



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0293]

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 July 24 and 25, 2013, from 8 a.m. to 6 p.m.

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

Contact Person: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, 301-796-7047, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 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 July 24, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Kineflex/C Cervical Artificial Disc sponsored by SpinalMotion. The Kineflex/C is a metal-on-metal (cobalt chrome molybdenum alloy) cervical total disc replacement device. The Kineflex/C is indicated for reconstruction of the intervertebral disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy or myelopathy due to a single-level abnormality localized to the disc space.

On July 25, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Kineflex Lumbar Artificial Disc sponsored by SpinalMotion. The Kineflex Lumbar Artificial Disc is a metal-on-metal (cobalt chrome molybdenum alloy) lumbar total disc replacement device. The Kineflex Lumbar Artificial Disc is indicated for reconstruction of the intervertebral disc at one level (L4-L5 or L5-S1) following single-level discectomy for lumbar degenerative disc disease (DDD) where DDD is defined as discogenic back pain with degeneration of the disc as confirmed by patient history, physical examination, and radiographic studies.

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 July 15, 2013. Oral presentations from the public will be scheduled on July 24 and 25, 2013, between approximately 11:30 a.m. and 12:30 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 July 5, 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 July 8, 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 at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov) 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> 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: April 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.