

Paperwork Reduction Act Burden Statement

(p) A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

Alternative Methods of Compliance (AMOCs)

(q)(1) The Manager, Atlanta ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

Related Information

(r) For more information about this AD, contact Carl Gray, Aerospace Engineer, Airframe Branch, ACE-117A, FAA, Atlanta Aircraft Certification Office (ACO), 1701 Columbia Avenue, College Park, Georgia 30337; phone: 404-474-5554; fax: 404-474-5606; e-mail: Carl.W.Gray@faa.gov.

(s) For service information identified in this AD, contact Lockheed Martin Corporation/Lockheed Martin Aeronautics Company, Airworthiness Office, Dept. 6A0M, Zone 0252, Column P-58, 86 S. Cobb Drive, Marietta, Georgia 30063; phone: 770-494-5444; fax: 770-494-5445; e-mail: ams.portal@lmco.com; Internet <http://www.lockheedmartin.com/ams/tools/TechPubs.htm>. You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on July 29, 2011.

Ali Bahrami,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 2011-19968 Filed 8-5-11; 8:45 am]

BILLING CODE 4910-13-P

CONSUMER PRODUCT SAFETY COMMISSION**16 CFR Part 1130**

[CPSC Docket No. CPSC-2011-0053]

Consumer Registration of Durable Infant or Toddler Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with section 104(d) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") the Consumer Product Safety Commission ("Commission," "CPSC," or "we") issued a final consumer product safety rule requiring manufacturers of durable infant or toddler products to establish a consumer registration program. The Commission is proposing an amendment to clarify and correct some of the requirements of the rule.

DATES: Written comments must be received by October 24, 2011.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2011-0053, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through <http://www.regulations.gov>.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided to <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or

comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Celestine T. Kiss, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7739; ckiss@cpsc.gov.

SUPPLEMENTARY INFORMATION:**A. Background**

On December 29, 2009, we published a final rule requiring manufacturers of durable infant or toddler products to: (1) Provide with each product a postage-paid consumer registration form; (2) keep records of consumers who register such products with the manufacturer; and (3) permanently place the manufacturer's name and contact information, model name and number, and the date of manufacture on each such product. 74 FR 68668. The rule specified formatting and text requirements for the registration forms. Subsequently, we published a correction notice on February 22, 2010. 75 FR 7550. Since December 29, 2010, registration forms have been required for all durable infant or toddler products covered by the rule.

Some manufacturers and testing laboratories have brought to our attention the need to clarify or correct certain aspects of the rule. We are proposing this amendment for that purpose.

We note that, although manufacturers of durable infant or toddler products must comply with the registration requirements, they are not required to have a third party testing laboratory "test" their product's compliance with the registration requirements.

B. Proposed Clarifications and Corrections**1. Simplifying the Provisions for the Format and Text of Registration Forms (Proposed § 1130.6)**

The rule specifies requirements for the format of registration forms in § 1130.6 and requirements for the text of registration forms in § 1130.7. Given the geometry of the registration forms, which have four surfaces (front, back, top, and bottom), we believe that it is confusing to explain the requirements in this way. Therefore, the proposed amendment would eliminate this framework, essentially collapsing the requirements from §§ 1130.6 and 1130.7 into one section and clarifying them. Proposed § 1130.6 would describe the registration form more clearly, moving logically from the front top of the form

to the front bottom of the form, to the back top of the form, and ending with the back bottom of the form. We believe that structuring the requirements this way will also align the text more closely with the illustration of the registration form in Figures 1 and 2. We are not eliminating any of the requirements for the registration forms but proposing to organize the requirements more clearly.

Restructuring the rule would require several corresponding changes. For example, the proposed rule would, in essence, combine the existing §§ 1130.6 and 1130.7 into a revised § 1130.6. The proposal would then renumber existing §§ 1130.8 and 1130.9 as §§ 1130.7 and 1130.8 respectively. Thus, any other sections in part 1130 that refer to §§ 1130.6 through 1130.9 (such as § 1130.3(a)(2), which refers to § 1130.9) would, themselves, need to be amended to reflect the renumbered sections.

2. Clarifying the Required Font Size (Proposed § 1130.6(b)(2))

Currently, § 1130.6(c) requires that registration forms use 12-point and 10-point type. Manufacturers and testing labs have reported confusion concerning the physical size required for the type. The dictionary defines a “point” as 1/72 of an inch. However, according to font charts, font sizes used in printing do not follow this formula and are actually smaller than this measurement.

To settle this confusion, the proposed amendment would specify the physical measurement of the type, rather than refer to “point.” For example, instead of requiring “12-point” type, the proposed amendment would require “0.12-inch (3.0 mm) type.” This change would be made in proposed § 1130.6(b)(2).

