

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D-0306]

Guidance for Industry and FDA Staff; Class II Special Controls Guidance

Document: Dental Sonography and Jaw Tracking Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

Display Date 12-1-03

Publication Date 12-2-03

Certifier A. Corbin

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices." This guidance document describes a means by which certain dental sonography and jaw tracking 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 classify certain types of these devices into class II (special controls).

DATES: Submit written or electronic 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 on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices" 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.

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See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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.

FOR FURTHER INFORMATION CONTACT: Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850301-827-5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 14, 2002 (67 FR 52901), FDA published a proposed rule to classify certain dental sonography and jaw tracking devices into class II. In the **Federal Register** of August 14, 2002 (67 FR 53005), FDA also identified the document “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers” as the special control, which in conjunction with general controls, is capable of providing reasonable assurance of safety and effectiveness for these devices. This guidance document describes a means by which certain dental sonography and jaw tracking devices may comply with the requirement of special controls for class II devices.

Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for the class II devices described in that final rule will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the

recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Interested persons were invited to comment on the draft guidance by November 12, 2002. FDA received no comments on the draft guidance document. FDA made minor revisions to the guidance to improve clarity and provide more detailed descriptions of our recommendations for electromagnetic compatibility testing and labeling.

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 agency's current thinking on dental sonography and jaw tracking devices. 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 statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/>

ecomments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified 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.

V. Electronic Access

To receive “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices” by 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 (1393) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. 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 manufacturer’s addresses), small manufacturer’s assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: 10/23/03
October 23, 2003.

Linda S. Kahan

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