

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N-0010]

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*PMB*  
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Certifier R. LEDESMA

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

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

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to classify the intraoral devices for snoring and/or obstructive sleep apnea, used to control or treat simple snoring and/or obstructive sleep apnea. Under the proposal, the intraoral devices for snoring and/or obstructive sleep apnea would be classified into class II (special controls). The agency is publishing in this document the recommendations of the Dental Devices Panel (the Panel) regarding the classification of these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final.

**DATES:** Submit written or electronic comments by *[insert date 90 days after date of publication in the Federal Register]*. See section VII of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments 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>.

**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 Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (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), generally referred to as preamendments devices, 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, generally referred to as postamendments devices, 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 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 the devices.

Snoring devices were marketed prior to the enactment of the 1976 amendments. 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. Intraoral devices to treat snoring and obstructive sleep apnea include three basic designs: Mandibular repositioners, tongue retaining devices, and palatal lifting devices. The treatment is viewed as a noninvasive and reversible treatment option. All of these devices provide the same therapeutic goal of increasing the pharyngeal space to improve the patient's ability to exchange air. The increase in airway space decreases the air turbulence, which is a causative factor in snoring. In addition to the removable devices, there are implantable screw devices that may be used with a suturing technique as part of a surgical procedure to lift the intraoral musculature and provide improved oropharyngeal patency (airway space). Implanted screw devices are not included in this classification. Extraoral devices, such as nasal dilators, are classified separately as ear, nose, and throat devices and are not included in this classification.

Recently, an increase in interest from the dental community to provide treatment for patients who snore or who have obstructive sleep apnea has resulted in an influx of premarket notification submissions for these devices to the agency. The majority of these new devices are designed as

mandibular repositioners. The sponsors of these devices primarily seek claims for the reduction of simple snoring, although some seek claims for treatment of sleep apnea. Review of these devices includes an analysis of the devices' specific intended use(s) and safety considerations relating to the design and manufacturing materials.

## **II. Recommendations of the Panel**

During a public meeting which was held on November 5, 1997, the Panel made the following recommendations regarding the classification of intraoral devices for snoring and/or obstructive sleep apnea.

### *A. Identification*

The Panel recommended that intraoral devices for snoring and/or obstructive sleep apnea be identified as devices that are worn over the natural teeth (not dentures) to improve oropharyngeal patency (airway space). The devices are intended to reposition and support the mandible in a more forward position, lift the soft palate, or retain and support the tongue and its associated musculature to increase airway space. With an increase in airway space, there is less air turbulence, resulting in a decrease in snoring. In patients who also suffer from obstructive sleep apnea, the resulting increase in airway space functions to diminish apneic episodes.

### *B. Recommended Classification of the Panel*

The Panel unanimously recommended that the intraoral devices for snoring and the intraoral devices for snoring and obstructive sleep apnea be classified into class II. The Panel believed that class II with a guidance document as the special control would provide reasonable assurance of the safety and effectiveness of the devices. The Panel believed that the guidance document should address labeling and advised that the labeling include the following:

#### 1. Precautions

- Use of the device may cause tooth movement or changes in dental occlusion.

- Use of the device may cause gingival or dental soreness.
- Use of the device may cause pain or soreness to the temporomandibular joint (TMJ).
- Use of the device may cause obstructed oral breathing.
- Use of the device may cause excessive salivation.

## 2. Contraindications

- The device should not be used in patients who have loose teeth or advanced periodontal disease.
- The device is contraindicated for patients who have congested nasal passages.
- The device should not be used in patients who are still growing.
- The device is not indicated for patients who have central sleep apnea.

### *C. Summary of Reasons for Recommendation*

After reviewing the information provided by FDA and considering the open discussions during the Panel meeting and the Panel members' personal knowledge of and clinical experience with the devices, the Panel gave the following reasons in support of its recommendation to classify the generic type of intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea used to improve oropharyngeal patency into class II:

1. The Panel believes that intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish special controls to provide such assurance.
2. The Panel believes that the benefits to health from use of the devices outweigh any of the known risks.
3. The Panel agrees with FDA that sufficient data already exists to support safe and effective use of these devices for patients who wish to treat or control simple snoring due to partial obstruction of the airway.

*D. Summary of Data Upon Which the Recommendation is Based*

Snoring is a medical and social problem that can cause patients and their partners to sleep poorly. This often causes excessive daytime drowsiness.

During the Panel meeting, a practitioner and researcher of sleep disorder medicine testified that many patients experience relief from obstructive sleep apnea and simple snoring with the use of intraoral devices (Ref. 1, pp. 208–214). A trade association published a literature review on the use of oral devices for the treatment of snoring (Ref. 3). The review analyzed a compilation of 21 publications covering 320 patients. The authors concluded that despite the variations in device design, the results consistently demonstrated an improvement in snoring, and often eliminated snoring with the use of oral devices. The authors also reported that complications are rare and that long-term compliance varies from 50 to 100 percent of patients.

