Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0258]

Molecular Diagnostic Instruments With Combined Functions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Molecular Diagnostic Instruments with Combined Functions.'' This draft guidance document provides industry and Agency staff with FDA's current thinking on regulation of molecular diagnostic instruments that have both device functions and non-device functions, and on the type of information that FDA recommends that applicants include in a submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 8, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Molecular Diagnostic Instruments with Combined Functions'' to the Division of Small Manufacturers, International, and Consumer Assistance,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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm.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: Andrew Grove, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5515, Silver Spring, MD 20993–0002, 301–796–6198; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, RKWL Bldg., suite 601, 11400 Rockville Pike, Rockville, MD 20852, 1–800–835–4709.

SUPPLEMENTARY INFORMATION:

I. Background

Molecular diagnostic instruments, for example, real-time thermocyclers, are critical components of certain in vitro diagnostic devices. They are often used to perform multiple unrelated assays, such as those that detect methicillin-resistant *Staphylococcus aureus,* Hepatitis C virus, and genetic markers of cystic fibrosis. These types of instruments cannot generally be approved alone, *i.e.,* without an accompanying assay, because their safety and effectiveness cannot be evaluated without reference to the assays that they run and their defined performance parameters. However, the same instruments may also be used for additional purposes that do not require FDA approval or clearance, such as for basic scientific research. In the past, FDA has provided informal advice in response to individual inquiries regarding the permissibility of having such non-device functions on an instrument intended to be used with approved in vitro diagnostic assays. This draft guidance is meant to communicate FDA's policy regarding molecular diagnostic instruments with combined functions.

This draft guidance applies to molecular diagnostic instruments that are medical devices used with assays that measure or characterize nucleic acid analytes, human or microbial, and that combine both approved and non-approved functions in a single instrument. This draft guidance applies to the instrument itself (hardware) as well as to any firmware or software intended to operate on or to control the instrument. This draft guidance also addresses software that is distributed as a stand alone device for use with an approved molecular diagnostic assay.

The draft guidance does not apply to instruments approved for use with assays that are intended to screen donors of blood and blood components, human cells, tissues, and cellular and tissue-based products for communicable diseases.

The recommendations in this draft guidance are not intended to imply that assays/reagents that have not received FDA marketing authorization may be marketed by an instrument manufacturer for clinical use on a molecular diagnostic instrument with combined approved and non-approved functions. They are also not intended to change FDA's position regarding the marketing of Research Use Only and Investigational Use Only assays for clinical use.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on molecular diagnostic instruments with combined functions. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health 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 ''Molecular Diagnostic Instruments with Combined Functions,'' you may either send an email request to *dsmica@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 1763 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

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 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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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 May 21, 2013, from 8 a.m. to 5 p.m. and on May 22, 2013, from 8 a.m. to 4 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301–948–8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, *Jamie.Waterhouse@fda.hhs.gov*, 301–796–3063, 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 May 21, 2013, the committee will discuss and make recommendations regarding the classification of one of the remaining preamendments class III devices, shortwave diathermy for all other uses except for the treatment of malignancies. The class III shortwave diathermy is a device that applies electromagnetic energy to the body in a radiofrequency band ranging between 13 megahertz to 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues.

On July 6, 2012 (77 FR 39953), FDA issued a proposed rule which, if made final, would make shortwave diathermy devices for all other uses class III requiring premarket approval (PMA) applications. In response to the proposed rule calling for PMAs, FDA received petitions under section 515(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(b)(2)(B)) requesting a change in classification. The reclassification petitions are available for public review and comment at *www.regulations.gov* under docket number FDA–2012–N–0378. The prior regulatory history of shortwave diathermy for all other uses has been discussed as part of the proposed rule (77 FR 39953).

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 I or class II (subject to premarket notification (510(k))), as directed by section 515(i) of the FD&C Act.

On May 22, 2013, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 (Docket No. FDA–2009–M–0101), for one of the remaining preamendments class III devices, pedicle screw spinal systems, intended to treat degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1, or degenerative spondylolisthesis with objective evidence of neurologic impairment. Pedicle screw spinal systems are posterior spinal screw and rod systems intended as an adjunct to fusion for the treatment of degenerative disc disease, trauma, deformity, failed previous fusion, tumor, infection, and inflammatory disorders in the thoracolumbar spine.

On July 27, 1998 (63 FR 40025), FDA published a final rule classifying certain previously unclassified preamendments pedicle screw spinal systems and reclassifying certain postamendments pedicle screw spinal systems. On May 22, 2001 (66 FR 28051), FDA published a technical amendment to the final rule to include an intended use that was inadvertently omitted from the codified language in the rule. As described in the summary of revisions in the technical amendment, FDA changed the intended uses for which pedicle screw spinal systems are class III from ''all other uses,'' to ''when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.'' Since the technical amendment, FDA has not established an effective date for the submission of PMAs for pedicle screw spinal systems with these class III indications for use; consequently, these systems have been subject to 510(k).

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 I or class II (subject to 510(k)), as directed by section 515(i) of the FD&C Act.

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.