3. Changes To Clarify That Consumers Should Return the Bottom Part of the Form Only (Proposed § 1130.6(c)(1) and (d)(1))

The rule requires firms to provide a form at least the size of two standard postcards connected together by a perforated line so that the two portions can be separated. The consumer retains the top portion which contains a statement of the purpose of the card and the manufacturer's contact information. According to several manufacturers, consumers have been confused about what they need to return to the manufacturer, and some consumers have been sending in the entire form or the top portion of the form only.

Currently, § 1130.7(b) requires that the back of the top portion of the form state the manufacturer's name and contact information (a U.S. mailing address, a telephone number, toll-free, if available), among other things. The

example shown in Figure 1 of the rule shows this information to be center justified, which makes this look like a mailing address.

To resolve this confusion, proposed § 1130.6(d)(1)(i) would specify that the manufacturer's name and contact information on the top portion of the form is to be stated in sentence format and appear underneath the heading: “*Manufacturer's Contact Information.*” In Figure 2 of the proposed amendment, the order of the manufacturer's contact information and the model name, model number, and manufacture date would be reversed from the order in the original Figure 2. This would place the manufacturer's contact information on top and further decrease the likelihood that a consumer would return the top part of the form.

In addition, proposed § 1130.6(d)(1)(ii) would add a new provision requiring that just above the perforation line, each form must state in capital letters: “KEEP THIS TOP PART FOR YOUR RECORDS. FILL OUT AND RETURN BOTTOM PART.”

Finally, the proposed amendment would revise the wording in the purpose statement to clarify that consumers should mail the bottom part of the form. Currently, § 1130.7(a) and Figure 1 state: “please complete and mail this card.” Proposed § 1130.6(c)(1) and proposed Figure 1 would state: “please complete and mail the bottom part of this card.”

4. Omitting Manufacturer's Name on the Back Bottom of the Form (Proposed § 1130.6(d)(2))

Currently, § 1130.7(d), as corrected in February 2010, requires that the bottom back portion of the form state the manufacturer's name with the product information. However, the illustration in Figure 2 of the rule does not show the manufacturer's name in this location. Some manufacturers have pointed out that there is limited space on this part of the form, and they have suggested that omitting the manufacturer's name would allow more space for the consumer's information. Others have indicated that the manufacturer's name may be useful on the back of the form when they use a third party to process the registration cards. Because the front of the bottom portion of the form will always have the manufacturer's name even when they use a third party to process the card, we believe it is not necessary to include the manufacturer's name at this location of the form. However, the Commission will allow a manufacturer to include its name on the back portion of the card if it wants to do so and further seeks comments on

whether some additional latitude is necessary to assist firms using a third party vendor to process their registration cards.

Proposed § 1130.6(d)(2) would omit the requirement, currently in § 1130.7(d), that the manufacturer's name be stated along with the product information at the back bottom portion of the form. It would continue to allow a manufacturer to include its name on the card should it choose to do so.

5. Identifying a Third Party That Is Processing the Forms (Proposed § 1130.6(c)(2))

Currently, § 1130.6(b)(3) requires that the registration form be pre-addressed “with the manufacturer's name and mailing address where registration information is to be collected.” As discussed in the preamble to the final rule (74 FR at 68670), a manufacturer is allowed to contract with a third party who would be responsible for maintaining the registration information. Some manufacturers have asked whether the third party's name could appear in the mailing information on the form in these circumstances.

Proposed § 1130.6(c)(2) would specify that, if a manufacturer uses a third party to process the registration forms, the third party's name may be included as a “c/o” on the form.

6. Clarifying the Location Where Registration Information Is To Be Maintained (Proposed § 1130.8(d))

Several manufacturers have asked whether the consumer registration information they receive must be maintained at a location in the United States. The rule does not specifically address this issue.

Because so much data and information is kept electronically and can be retrieved quickly, we do not believe it is necessary to require that registration information be maintained in the United States. However, manufacturers must be able to access the information when requested. Therefore, proposed § 1130.8(d) would state that registration records shall be made available within 24 hours of a request by CPSC.

7. Correcting Text Requirement for Purpose Statement To Match Figure 1 (Proposed § 1130.6(c)(1))

Currently, § 1130.7(a) provides, in part, that: “The front top portion of each form shall state ‘PRODUCT REGISTRATION FOR SAFETY ALERT OR RECALL. We will use the information provided on this card to contact you only if there is a safety alert or recall for this product. We will not

sell, rent, or share your personal information. To register your product, please complete and mail this card or visit our online registration at <http://www.websitename.com>.” There are two discrepancies between the wording of the text and the illustration in Figure 1.

