

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0311]

DMB

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Certifier D. Hawkins

Medical Devices: Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Final Guidance for Industry Availability

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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: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA." This document describes a means by which the endolymphatic shunt tube with valve 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 endolymphatic shunt tubes with valve into class II (special controls).

DATES: Submit written or electronic comments on the 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: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA" 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 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 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 information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Eric 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

In the **Federal Register** of August 15, 2001 (66 FR 42809), FDA published a proposed rule to reclassify the endolymphatic shunt tube with valve from class III (premarket approval) into class II (special controls) based on new information regarding this device. E. Benson Hood Laboratories, Inc. (Hood Laboratories), submitted the new information in a reclassification petition. FDA also identified the document “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Draft Guidance for Industry and FDA” as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by November 13, 2001. FDA received one comment. The comment, from the petitioner, Hood Laboratories, strongly supported the draft guidance as the proposed special control.

FDA has since revised the draft guidance to provide to manufacturers the option of submitting an abbreviated 510(k) to further reduce regulatory burden.

II. Significance of Guidance

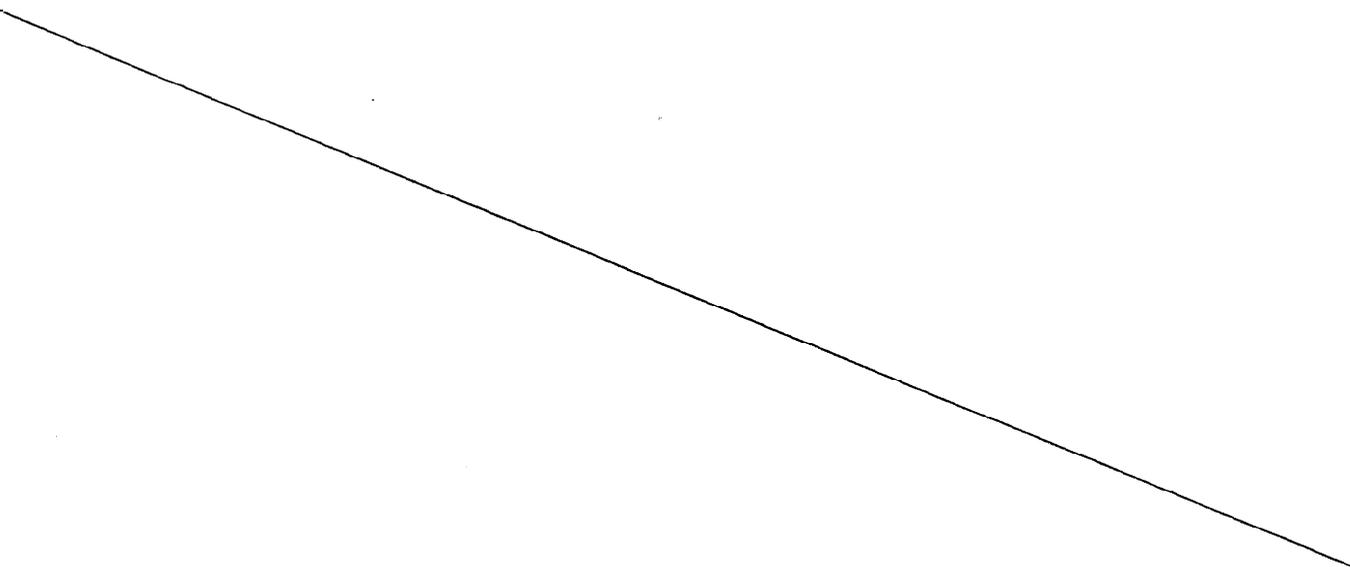
This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on “Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA.” It does not create or confer 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

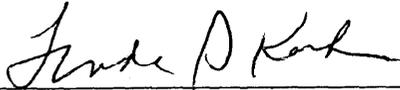
In order to receive the document "Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMICA Facts, at second voice prompt press 2, and then enter the document number (791) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains a home page at <http://www.fda.gov/cdrh> on the Internet for easy access to information that may be downloaded 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 medical device oriented information. The CDRH home page also includes the document "Class II Special Controls Guidance Document: Endolymphatic Shunt



Tube with Valve; Guidance for Industry and FDA” which may be accessed at <http://www.fda.gov/cdrh/ode/guidance/791.html>. A search capability for all guidance documents may be found 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>.

Dated: 4/15/02
April 15, 2002.



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

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