

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 02D-0011]

### **Medical Devices: Draft Guidance on Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA; Availability**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA.” This draft guidance document was developed as a special control to support the classification of intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea into class II and to provide guidance to manufacturers attempting to establish that their intraoral devices for snoring and obstructive sleep apnea are substantially equivalent to a predicate device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify these devices. This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments concerning this draft guidance by [*insert date 90 days after date of publication in the **Federal Register***].

**ADDRESSES:** Submit written requests for single copies on a 3.5” diskette of the draft guidance document entitled “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA” to the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health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 adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Susan Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance entitled “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA.” Intraoral devices to treat snoring are removable medical devices that are fitted in the patient’s mouth to reduce or eliminate snoring. In some cases the devices may also be used to treat obstructive sleep apnea. Currently, intraoral devices for snoring and/or sleep apnea are unclassified. FDA is proposing to classify these devices into class II. FDA intends that the draft guidance document, if finalized, will serve as the special control for intraoral devices for snoring and/or obstructive sleep apnea. The draft guidance document offers recommendations to the regulated industry and FDA staff about the content and format of a premarket notification submission (510(k)) for such devices in order to establish safety and effectiveness. The draft guidance document is intended to facilitate the assembly of necessary data, maintain consistency of reviews, and provide for a more efficient regulatory process.

## II. Significance of Guidance

The draft guidance represents the agency's current thinking on intraoral devices for snoring and obstructive sleep apnea. 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 applicable statutes and regulations.

The draft guidance document is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

## III. Electronic Access

In order to receive "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; 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 1378 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 on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets/default.htm>.

#### **IV. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the draft guidance by [*insert date 90 days after date of publication in the **Federal Register***]. Submit two copies of any comments, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 28, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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