DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0421]

Medical Devices; Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA.'' Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls). If the device is reclassified, FDA intends that this guidance document will serve as the special control. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by March 13, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA,'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (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. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ- 450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls). This draft guidance document describes a means by which arrhythmia detector and alarm (including ST-segment measurement and alarm) devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate arrhythmia detector and alarm (including ST-segment measurement and alarm) device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft 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 special controls for the arrhythmia detector and alarm. 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

In order to receive ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1363) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of the draft guidance from the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at http://www.fda.gov/cdrh. You may search for all CDRH guidance documents at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Brach Internet site at http://fda/gov/ohrms/dockets.

IV. Comments

Interested persons may submit to Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this draft guidance by (see **DATES**). Two copies of any comment are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 23, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0577]

Medical Devices; Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide and Oxygen Monitors; 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: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA.'' This guidance document describes a means by which $PcCO_2$ monitors and the PcO_2 monitor may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the $PcCO_2$ monitor from class II (performance standards) into class II (special controls), the PcO_2 monitor for an infant