II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: October 6, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27119 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0077]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 008; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 28, 2003 (68 FR 22391). The document announced a publication entitled ''FDA Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 008.'' The publication contains modifications the agency is making to the list of standards FDA recognizes for use in the premarket reviews. The document was published with inadvertent errors. This document corrects those errors and provides clarification.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 156.

SUPPLEMENTARY INFORMATION: FDA also intended to note that it is limiting its recognition of standards 31 and 32 to the use of 25 symbols for labeling of in vitro diagnostic (IVD) devices used by professional IVD users. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of a draft guidance document concerning the use of these symbols in labeling of IVDs.

In FR Doc. 03–10417, appearing on page 22391 in the **Federal Register** of Monday, April 28, 2003, the following corrections are made:

1. On page 22398, under ''*B. General*'', correct the table to read:

Item No.	Title of Standard	Reference No. and Date
30	Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatability—Requirements and Tests	ANSI/AAMI/IEC 60601–1–2:2001
31	Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied	ISO 15223:2000
32	Graphical Symbols for Use in the Labeling of Medical Devices	EN 980:1996+A1:1999+A2:2001

2. On page 22399, in the first table, the entries for item nos. 30, 31, and 32 are removed.

Dated: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27118 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0421]

Guidance for Industry and FDA Staff on 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 guidance document entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.'' This guidance document describes a means by which arrhythmia detector and alarm devices 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 to reclassify these devices from class III into class II (special controls).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, CDRH (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext 177.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 13, 2002 (67 FR 76749), FDA announced the availability of a draft of this guidance document and invited interested persons to comment on it by