amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 10, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–20050 Filed 8–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0967]

Intent To Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices From Premarket Notification Requirements; 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 a guidance entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements,'' which updates an earlier guidance of the same title published in the **Federal Register** on July 1, 2015. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices from premarket notification requirements. Due to an administrative error, certain comments to this Docket were not considered prior to the July 1, 2015, guidance publication. These comments have now been considered. FDA believes additional devices and product codes are sufficiently well understood and do not require premarket notification to assure their safety and effectiveness. As such, FDA is updating and adding these to the guidance.

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: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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: Angela C. Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380.

SUPPLEMENTARY INFORMATION:

I. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA committed to identifying low-risk medical devices to exempt from premarket notification requirements. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices (that no longer meet the ''reserved'' criteria in section 510(*l*) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(*l*))) from premarket notification requirements. FDA believes the devices and product codes being added to this guidance document are sufficiently well understood and do not require 510(k) notification to assure their safety and effectiveness.

The draft of this guidance was made available in the **Federal Register** on August 1, 2014 (79 FR 44804). The comment period closed on September 30, 2014. FDA received 55 sets of comments on the draft guidance. FDA published a final guidance on July 1, 2015 (80 FR 37633). However, due to an administrative error, certain comments were not considered prior to the July 1, 2015, guidance publication. These comments have now been considered, and, based on that review, FDA is updating and adding certain devices and product codes to the guidance.

These comments requested that FDA include approximately 390 additional product codes in the guidance. Of these product codes, more than 110 were ones regulated by the Office of In Vitro Diagnostics and Radiological Health, which were outside of the scope of FDA's review to identify low-risk devices to ultimately exempt from premarket notification requirements. Additionally, for approximately 75 of the product codes, the comments noted that additional controls, such as conformance to recognized standards, would be necessary if 510(k)s were not submitted for these devices. Because the imposition of such controls would go beyond the scope of this guidance, FDA is not adding these device types and product codes to the guidance.

The comments also requested the addition of 18 product codes to the guidance that were either already in the final guidance published on July 1, 2015, exempt from premarket notification, or for which FDA is currently exercising enforcement discretion (Ref. 1). For example, more than 30 comments spoke to the inclusion of product code NUQ (Pad, Menstrual, Reusable), which was included in the draft guidance document, and remained in the final guidance document issued July 1, 2015.

FDA has considered the remaining product codes proposed in the comments and has determined that the following eight additional product codes should be included in the guidance document: Product code DTL, Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (see 21 CFR 870.4290—Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting); product code OCY, Endoscopic Guidewire, Gastroenterology-urology (see 21 CFR 876.1500—Endoscope and accessories); product code KOE, Dilator, urethral (see 21 CFR 876.5520—Urethral dilator); product code FTA, Light, Surgical, Accessories (see 21 CFR 878.4580—Surgical lamp); product code GZM, Analyzer, Rigidity (see 21 CFR 882.1020—Rigidity analyzer); product code GZO, Device, Galvanic Skin Response Measurement (see 21 CFR 882.1540—Galvanic skin response measurement device); product code HCJ, Device, Skin Potential Measurement (see 21 CFR 882.1560—Skin potential measurement device);

and product code HLJ, Ophthalmoscope, Battery-powered (see 21 CFR 886.1570—Ophthalmoscope). FDA has determined it is appropriate to add these product codes to the guidance because FDA has tentatively concluded they are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness.

Seven comments also requested the removal or clarification of specific product codes in the draft guidance. The issues raised in these comments were addressed by the removal of certain product codes from the draft guidance, and the clarification of two product codes: Product code MRQ, Analyzer, Nitrogen Dioxide; and product code KKX, Drape, Surgical. Moreover, in response to the issues raised, FDA is clarifying that it is not the Agency's intent to exempt combination products or single entity products containing antimicrobial agents. For the remaining product codes identified in those comments, FDA believes that the product codes are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness. Thus, FDA has not removed these products codes from the guidance.

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 current thinking of FDA on the intent to exempt certain unclassified, class II, and class I reserved medical devices from premarket notification requirements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it 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 downloading an electronic copy from 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.* Persons unable to download an electronic copy of ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1300046 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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.

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.*

VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA announced that it would exercise enforcement discretion for premarket notification for the following product codes, among others, if the devices meet the criteria set forth in guidance: OFX, OKF, OKG, OKH, OKI, LRO, and OJW. See Convenience Kits Interim Regulatory Guidance (May 1997), available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080217.pdf.*

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20005 Filed 8–13–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2711]

Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two-day public workshop entitled, ''Neurodiagnostics and Non-Invasive Brain Stimulation Medical Devices Workshop''. The focus of the first day of the workshop will be cognitive assessment medical devices, which are intended to provide healthcare professionals with an evaluation of cognitive function through non-invasive measurements. The focus of the second day of the workshop will be non-invasive brain stimulation medical devices, which are medical devices that are intended to improve, affect, or otherwise modify the cognitive function of a normal individual (*i.e.,* without a treatment objective) by means of non-invasive electrical or electromagnetic stimulation to the head. The purpose of this workshop is to obtain public input and feedback on scientific, clinical, and regulatory considerations associated with medical devices for assessing and influencing cognitive function. Ideas generated during this workshop may facilitate further development of guidance regarding the content of premarket submissions for neurodiagnostics and non-invasive brain stimulation medical devices and help to speed development and approval of future submissions.

Dates and Times: The public workshop will be held on November 19 and 20, 2015, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*