An analysis of risk factors for mortality in sleep apnea patients suggests that sleep apnea syndrome contributes indirectly to mortality, most likely as a risk factor for hypertension (Ref. 5). Another study reports that there is an association between mortality and impaired respiration in an aged population during sleep (Ref. 4).

According to representatives of the Sleep Disorders Dental Society, the success rate of these devices is well documented (Ref. 1, pp. 34–42). In one study, the role of mandibular repositioning oral appliances in the treatment of obstructive sleep apnea was reported. The study evaluated patients with obstructive sleep apnea and concluded that the devices are useful in long-term treatment of patients with mild to moderate obstructive sleep apnea (Ref. 2).

Another study compared oral devices to nasal continuous positive airway pressure (C–PAP) (Ref. 6). The authors reported that oral appliance therapy is an effective treatment for some patients who suffer from mild to moderate obstructive sleep apnea and noted that fewer side effects existed. The study also revealed that patients reported greater satisfaction from the use of the oral devices than those who were treated with nasal C–PAP.

### *E. Risks to Health*

Intraoral snoring and obstructive sleep apnea devices may present moderate risks to health. The Panel identified the following risks they believe the use of intraoral devices present: Dental soreness, gingival soreness, TMJ dysfunction syndrome, obstruction of oral breathing, and tooth movement.

Dental or gingival soreness may result from pressure on oral structures while wearing a mandibular repositioning device. Soreness of palatal tissues may result from palatal lifting devices. TMJ dysfunction syndrome may result from use of the devices if the TMJ is strained or if the muscular attachments are stretched for prolonged periods. Joint dysfunction or discomfort may occur from unfavorable loading even if the mandible is repositioned appropriately. Oral appliances that do not include a breathing space can completely obstruct oral breathing, forcing the patient to breathe through the nose. Loosening or flaring of lower anterior teeth or general tooth movement may result when a mandibular repositioning device exerts pressure on the teeth. Periodontally compromised teeth are especially susceptible to flaring.

On the basis of its review of the literature and the Panel's recommendation that these devices be classified into class II, FDA believes that intraoral snoring and/or obstructive sleep apnea devices do not present an unreasonable risk to health and that the guidance, "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea," as a special control, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices.

### *F. Special Control*

Based on the available information, FDA believes that, in addition to general controls, the guidance document, "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA," is adequate to address the risks to health identified above. As discussed below, sections of the guidance address the risks to health by providing material composition and biocompatibility recommendations, providing

labeling recommendations, describing when clinical data are needed, and identifying the kinds of clinical observations that should comprise these data. Other sections identify the kinds of material composition and biocompatibility information that address the risks to health.

### 1. Material Composition and Biocompatibility

Material composition and biocompatibility recommendations in the guidance document help prevent intraoral gingival, palatal, or dental soreness by ensuring that materials used in these devices can maintain dimensional stability, do not leech any chemical compounds into the oral cavity, and have patient contacting surfaces appropriate to the design of the device.

### 2. Labeling

Labeling recommendations in the guidance document include contraindications, warnings, precautions, and adequate directions for fitting, use, and care of these devices. FDA believes that these labeling recommendations help ensure that these devices are used correctly by patients for whom these devices are appropriate.

### 3. Clinical Data

When clinical data are necessary, they should demonstrate a reduction in snoring and/or reduction in apneic episodes for intraoral devices for snoring and/or obstructive sleep apnea, respectively. Reduction in snoring should be based on clinical observation. Reduction in apneic episodes should be based on baseline and post-insertion polysomnograms that include measurements of the respiratory disturbance index, apnea index, duration of the apnea, and oxygen saturation.

FDA believes that compliance with the recommendations in the guidance document, when combined with the general controls, will provide reasonable assurance of the safety and effectiveness of intraoral devices for snoring and/or obstructive sleep apnea.

### **III. Proposed Classification**

FDA believes the intraoral devices for snoring and/or obstructive sleep apnea should be classified into class II because the special control, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish special controls to provide such assurance.

### **IV. 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 environmental assessment nor an environmental impact statement is required.

### **V. Analysis of Impacts**

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed 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. Manufacturers of unclassified preamendments devices are already subject to the general controls of the act including premarket notification. FDA believes that manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance document that would be

the special control for the device. FDA, therefore, believes that the rule will impose no significant economic impact on any small entities. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## **VI. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

## **VII. Submission of Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposed rule 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

## **VIII. References**

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Transcript of the Dental Products Panel Meeting, November 3–5, 1997.
2. Menn, S. et al., "The Mandibular Repositioning Device: Role in the Treatment of Obstructive Sleep Apnea," *Sleep*, vol. 19, no. 10, pp. 794–800, 1996.

