device(s) could be classified according to the risk posed to patient safety by the new intended use, for example, if the intended use of a mobile medical app is to provide prognosis relating to a certain disease or condition and the mobile medical app is connected to a device that does not have that intended use, the mobile medical app may have a different level of risk than the connected device, resulting in a different classification to assure of safety and effectiveness of the mobile medical app.

2. FDA has not addressed in this guidance stand-alone software (mobile or traditional workstation) that analyzes, processes, or interprets medical device data (collected electronically or through manual entry of the device data) for purposes of automatically assessing patient specific data or for providing support in making clinical decisions. FDA plans to address such stand-alone software in a separate guidance. In order to provide a reasonable assurance of the safety and effectiveness of such software, and to ensure consistency between this guidance and the planned guidance on stand-alone software that provides clinical decision support (CDS), FDA is seeking comments on the following issues:

- What factors should FDA consider in determining the risk classification of different types of software that provide CDS functionality? Please provide examples of how those factors would be applied for such software that you believe should be in class I, class II, and class III.
- How should FDA assess stand-alone software that provides CDS functionality, to assure reasonable safety and effectiveness? For example, to what extent can FDA rely on a manufacturer's demonstration that it has a robust quality system with appropriate quality assurance and design controls? Under what circumstances should the submission of clinical data be required?
- Are there specific controls that manufacturers should implement that could change the risk classification or reduce the premarket data requirements for particular types of stand-alone software that provide CDS functionality?

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on mobile medical applications. 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 CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at either *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''Mobile Medical Applications'' from CDRH, you may either send an e-mail 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 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485; the collection of information in 21 CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 806 are approved under OMB control number 0910–0359; the collections of information in 21 CFR part 807, subpart B, are approved under OMB control number 0910–0387; the collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: July 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–18537 Filed 7–19–11; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0149] (Formerly 2007D–0309)

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' The special controls identify the following risks to health associated with electrocardiograph electrodes: Adverse tissue reaction to the skin-contacting electrode materials and misdiagnosis. The guidance document provides information on how to mitigate these risks and recommends testing and labeling for these devices. This guidance document describes a means by which electrocardiograph electrodes may comply with the requirement of special controls for class II devices.

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 ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' 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 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: Sharon Lappalainen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1238, Silver Spring, MD 20993–0002, 301–796–6322.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance describes a means by which electrocardiograph electrodes may comply with the requirement of special controls for class II devices. In the **Federal Register** of October 4, 2007 (72 FR 56771), and Docket No. FDA–2007D–0309, FDA proposed to classify electrocardiograph electrodes, intended to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram, into class II. FDA also proposed to exempt this device from premarket notification requirements and issued a draft guidance document to describe the special control requirements. FDA invited interested persons to comment on the proposed regulation and the draft guidance document by January 8, 2008. FDA received seven comments on the proposed rule. These comments addressed issues pertaining to labeling, the scope of the devices subject to the classification rule, and testing. In response, FDA has revised the labeling section of the guidance, has clarified the scope of the guidance, and has clarified the information regarding testing for shelf life. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify electrocardiograph electrodes into class II (special controls) and to exempt the device from 510(k) premarket notification procedures.

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of electrocardiograph electrodes classified under § 870.2360 (21 CFR 870.2360). In order to be classified as a class II device under § 870.2360, an electrocardiograph electrode must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

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 ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes,'' you may either send an e-mail 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 paper copy. Please use the document number (#1597) to identify the guidance you are requesting.

IV. Paperwork Reduction Act

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; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: July 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0495]

Unique Device Identification for Postmarket Surveillance and Enforcement; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on the adoption, implementation, and use of unique device identifiers (UDIs) in various health-related electronic data systems. The purpose of this workshop is to engage multiple stakeholders to obtain information and comments on issues confronting the effective and efficient incorporation of UDIs into appropriate data sets, to identify barriers and incentives to their adoption and use, and to understand the best solutions and practices to resolve open issues.

Dates and Times: The public workshop will be held on September 12, 2011, from 1 to 5 p.m. and on September 13, 2011, from 9 a.m. to 5 p.m. Submit electronic and written comments by October 13, 2011.

Location: The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852; 301–822–9200.

Contact Person: Jay Crowley, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–980–1936, e-mail: *jay.crowley@fda.hhs.gov*

Registration: Registration is free and will be on a first-come, first-served basis. To register for the public workshop—whether attending in person or for the Web cast—please visit *http://www.fda.gov/UDI* (or go the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please contact Jay Crowley (see Contact Person) to register. Registration requests should be received by 5 p.m. on September 5, 2011. Early registration is recommended because seating is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the