To make the text and Figure 1 consistent, proposed § 1130.6(c)(1) would make two changes to the text. The word “ONLY” would be added at the end of the first sentence, and “[http://](http://www.websitename.com)” would be deleted from the Web site name.

C. Effective Date

This proposed amendment would clarify and correct several provisions of the consumer registration rule. It would not alter the substantive requirements of the existing rule. We recognize that manufacturers may have an existing inventory of registration forms. Because the proposed changes to the forms are minor and would not affect safety, we believe that it is appropriate to allow sufficient time for manufacturers to use their existing stock of registration forms before they must meet the amended requirements. Thus, we propose that this amendment would take effect 12 months after publication of a final rule. Until the proposed amendment takes effect, we would consider registration forms that meet either the existing rule or the proposed amendment to be in compliance.

D. Regulatory Flexibility Analysis or Certification

The Regulatory Flexibility Act (“RFA”) generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. However, section 104(d)(1) of the CPSIA removes this requirement for the rule implementing the CPSIA’s consumer registration provision. Consequently, no regulatory flexibility analysis or certification is necessary for this proposed amendment clarifying and correcting the consumer registration rule. Moreover, the proposed changes are minor and would not alter the impact that the registration rule has on small entities.

E. Paperwork Reduction Act

Section 104(d)(1) of the CPSIA also excludes the consumer registration rule from requirements of the Paperwork Reduction Act, 44 U.S.C. sections 3501 through 3520. Consequently, no Paperwork Reduction Act analysis is necessary for this proposed amendment clarifying and correcting the consumer registration rule. Moreover, the proposed changes are minor and would

not alter any collection of information required under the registration rule.

F. Environmental Considerations

The Commission’s regulations provide a categorical exemption for the Commission’s rules from any requirement to prepare an environmental assessment or an environmental impact statement as they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(2). This proposed amendment falls within the categorical exemption.

List of Subjects in 16 CFR 1130

Administrative practice and procedure, Business and industry, Consumer protection, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 16 CFR part 1130 as follows:

PART 1130—REQUIREMENTS FOR CONSUMER REGISTRATION OF DURABLE INFANT OR TODDLER PRODUCTS

1. The authority citation for part 1130 continues to read as follows:

Authority: 15 U.S.C. 2056a, 2065(b).

§ 1130.3 [Amended]

2. In § 1130.3(a)(2), remove “§ 1130.9” and add in its place “§ 1130.8”.

3. Section 1130.5 is amended as follows:

a. In § 1130.5 (a), remove “and 1130.7”.

b. In § 1130.5 (f), remove “1130.7(a)” and add, in its place “1130.6(c)(1)”.

4. Revise § 1130.6 to read as follows:

§ 1130.6 Requirements for format and text of registration forms.

(a) *Size of form.* The form shall be at least the size of two standard post cards connected with perforation for later separation, so that each of the two portions is at least 3½ inches high x 5 inches wide x 0.007 inches thick.

(b) *Layout of form—(1) General.* The form shall consist of four parts: top and bottom, divided by perforations for easy separation, and front and back.

(2) *Font size and typeface.* The registration form shall use bold black typeface. The size of the type shall be at least 0.12 in (3.0 mm) for the purpose statement required in § 1130.6(c)(1), and no less than 0.10 in (2.5 mm) for the other information in the registration form. The title of the purpose statement and the retention statement required in § 1130.6(d)(2) shall be in all capitals. All other information shall be in capital and lowercase type.

(c) *Front of form—(1) Top front of form: Purpose statement.* The top

portion of the front of each form shall state: “PRODUCT REGISTRATION FOR SAFETY ALERT OR RECALL ONLY. We will use the information provided on this card to contact you only if there is a safety alert or recall for this product. We will not sell, rent, or share your personal information. To register your product, please complete and mail the bottom part of this card, or visit our online registration at: <http://www.websitename.com>.” Manufacturers that do not have a Web site may provide an e-mail address and state at the end of the purpose statement: “To register your product, please complete and mail the bottom part of this card, or e-mail your contact information, the model name and number, and date of manufacture of the product, as provided on this card, to: name@firmname.com.”

(2) *Bottom front of form: Manufacturer’s mailing address.* The bottom portion of the front of each form shall be pre-addressed and postage-paid with the manufacturer’s name and mailing address where registration information is to be collected. If a manufacturer uses a third party to process registration forms, the third party’s name may be included as a “c/o” (“in care of”) in the address on the form.

