

be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2013-09797 Filed 4-24-13; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0642]

#### Assay Migration Studies for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Assay Migration Studies for In Vitro Diagnostic Devices.” This guidance presents a least burdensome regulatory approach to gain FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a new system for which the assay has not been previously approved, licensed, or cleared.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled “Assay Migration Studies for In Vitro Diagnostic Devices” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. Alternatively, you may submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for

information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Sally Hojvat, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5524, Silver Spring, MD 20993-002, 301-796-5455.

For further information concerning the study designs in the guidance:

Marina V. Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5666, Silver Spring, MD 20993-002, 301-796-6036.

For further information concerning the guidance as it relates to devices regulated by CBER:

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry and FDA staff entitled “Assay Migration Studies for In Vitro Diagnostic Devices.” This guidance presents a least burdensome regulatory approach to gain FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a new system for which the assay has not been previously approved or licensed. The approach in this guidance is also applicable for some 510(k) cleared devices for which transition to a new system presents specific concerns, either because of the nature of the analyte and indications, or because of the specific technology used (e.g., nucleic acid amplification tests). The focus of this guidance is on the study designs and performance criteria that should be fulfilled in order for a sponsor to utilize the migration study approach in support of the change. The FDA believes that the assay migration study paradigm discussed in this guidance provides a least burdensome scientific and regulatory pathway for manufacturers to transfer a previously approved or licensed assay with full

clinical data from an old system to a new system (previously not approved or licensed). The paradigm is suitable in cases when sufficient knowledge can be derived from the documentation of design controls, risk analyses, and prior performance studies on an old system.

The draft of this guidance was issued on January 5, 2009 (74 FR 302). The comment period closed on April 6, 2009. Three sets of comments were received and reviewed by FDA. The guidance was updated to address comments where appropriate. The updated guidance contains additional examples and explanations and supersedes the draft guidance “Assay Migration Studies for In Vitro Diagnostic Devices” issued on January 5, 2009.

##### II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on “migration studies” for in vitro diagnostic device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive “Assay Migration Studies for In Vitro Diagnostic Devices,” you may either send an email request to [ds mica@fda.hhs.gov](mailto:ds mica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1660 to identify the guidance you are requesting. Guidance documents are also available on the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

##### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 807 subpart E have been approved under OMB control number 0910-0120; 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 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

## V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 19, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-09759 Filed 4-24-13; 8:45 am]

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## 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.*

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