

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

DMB

Display Date 11-8-02  
Publication Date 11-12-02  
Certifier N. Hawkins

[Docket No. 02N-0010]

**Dental Devices; Classification for Intraoral Devices for Snoring and/or Obstructive Sleep Apnea**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug (FDA) is classifying the intraoral devices for snoring and/or obstructive sleep apnea into class II (special controls). These devices are used to control or treat simple snoring and/or obstructive sleep apnea. This classification is based on the recommendations of the Dental Devices Panel (the Panel), and is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the guidance document that will serve as the special control for this final rule.

**DATES:** This rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

NFR 1

**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**

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94-295), the SMDA (Public Law 101-629), and the FDAMA (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), are generally referred to as preamendments devices, and are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, are generally referred to as postamendments devices, and are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require

premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act), as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval.

The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee, regarding the classification of these devices.

## **II. Regulatory History of the Device**

In the **Federal Register** of April 5, 2002 (67 FR 16338), FDA issued a proposed rule to classify the intraoral devices for snoring and/or obstructive sleep apnea, used to control or treat simple snoring and/or obstructive sleep apnea into class II. The agency also issued a guidance document as the special control. Interested persons were given until July 5, 2002, to comment on the proposed regulation and guidance document.

FDA received one comment from the National Association of Dental Laboratories.

### **III. Summary of Final Rule**

As required by 21 CFR 860.84(g)(2) of the regulations, FDA is classifying intraoral devices for snoring and/or obstructive sleep apnea into class II with the guidance document "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea" (Ref. 1), as the special control.

### **IV. Analysis of Comment and FDA's Response**

The one comment FDA received expressed concerns about the effect the guidance document would have on dental laboratories. FDA has concluded that the guidance document does not change the regulatory requirements for dental laboratories.

Therefore, under section 513 of the act, FDA is adopting the summary of reasons for the Panel's recommendation and the summary of data upon which the Panel's recommendation is based, in their entirety. FDA also agrees with the Panel's assessment of the risks to public health stated in the proposed rule published on April 5, 2002. FDA is issuing this final rule, which classifies these generic type of intraoral devices for snoring and obstructive sleep apnea into class II.

### **V. Environmental Impact**

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

## VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The classification of these devices into class II is not adding any additional burden to manufacturers, because most manufacturers, including small manufacturers, are already substantially in compliance with the recommendations of the guidance document that is the special control for the devices. The agency, therefore, certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

## IX. Reference

The following reference has been placed on display in the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA,” April 5, 2002.

## List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 in subpart F is amended as follows:

### **PART 872—DENTAL DEVICES**

1. The authority citation for 21 CFR part 872 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.5570 is added to subpart F to read as follows:

**§ 872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.**

(a) *Identification.* Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to decrease air turbulence and airway obstruction. The classification includes palatal lifting devices, tongue retaining devices, and mandibular repositioning devices.

(b) *Classification.* Class II (special controls). The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA.”

Dated: \_\_\_\_\_

10/28/02

October 28, 2002.

Linda S. Kahan

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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

**BILLING CODE 4160-01-S**

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Dawn P. Hawkins