



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2011-N-0650]

Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices;
Reclassification of Pacing System Analyzers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify external pacemaker pulse generator (EPPG) devices, which are currently preamendments class III devices (regulated under product code DTE), into class II (special controls) and to reclassify pacing system analyzers (PSAs) into class II (special controls) based on new information and subject to premarket notification. This final order also creates a separate classification regulation for PSAs and places single and dual chamber PSAs, which are currently classified with EPPG devices, and triple chamber PSAs (TCPSAs), which are currently postamendments class III devices, into that new classification regulation.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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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 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (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), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), among other amendments, establishes 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) establishes 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(d) 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.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially

equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

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 postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device under that section from rulemaking to an administrative order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon “new information.” FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify an eligible device type. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Department of Health, Education, and Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see Bell, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F. Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in “medical science” (Upjohn, 422 F.2d at 951). Whether data before the Agency are old or new data, the “new information” to support reclassification under section 513(e) must be “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Manufacturers Assoc. v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).) FDA relies upon “valid scientific evidence” in the reclassification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c))).

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order to reclassify a device under that section. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act and (3) consideration of comments to a public docket. FDA published a proposed order to reclassify EPPG and PSA devices in the Federal Register of September 15, 2014 (79 FR 54927) (the “proposed order”). On September 11, 2013, FDA held a meeting of a device classification panel described in section 513(b) to discuss reclassification of EPPG and PSA devices (the “2013 Panel”). FDA has also received and considered comments on the proposed order as discussed in section III. Therefore, FDA has satisfied the requirements for issuing a final order under section 513(e)(1) of the FD&C Act.

II. Regulatory History of the Devices

As noted in the proposed order, on March 9, 1979, the Agency published a proposed rule for the classification of EPPG devices into class III (44 FR 13284). FDA subsequently published a final rule classifying EPPG devices into class III under § 870.3600 (21 CFR 870.3600) after receiving no comments on the March 9, 1979, proposed rule (45 FR 7904, February 5, 1980). In 1987, FDA published a final rule to codify language clarifying that no effective date had been established for the requirement for premarket approval for EPPG devices (52 FR 17732, May 11, 1987). In 2009, FDA published an order (the “515(i) Order”) requiring manufacturers of remaining class III devices for which regulations requiring PMAs had not been issued, including EPPGs, to submit a summary of information concerning those devices by August 7, 2009 (74 FR 16214, April 9, 2009). On October 17, 2011, FDA published a proposed rule proposing the reclassification of EPPG devices from class III to class II (76 FR 64224), which the Agency

subsequently withdrew on September 15, 2014 (79 FR 54927). FDA withdrew the proposed rule in response to the new process for reclassifications under section 513(e) of the FD&C Act, as amended by FDASIA, and new information, including new information discussed during the 2013 Panel meeting.

Single and dual chamber PSAs have historically been classified with EPPG devices. Single and dual chamber PSAs combine the functionality of a single or dual chamber EPPG, which is currently a class III device, and the functionality of a pacemaker electrode function tester, which is regulated as a class II device under § 870.3720 (21 CFR 870.3720). Single and dual chamber PSA devices have been found substantially equivalent to EPPG devices through the 510(k) process. TCPSA devices have not been determined to be substantially equivalent to a predicate device through the 510(k) process and, because TCPSAs were not on the market before May 28, 1976, TCPSAs have been reviewed through the PMA process as postamendments class III devices. This order creates a new classification regulation for single, dual, and triple chamber PSA devices, which combine the functionality of an EPPG and the functionality of a pacemaker electrode function tester.

As discussed in the proposed order, FDA considered the available information on these devices (EPPG and PSA devices) and concluded that reclassifying these devices to class II, subject to the identified special controls, would provide reasonable assurance of their safety and effectiveness. As required by section 513(e)(1) of the FD&C Act, FDA convened a meeting of a device classification panel described in section 513(b) of the FD&C Act to discuss whether EPPG and PSA devices should be reclassified or remain in class III on September 11, 2013 (78 FR 49272). The reclassification of EPPG and PSA devices was supported by the 2013 Panel. The 2013 Panel recommended that EPPG devices (including single and dual chamber PSAs) be

reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention. In addition, the 2013 Panel agreed that EPPG devices are life-supporting and, per § 860.93 (21 CFR 860.93), explained that its rationale for recommending that EPPG devices be reclassified to class II was based on the proposed special controls FDA presented, which the 2013 Panel believed were adequate (along with general controls) to mitigate the risks of the device.

