Meeting Notice: September 11-12, 2013 Circulatory System Devices Panel of the Medical Devices Advisory Committee

U.S. Food & Drug Administration

Hilton Washington DC North/Gaithersburg
Salons A, B, C, and D
620 Perry Pkwy.
Gaithersburg, MD 20877
301–977–8900

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11 and 12, 2013, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Montgomery Room, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3063, Jamie.Waterhouse@fda.hhs.gov [1], or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published

quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm [2] and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 11, 2013, during session I, the committee will discuss and make recommendations regarding the proposed classification of external cardiac compressor (ECC) devices, one of the remaining preamendments class III devices regulated under the section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) (510(k)) pathway. ECCs, also known as chest compressors, assist in the act of cardiopulmonary resuscitation (CPR). The devices in this classification are divided into two types: (1) Devices that provide automatic chest compressions at a fixed compression rate and depth (automated ECCs), which are placed directly on the patient's chest and are powered manually, pneumatically, or electrically and (2) devices that aid the emergency medical professional in delivering manual compressions at a compression depth and rate that are consistent with current guidelines (CPR Aids). These devices are placed beneath the hands of the emergency medical professional or in the vicinity of the cardiac arrest victim and provide audio and/or visual feedback to assist emergency personnel in following the recommended steps for CPR and maintaining the recommended rate and depth of compressions for the duration of CPR.

On January 8, 2013 (78 FR 1162), FDA issued a proposed order which, if made final, would make the class III ECC devices class II subject to special controls and, except as noted below, premarket notification (510(k)). The CPR aid device is proposed to be exempt from section 510(k) of the FD&C Act if it is a prescription use device that provides feedback to the rescuer consistent with the current American Heart Association guidelines for CPR and in compliance with the special controls, subject to the limitations of exemptions in 21 CFR 870.9. The regulatory history of ECC devices has been discussed as part of the proposed rule (77 FR 36951, June 20, 2012).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application (PMA)) or reclassify to class I or class II. The committee will further be asked to comment on whether general and/or special controls are adequate to assure the safety and effectiveness of the device and whether, if reclassified to class II, these devices should be exempt from premarket notification requirements.

On September 11, 2013, during session II, the committee will discuss and make recommendations regarding classification of external pacemaker pulse generators (EPPGs), one of the remaining preamendments class III devices regulated under the 510(k) pathway. An EPPG is a 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.

On October 17, 2011 (76 FR 64224), FDA issued a proposed rule which, if made final, would make the class III external pacemaker pulse generator devices class II subject to premarket notification (510(k)) and special controls. The regulatory history of external pacemaker pulse generator devices has been discussed as part of the proposed rule (77 FR 36951).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA) or reclassify to class II and comment on whether special controls are adequate to assure the safety and effectiveness of this device.

Also during session II, FDA will be seeking feedback from the committee regarding classification of triple chamber pacing system analyzers (PSAs) with external pacing capability, a postamendments device classified through the premarket approval process as class III. A triple chamber PSA is intended to be used during the implant procedure of pacemakers and defibrillators, including biventricular devices, to evaluate the placement and integrity of pacing leads for determination of appropriate pacing parameters for the implanted device. The device provides pacing and sensing in up to three chambers during the implant procedure. The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA) or reclassify to class II and comment on whether special controls are adequate to assure the safety and effectiveness of this device.

On September 12, 2013, the committee will discuss and make recommendations regarding the proposed classification of membrane lung for long-term pulmonary support systems, one of the remaining preamendments class III devices regulated under the 510(k) pathway. A membrane lung for long-term pulmonary support refers to the oxygenator component of an extracorporeal circuit used during long-term procedures, commonly referred to as an ECMO. An ECMO procedure provides assisted extracorporeal circulation and physiologic gas exchange of a patient's blood when an acute (reversible) condition prevents the patient's own body from providing the physiologic gas exchange needed to sustain life. The circuit is comprised of multiple device types, including, but not limited to, an oxygenator, blood pump, cannulae, heat exchanger, tubing, filters, monitors/detectors, and other accessories; the circuit components and configuration (e.g., arteriovenous, veno-venous) may differ based on the needs of the individual patient or the condition being treated. ECMO is intended for patients with acute reversible respiratory or cardiac failure, unresponsive to optimal ventilation and/or pharmacologic management.

On January 8, 2013 (78 FR 1158), FDA issued a proposed order which, if made final, would make the class III ECMO devices class II subject to premarket notification (510(k)) and special controls. The regulatory history of ECMO devices has been discussed as part of the proposed rule (78 FR 1158).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA) or reclassify to class II and comment on whether special controls are adequate to assure the safety and effectiveness of this device.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm [3][2]. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 28, 2013. On September 11, 2013, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. On September 12, 2013, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 20, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 22, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at Annmarie.Williams@fda.hhs.gov [4] or 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm [5] for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

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[1] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:Jamie.Waterhouse@fda.hhs.gov
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