(d) *Back of the form—(1) Top back of form—*

(i) *Product information and manufacturer’s identification.* The top portion of the back of each form shall state: “Manufacturer’s Contact Information” and provide the manufacturer’s name and contact information (a U.S. mailing address displayed in sentence format, website address, a telephone number, toll-free, if available), product model name and number (or other identifier as described in § 1130.4(a)(1) and (2)), and manufacture date of the product. A rectangular box shall be placed around the model name, model number, and manufacture date.

(ii) *Retention statement.* On the back of each form, just above the perforation line, the form shall state: “KEEP THIS TOP PART FOR YOUR RECORDS. FILL OUT AND RETURN BOTTOM PART.”

(2) *Bottom back of form.*

(i) *Consumer information.* The bottom portion of the back of each form shall have blocks for the consumer to provide his/her name, address, telephone number, and e-mail address. These blocks shall be 5 mm wide and 7 mm high, with as many blocks as possible to fill the width of the card allowing for normal printing practices.

(ii) *Product information.* The following product information shall be provided on the bottom portion of the back of each form below the blocks for

consumer information printed directly on the form or on a pre-printed label that is applied to the form: the model name and number (or other identifier as described in § 1130.4(a)(1) and (2)), and the date of manufacture of the product. A rectangular box shall be placed around the model name, model number, and manufacture date. A manufacturer may include its name on the bottom portion of the back of the form if they choose to do so.

5. Remove § 1130.7.
6. Redesignate §§ 1130.8 and 1130.9 as §§ 1130.7 and 1130.8, respectively.
7. In newly redesignated § 1130.8, add new paragraph (d) to read as follows:

§ 1130.8 Recordkeeping and notification requirements.

* * * * *

- (d) Records required under this section shall be made available within 24 hours, upon the request of any

officer, employee, or agent acting on behalf of the Consumer Product Safety Commission.

7. Revise Figure 1 to part 1130 to read as follows:

FIGURE 1 TO PART 1130—FRONT OF REGISTRATION FORM

BILLING CODE 6355-01-P

PRODUCT REGISTRATION FOR SAFETY ALERT OR RECALL ONLY

We will use the information provided on this card to contact you only if there is a safety alert or recall for this product. We will not sell, rent, or share your personal information. To register your product, please complete and mail the bottom part of this card, or visit our online registration at: www.website.com.

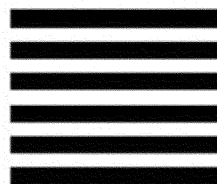


BUSINESS REPLY MAIL

FIRST-CLASS MAIL PERMIT NO.

POSTAGE WILL BE PAID BY ADDRESSEE

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



Manufacturer's Name
Post Office Box 0000
Anytown, ST 01234

8. Revise Figure 2 as follows:

<u>Manufacturer's Contact Information</u>	
Manufacturer's Name • 111 Main St • Anytown, ST 01234 www.website.com Phone Number – Toll-Free (if available)	
<div style="border: 2px solid black; padding: 10px; min-height: 150px;"> <p>Model Name:</p> <p>Model Number:</p> <p>Manufacture Date:</p> </div>	
KEEP THIS TOP PART FOR YOUR RECORDS. FILL OUT AND RETURN BOTTOM PART.	
<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p>Name</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> <div style="width: 35%;"> <p>State</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 60%;"> <p>Mailing Address</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> <div style="width: 35%;"> <p>Zip Code</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 60%;"> <p>City</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> <div style="width: 35%;"> <p>State</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div> </div> <div style="margin-top: 10px;"> <p>Telephone Number</p> <div style="display: flex; align-items: center;"> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border-bottom: 1px solid black; width: 20px; height: 20px;"></div> </div> </div> <div style="margin-top: 10px;"> <p>E-mail address</p> <div style="border-bottom: 1px solid black; height: 20px; width: 100%;"></div> </div>	
<div style="border: 2px solid black; padding: 10px; min-height: 150px;"> <p>Model Name:</p> <p>Model Number:</p> <p>Manufacture Date:</p> </div>	

FIGURE 2 TO PART 1130—BACK OF REGISTRATION FORM

Dated: August 2, 2011.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2011–19912 Filed 8–5–11; 8:45 am]

BILLING CODE 6355–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0505]

Effective Date of Requirement for Premarket Approval for Cardiovascular Permanent Pacemaker Electrode

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following class III preamendments device: Cardiovascular permanent pacemaker electrode. The Agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the statute's approval requirements and the benefits to the public from the use of the device. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of the cardiovascular permanent pacemaker electrode based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by November 7, 2011. Submit requests for a change in classification by August 23, 2011. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the effective date of the final rule. Please see section XI of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0505, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0505 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993–0002, 301–796–6216.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the

regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a PMA until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the FD&C Act is not required to have an approved investigational