The 2013 Panel also recommended that TCPSA devices be reclassified to class II with special controls when intended for use during the pulse generator implant procedure. The 2013 Panel acknowledged that TCPSA devices are life-supporting devices and provided the following rationale per § 860.93 for recommending that TCPSA devices be reclassified to class II: (1) These devices are used only during the implant procedure where backup monitoring is continuous, hazards can be recognized and treated immediately, and where there is a reasonable expectation that users are adequately trained; (2) these devices are not intended to provide the long-term hemodynamic benefit of biventricular pacing or cardiac resynchronization therapy; and (3) the recommended special controls will mitigate the health risks associated with the device. The 2013 Panel transcript and other meeting materials are available on FDA's Web site (Ref. 1). Since the 2013 Panel meeting, FDA has not become aware of new information that would provide a basis for a device classification panel to make a different recommendation or different findings.

III. Public Comments in Response to the Proposed Order

In response to the September 15, 2014, proposed order to reclassify EPPG and PSA devices (79 FR 54927), FDA received two comments. FDA previously received three sets of comments on the October 17, 2011, proposed rule to reclassify EPPG devices that was

subsequently withdrawn (79 FR 54927). The Agency has considered all of these comments in drafting this final order.

The comments and FDA's responses to the comments are summarized in this section. Certain comments are grouped together under a single number because the subject matter of the comments is similar. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

(Comment 1) Four comments suggested that EPPG devices are life-sustaining and should be subject to premarket approval to provide better assurance of safety and effectiveness; as such, the comments asserted that EPPG devices should remain in class III. Further, one comment indicated that the proposed special controls are not sufficient to mitigate the risks associated with EPPG devices. Three other comments also discussed the risks associated with these devices and the need for adequate mitigation through premarket approval.

(Response 1) These comments were considered by FDA in drafting this final order. Per 21 CFR 860.3(c)(3), a device is in class III if two conditions are met: (1) Insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that application of special controls described in 21 CFR 860.3(c)(2) would provide such assurance, and (2) the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. FDA has concluded that for EPPG devices, special controls will provide reasonable assurance of safety and effectiveness to appropriately mitigate risks to health. Therefore, these life-supporting

devices can be reclassified into class II. As discussed in section II, the 2013 Panel agreed with FDA's recommendation of class II for EPPG and TCPSA devices.

EPPG devices are therapeutic devices designed to be used temporarily and in a controlled clinical setting. The expected presence of clinical support and physician monitoring mitigates many potential complications. Specifically, EPPG devices are used exclusively in hospital environments with the patients supervised by qualified medical personnel. The environment of care for EPPG devices includes resuscitation equipment, hospital level monitoring of heart rhythm, and patient vital status by other devices with alarm functions. The special controls require labeling for EPPG devices to "clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use." Further, the non-clinical performance testing and labeling special controls appropriately mitigate the risks for EPPG devices by helping to ensure adequate device performance/pacing, as well as proper maintenance of the device.

(Comment 2) Three comments referenced the number of medical device reports (MDRs) associated with EPPG devices and suggested that MDR data support keeping EPPG devices in class III. Two of those comments also discussed the number of MDR reports for malfunctions associated with EPPG devices and suggested that this shows the performance standards that have been developed and used to support EPPG marketing applications are insufficient to provide reasonable assurance of safety and effectiveness.

(Response 2) Increased premarket regulatory requirements cannot be assumed to result in fewer MDRs, nor are MDRs necessarily an indicator of poor device performance. FDA performed multiple analyses of MDRs for EPPG devices in the Manufacturer and User Facility Device Experience (MAUDE) database. The Agency's analysis of the available data shows that

over 85 percent of reports had either no patient involvement or no known consequences to the patient. These types of malfunction reports were generally discovered during routine servicing, which may be anticipated for reusable electrical devices. FDA's MDR analyses were conducted multiple times during the reclassification process and showed trends of increased reporting, but with an associated sharp decline in the relative number of death and injury reports over the last several years (i.e., the increased reporting was largely for device malfunctions). FDA believes these trends are indicative of tighter adherence to MDR requirements and a related change in reporting practices rather than a change in device performance. FDA's detailed review of MDRs for EPPG devices also did not suggest design or functional issues that would be decreased by requiring premarket approval for EPPG devices.

FDA also reviewed device recalls for EPPGs over the past 15 years and did not find evidence indicating the need for class III premarket approval regulation of these devices. FDA presented its analysis of MDR and recall data to the 2013 Panel that ultimately recommended reclassification of EPPG devices from class III to class II (special controls). The 2013 Panel identified no new or different risks for EPPG devices based on that information. Therefore, FDA believes that the identified special controls provide adequate mitigation of the health risks posed by the EPPG device.

(Comment 3) One comment suggested that EPPG devices remain in class III and require PMAs because FDA failed to identify new information on which to base the reclassification recommendation, specifically noting: (1) Performance standards developed in support of PMAs are not publicly available, and (2) FDA used information submitted in response to the 515(i) Order that was not publicly available in the Agency's analysis of risks to health for EPPG devices.

