4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

# Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the Federal Register of November 23, 2015. The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm.1643, 10903 New Hampshire Ave., 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). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 23, 2015, 80 FR 72971, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee would be held on February 19, 2016. On page 72972, in the first column, the Agenda portion of the document is changed to read as follows:

The Committee will discuss, make recommendations, and vote on information regarding the premarket application (PMA) for the DIAM Spinal Stabilization System, sponsored by Medtronic Sofamor Danek USA. The DIAM Spinal Stabilization System is indicated for skeletally mature patients that have moderate low back pain (with or without radicular pain) with current episode lasting less than 1 year in duration secondary to lumbar degenerative disc disease (DDD) at a single symptomatic level from L2-L5. DDD is confirmed radiologically with one or more of the following factors: (1) Patients must have greater than 2 mm of decreased disc height compared to the adjacent level; (2) scarring/thickening of the ligamentum flavum, annulus fibrosis, or facet joint capsule; or (3) herniated nucleus pulposus. The DIAM device is implanted via a minimally invasive posterior approach.

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.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-33262 Filed: 1/5/2016 8:45 am; Publication Date: 1/6/2016]