records, as OIG notes, a portion of the administrative file documents may have been in paper copy form and may not have been reviewed by OIG as part of the electronic portion of the administrative file.⁵ Without an accounting of the missing documents cited by OIG, FDA cannot reconcile the findings to determine the extent to which any missing files exist in paper form. OIG has not fulfilled an

⁴ Center for Devices and Radiological Health Standard Operating Procedure, *Compiling the Administrative File and Administrative Record for Premarket Submissions Decisions*, implemented September 20, 2012.

⁵ Under 21 CFR 10.3(a), an administrative file means "the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations." FDA's administrative files can include both electronic and paper documents.

FDA request to identify these deficiencies. If the administrative files are incomplete, FDA will review, verify, and attempt to address OIG's findings and to make any necessary corrections to our files.

In Appendix B, OIG lists documents that OIG states reasonably should be included in the administrative file. However, FDA believes that OIG included in this list some documents that are not required by either FDA's implementing regulations or SOP and that, in our view, are not essential to the documentation of a review. FDA's SOP maintains that "[t]he Administrative File consists of all materials pertaining directly or indirectly to the premarket submission decision, including all documents and materials prepared, reviewed, or received by agency personnel." Thus, if a document is not prepared or reviewed as part of the review decision, it is not a required element of the administrative file.

Among the more important examples of discrepancies between OIG's list and FDA requirements are documents A.3 (Reviewer Decision Flowchart) and B.9 (Medical Device User Fee Form). Neither of these two documents is specifically required to be in the administrative file under FDA's regulations (see 21 CFR 10.3 and 10.70) or the SOP, unless the reviewer actually generated or reviewed either of these documents as part of the review decision. Below we explain why.

- Reviewer Decision Flowchart: According to OIG, "The Reviewer Decision Flowchart documents the logic used to clear the device through the 510(k) process" (Appendix B). In fact, the flowchart merely sets forth the process for 510(k) decision-making in a visual schematic, duplicating the same information that is already in the 510(k) review template, which is included in the file. The template flowchart is not intended to contain each reviewer's "logic used" in making a 510(k) determination. Neither SOP nor regulation requires the use of this document in the decision-making process. Thus, if the flowchart is not generated by the reviewer during the decision-making process, it is not expected to be in the administrative file.
- Medical Device User Fee Form: The 510(k) review decision-making process generates an administrative file that is separate and distinct from user fee determinations. The records for user fee determinations are not material to the scientific and regulatory decision-making process, and therefore are not part of the administrative file for those clearances. Rather, FDA's documentation of the user fee payment is stored separately within another division of the agency.⁶

In light of the legitimate reasons for excluding these particular documents from the administrative file and the discrepancies between the administrative file document checklist generated by OIG and the actual list of documents required to be in the administrative file by FDA regulations and the applicable SOP, FDA questions the relevance of OIG's finding.

⁶ Documentation of appropriate user fee payment, including payment identification number and amount paid for all files reviewed by OIG, has been provided to OIG.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office, and Jaime Durley, Deputy Regional Inspector General.

Janna Sayer served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Atlanta regional office who contributed to the report include Starr Kidda and Sarah Langford; central office staff who contributed include Kevin Farber and Talisha Searcy.

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