(Response 3) FDA's presentation to the 2013 Panel included a summary of the available safety and effectiveness information for EPPG devices, including FDA's analysis of adverse event reports from FDA's MAUDE database and available literature. The 2013 Panel agreed with FDA's conclusion that the available scientific evidence is adequate to support reasonable assurance of the safety and effectiveness of EPPG devices and to reclassify EPPG devices to class II. While the 2013 Panel agreed with the identified risks to health presented at the September 11, 2013, meeting, it recommended that FDA consider rewording some of the language for clarity and also to ensure that certain hazards, such as asynchronous pacing and arrhythmia induction, are included in the risks to health. FDA agreed with the 2013 Panel's recommendations and modified the risks to health accordingly as outlined in section V of the 2014 proposed order. The Agency identified in the proposed order special controls, including non-clinical performance testing data and labeling that, together with general controls (including prescription use), would provide reasonable assurance of the safety and effectiveness of EPPG devices. Since the 2013 Panel, FDA has not become aware of new information that would provide a basis for a different recommendation or finding for these devices.

Information submitted in response to the 2009 515(i) Order that FDA used in its reclassification determination was incorporated in what the Agency presented to the 2013 Panel (see Ref. 1). In addition, that information was listed in the September 15, 2014, proposed order and is publicly available through other sources. The information presented to the 2013 Panel and discussed in the 2014 proposed order also identified and provided information regarding the two recognized consensus standards that address various aspects of design and performance of EPPG devices (IEC 60601-1 and IEC 60601-2-31). The information provided by these consensus standards is particularly important as design control measures and aided in forming part of the

basis for FDA's reclassification determination. Therefore, the information that forms the basis for FDA's reclassification determination has been made publicly available.

(Comment 4) One comment suggested that PSA devices remain in class III because the special controls rely heavily on labeling to mitigate risks, and expressed doubt that labeling would be sufficient to protect the health of patients.

(Response 4) It should be noted that labeling is not the only mitigation that is proposed to reasonably assure safety and effectiveness of PSAs. Further, neither FDA nor the 2013 Panel believed that clinical performance testing was necessary to provide reasonable assurance of safety or effectiveness. The environment of care for PSAs is limited to the surgical implant suite, which must have backup pacing, defibrillation and resuscitation equipment, and capabilities including intensive care level monitoring of heart rhythm and patient vital signs. Therefore, FDA believes that the non-clinical performance testing and labeling special controls, in addition to general controls, can be established to mitigate the identified risks and provide reasonable assurance of the safety and effectiveness of PSA devices when indicated for use during the implant procedure of pacemakers and defibrillators for the evaluation of the placement and integrity of pacing leads to determine the appropriate pacing parameters for the implanted device. Furthermore, the 2013 Panel agreed that the special controls would mitigate the health risks associated with the PSA devices.

IV. The Final Order

Based on the information discussed in the preamble to the proposed order (79 FR 54927, September 15, 2014), the comments received, a review of the MAUDE database and recall data, a review of current scientific literature, and the 2013 Panel deliberations (see the 2013 Panel transcript (Ref. 1)), FDA concludes that special controls, in conjunction with general controls,

will provide reasonable assurance of the safety and effectiveness of EPPG and PSA devices. Under sections 513(e) and 513(f) of the FD&C Act, FDA is adopting its findings, as published in the preamble to the proposed order. FDA is issuing this final order to reclassify EPPG devices from class III to class II (special controls), as well as to create a separate classification regulation for PSA devices and reclassify PSA devices into class II (special controls). As noted in the proposed order, FDA is also making a slight modification to the identification for EPPG devices in § 870.3600 to clarify that these are prescription devices.

Following the effective date of this final order, firms marketing an EPPG or PSA device must comply with the applicable mitigation measures set forth in the codified special controls. Manufacturers of EPPG or PSA devices that have not been legally marketed prior to the effective date of this final order, or models (if any) that have been marketed but are required to submit a new 510(k) under 21 CFR 807.81(a)(3) because the device is about to be significantly changed or modified, must obtain 510(k) clearance and demonstrate compliance with the special controls included in this final order, before marketing the new or changed device.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of EPPG and PSA devices for their intended uses, and therefore, these device types are not exempt from premarket notification requirements.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does

not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously promulgated regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, pursuant to section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in § 870.3600 related to the classification of EPPG devices as class III devices, and codifying the reclassification of EPPG and PSA devices into class II (special controls).

VIII. Reference

The following reference is on display in the Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site address, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. The panel transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm>.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870--CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.3600 is revised to read as follows:

§ 870.3600 External pacemaker pulse generator.

(a) Identification. An external pacemaker pulse generator (EPPG) is a prescription device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction.

The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (-) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

3. In Subpart D, add § 870.3605 to read as follows:

§ 870.3605 Pacing system analyzer.

(a) Identification. A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

(4) Appropriate software verification, validation, and hazard analysis must be performed.

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the PSA. The markings should identify positive (+) and negative (-) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

- (iii) The labeling must list all pacing modes available in the device;
- (iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);
- (v) Labeling must limit the use of external pacing to the implant procedure; and
- (vi) Appropriate electromagnetic compatibility information must be included.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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