3. Schmidt-Nowara, W. et al., "Oral Appliances for the Treatment of Snoring and Obstructive Sleep Apnea: A Review," *Sleep*, vol. 18, no. 6, pp. 501–510, 1995.
4. Bliwise, D. L. et al., "Sleep Apnea and Mortality in an Aged Cohort," *American Journal of Public Health*, vol. 78, no. 5, pp. 544–547, 1988.
5. Lavie, P. et al., "Sleep Apnea Research Mortality in Sleep Apnea Patients: A Multivariate Analysis of Risk Factors," *Sleep*, vol. 18, no. 3, pp. 149–157, 1995.
6. Ferguson, K. A. et al., "A Randomized Crossover Study of an Oral Appliance vs. Nasal-Continuous Positive Airway Pressure in the Treatment of Mild-Moderate Obstructive Sleep Apnea," *Chest*, vol. 109, no. 5, pp. 1269–1275, 1996.

### 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, it is proposed that 21 CFR part 872 be amended in subpart F as follows:

### PART 872—DENTAL DEVICES

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

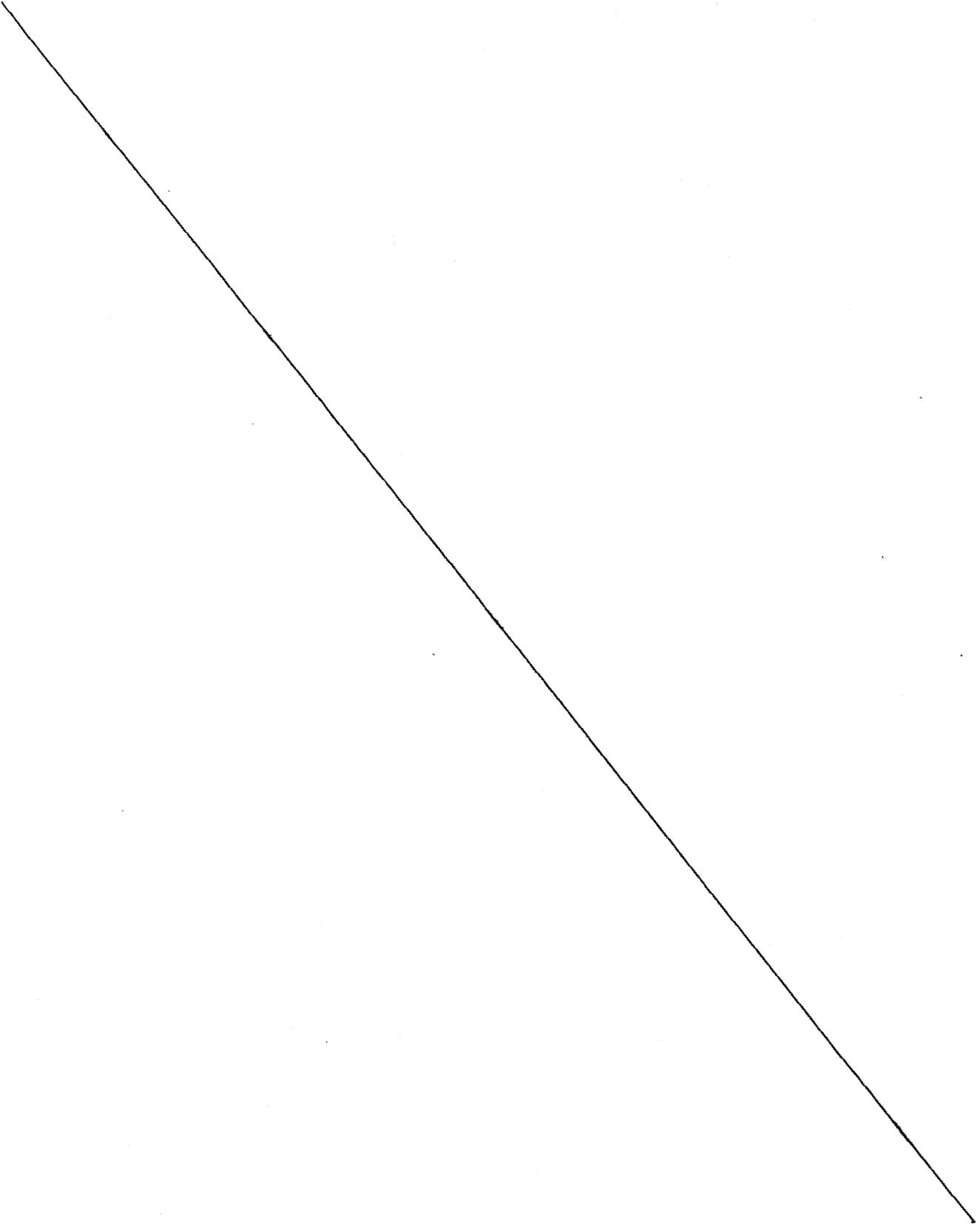
**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

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.**

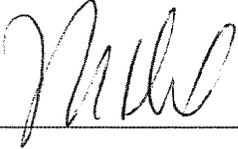
(a) *Identification.* Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea are devices that are worn during sleep to reduce the incidence of snoring and to treat obstructive sleep apnea. The devices are designed to increase the patency of the airway and to

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; Draft Guidance for Industry and FDA."

Dated: 2/28/02  
February 28, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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

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