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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0113]

Medical Devices; Draft Guidance for Industry and FDA on Class II Special Controls: Root-Form Endosseous Dental Implants and Abutments; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA." This draft guidance document was developed as a special control guidance to support the reclassification of the root-form endosseous dental implant device from class III to class II and the reclassification of the endosseous dental implant abutment device from class III to class II. Elsewhere in this issue of the FEDERAL REGISTER, FDA is issuing a proposed rule to reclassify these device types. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by [insert date 90 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health,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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Angela E. Blackwell,
Center for Devices and Radiological Health (HFZ-480),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-443-8879.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document describes a means by which the root-form endosseous dental implant device and the endosseous dental implant abutment device may comply with the requirement of special controls for class II devices. A root-form endosseous dental implant device is intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. An endosseous dental implant abutment device is a separate component that is attached to the implant and is intended to aid in prosthetic rehabilitation.

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 root-form endosseous dental implant and endosseous dental implant abutment 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. Electronic Access

In order to receive the draft guidance entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; 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 (1389) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

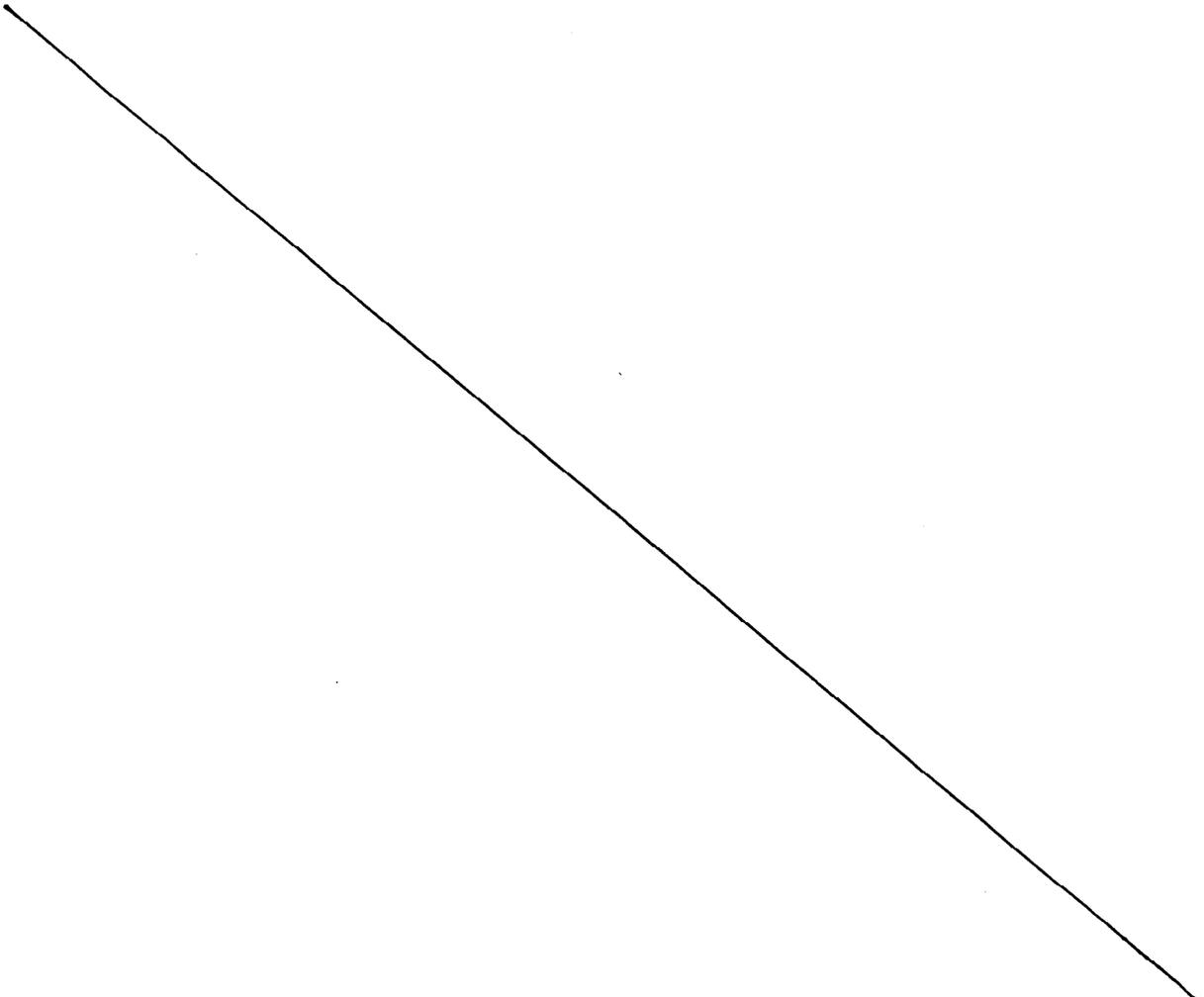
Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents

are also available at

<http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments on the draft guidance by [insert date 90 days after date of publication in the FEDERAL REGISTER]. Two copies of any comments 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 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: 4/23/02
April 23, 2002.



Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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