4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Orthopaedic and Rehabilitation 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: Orthopaedic and Rehabilitation 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 December 12, 2013, from 8 a.m. to 6:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993, Sara.Anderson@fda.hhs.gov, 301 796-7047; 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 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 December 12, 2013, during Session I, the committee will discuss and make recommendations regarding the classification of spinal sphere devices. These devices are spheres manufactured from metallic (e.g., cobalt chromium molybdenum) or polymeric (e.g., polyetheretherketone) materials. They are intended to be inserted between the vertebral bodies into the disc space from L3-S1 to help provide stabilization and to help promote intervertebral body fusion. During the arthrodesis procedure, they are to be used with bone graft. These devices are not intended for use in motion-sparing, non-fusion procedures.

Spinal sphere devices are considered preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Spinal sphere devices are currently regulated under the heading of "Intervertebral Fusion Device with Bone Graft, Solid-Sphere, Lumbar", Product Code NVR, as unclassified devices and reviewed under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness of spinal sphere devices and the regulatory classification for spinal sphere devices.

On December 12, 2013, during Session II, the committee will discuss and make recommendations regarding the reclassification petition received on November 20, 2012, from DEKA Research & Development Corp. requesting that FDA reclassify stair climbing wheelchairs (21 CFR 890.3890) from Class III to Class II. A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted

to a sitting position. The device is intended to climb stairs. On June 12, 2013 (78 FR 35173), FDA issued a proposed order which, if made final, would reclassify stair-climbing wheelchairs as Class II subject to premarket notification (510(k)) and special controls. The petitioner has one stair-climbing wheelchair approved, the iBot (P020033), and it is indicated for the following: to provide indoor and outdoor mobility in confined spaces, at an elevated height, climb curbs, ascend/descend stairs, traverse obstacles, travel over a wider variety of terrain, and negotiate uneven/inclined surfaces.

Stair-climbing wheelchairs are preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Stair-climbing wheelchairs are currently regulated as Class III devices. A call for premarket approval (PMA) applications was issued on April 13, 2000 (effective July 12, 2000) (65 FR 19834).

The committee's discussion will include recommendations regarding the regulatory classifications noted above. The committee will also discuss whether the proposed special controls are adequate to reasonably ensure the safety and effectiveness of stair-climbing wheelchairs.

On December 12, 2013, during Session III, the committee will discuss and make recommendations regarding the possible reclassification of mechanical wheelchairs (21 CFR 890.3850) from Class I, currently subject to premarket notification (510(k)), to Class II, subject to special controls. The mechanical wheelchairs are being considered for exemption from premarket notification (510(k)) requirements. A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted

to a sitting position. No proposed order has been issued for this proposed change in classification.

Mechanical wheelchairs are preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Mechanical wheelchairs are currently regulated as Class I devices that are subject to premarket notification (510(k)) requirements (48 FR 53041).

The committee will discuss whether general and/or special controls are appropriate to demonstrate a reasonable assurance of safety and effectiveness of mechanical wheelchairs and whether, if reclassified to Class II, these devices should be exempt from premarket notification (510(k)) requirements.

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/Calendar/default.htm. 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 November 21, 2013. Oral presentations will be scheduled between approximately 9:15 a.m. and 9:35 a.m. for Session I and between approximately 2:40 p.m. and 3:20 p.m. for Session II and Session III. 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 the proposed participants, and an indication of the approximate time requested to make their presentation on or before November 13, 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 November 14, 2013.

Persons attending FDAs 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 James Clark, James.Clark@fda.hhs.gov or 301-796-5293, 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 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).

Dated: November 4, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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