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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 02D-0439]

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Certifier A. Corbin

**Medical Devices; Class II Special Controls Guidance Document:  
Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry  
and FDA; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA." This document describes a means by which transcutaneous air conduction hearing aid systems (TACHAS) 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 classifying TACHAS into class II (special controls).

**DATES:** Submit written or electronic comments on this 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 guidance document entitled "Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; 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. Comments should be identified 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:** Eric M. Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The TACHAS is intended to compensate for impaired hearing without occluding the ear canal. It consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through the soft tissues between the post auricular region and the outer ear canal. This special control guidance document lists the risks to health identified by FDA and describes measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying TACHAS into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the TACHAS device. Section 513(f)(2) of the act provides that any person who submits a

premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115). The guidance represents the agency's current thinking on TACHAS. 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. This guidance document is issued as a level 1 guidance consistent with GGPs.

### III. Electronic Access

In order to receive the "Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; 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 (1414) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of the 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 Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

### IV. Comments

Interested persons may submit to Dockets Management Branch (see **ADDRESSES**) written comments regarding this immediately in effect guidance by (see **DATES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Identify comments with the docket number

found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/28/02  
October 28, 2002.

*Linda S. Kahan*

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

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COPY OF THE ORIGINAL**

*[Signature]*