

Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA

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Guidance Document: Intraoral Devices for Snoring and/or Obstructive
Sleep Apnea; Guidance for Industry and FDA, dated April 5, 2002**



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Dental Branch
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation**

Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to Docket No. 02D-0011 and the title of the guidance. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Susan Runner, D.D.S. at 240-276-3700 or by email susan.runner@fda.hhs.gov.

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Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

1. Introduction

This guidance document was developed as a special control guidance to support the classification of the intraoral devices for snoring and/or obstructive sleep apnea into class II. Intraoral devices for snoring and obstructive sleep apnea are preamendments devices, i.e., were in commercial distribution prior to May 28, 1976 (the enactment date of the Medical Device Amendments of 1976) and are currently unclassified. The Dental Devices Panel met to consider the classification of these devices in November 1997. The Panel recommended these products be classified into Class II (special controls). The device, as proposed, is intended for use during sleep to aid in the treatment of simple snoring and/or obstructive sleep apnea. This guidance will be issued in conjunction with a Federal Register notice announcing the proposal to classify this device type.

Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for intraoral devices for snoring and/or obstructive sleep apnea will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of intraoral devices for snoring and/or obstructive sleep apnea. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with intraoral devices for snoring and/or obstructive sleep apnea identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device, unless exempt from the

premarket notification requirements of the Act (refer to 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the intraoral devices for snoring and/or obstructive sleep apnea (Refer to Section 4 – **Scope**). In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these intraoral devices for snoring and/or obstructive sleep apnea and lead to a timely premarket notification [510(k)] review and clearance. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and other FDA documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, <http://www.fda.gov/cdrh/manual/510kprt1.html>.

Under “**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**¹,” a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a special controls guidance document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the “**A Suggested Approach to Resolving Least Burdensome Issues**” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA

¹ <http://www.fda.gov/cdrh/ode/parad510.html>

may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this class II special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to **Section 9** for specific information that should be included in the labeling for devices of the types covered by this document.)

Summary report

We recommend that the summary report contain:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. You should also submit an "indications for use" enclosure.²
- Description of device design requirements.
- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to **Section 5** for the risks to health generally associated with the use of this device that FDA has identified.)
- Discussion of the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.
- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 6-8** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested

² Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.³ (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.⁴ Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). For more information refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, <http://www.fda.gov/cdrh/ode/guidance/1131.html>.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification for intraoral devices for snoring and/or obstructive sleep apnea.

³ If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

⁴ See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

4. Scope

The scope of this document is limited to the generic type of device described below.

21 CFR 872.5570 Intraoral devices for snoring and/or obstructive sleep apnea.

Product codes: LRK Anti-Snoring Device
LQZ Jaw Repositioning Device

This generic type of device includes intraoral devices for snoring and/or obstructive sleep apnea. These are removable medical devices that are fitted in the patient's mouth and are indicated to treat patients who snore and patients who have obstructive sleep apnea. The devices are indicated to be used when the diagnosis is simple snoring or obstructive sleep apnea. The devices are indicated for use during sleep to aid in the treatment of these conditions. Simple snoring is a form of sleep disordered breathing in which there is a narrowing of the upper airway which leads to an inspiratory noise produced by vibration of the pharyngeal soft tissues. These devices are not indicated for the treatment of central apnea. Intraoral devices to treat snoring and/or obstructive sleep apnea are prescription devices unless adequate directions for use (21 CFR 801.5) are developed and FDA clears a 510(k) specifically for over-the-counter (OTC) distribution.

Intraoral devices to treat snoring and/or obstructive sleep apnea include three basic designs: mandibular repositioners, tongue retaining devices, and palatal lifting devices. 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). **Implantable screw devices are not included in this classification.**

5. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the intraoral devices for snoring and/or obstructive sleep apnea addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to submitting your premarket notification, to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance,

you should provide sufficient detail to support the approach you have used to address that risk.

| Identified risk | Recommended mitigation measures |
|--|---------------------------------|
| Intraoral gingival, palatal, or dental soreness | Sections 6, 7, 8, 9 |
| Temporomandibular Joint (TMJ) Dysfunction Syndrome | Section 8, 9 |
| Obstruction of oral breathing | Sections 8, 9 |
| Loosening or flaring of lower anterior teeth or general tooth movement | Sections 8, 9 |

6. Material Composition

Your summary report should include the following information for all components.

- The material identity
- The complete chemical composition, unless declaring conformance to a materials standard
- Material safety data sheets (MSDS) for all materials used in the device (appended to your summary report).

7. Biocompatibility

You should perform biocompatibility testing as outlined in the FDA-modified "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" <http://www.fda.gov/cdrh/g951.html> for a surface device that contacts intraoral (i.e., mucosal, gingival, and palatal) surfaces for prolonged contact. Your summary report should contain a statement that testing will be conducted as described in Parts 5 and 10 of ISO-10993 the standard (the statement should also include the acceptance criteria to be applied).

8. Clinical Testing

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will not request clinical studies for new devices unless there is a specific justification for asking for such information to support a substantially equivalent determination. FDA recommends that you conduct clinical studies for intraoral devices for snoring and/or obstructive sleep apnea when your device:

- uses designs dissimilar from designs previously cleared under a 510(k) [Please note: Devices that use the same mechanism of action are not necessarily similar devices.]
- uses new technology, i.e., technology different from that used in legally marketed intraoral devices for snoring and/or obstructive sleep apnea
- makes changes in the indication for use.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. Please contact the Dental Devices Branch to discuss any clinical testing before initiating studies.

When a clinical study is needed, the summary report should include the clinical protocol defining inclusion and exclusion criteria and a sample size justification.

For devices for simple snoring, performance measurements should include the rate of reduction of snoring based on clinical observation.

For devices for obstructive sleep apnea, performance measurements should include the rate of reduction of apneic events measured by polysomnograms. Baseline and post-insertion polysomnograms should be obtained for each subject in the study. These polysomnograms should include measurements of the respiratory disturbance index, apnea index, duration of the apnea, and oxygen saturation. FDA believes that polysomnographic data are needed for the intended use of obstructive sleep apnea.

Clinical studies to support a substantially equivalent determination for a non-prescription intraoral device for simple snoring also need to demonstrate the adequacy of the instructions for use. We suggest that you discuss your proposed protocol with the Dental Devices Branch before initiating a clinical study of this kind.

If a clinical study is needed to demonstrate substantial equivalence, i.e., conducted prior to obtaining 510(k) clearance of the device, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR 812. FDA has determined that the device addressed by this guidance document is a non-significant risk device, therefore the study is subject to the abbreviated requirements of 21 CFR 812.2(b).⁵ In addition to the requirements of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are

⁵ Refer to Blue Book Memorandum entitled “SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES “ at <http://www.fda.gov/cdrh/d861.html>.

exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with Parts 50 and 56.

9. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).⁶

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

Devices with Thermal Setting Resins

If the device contains a thermal setting resin, you should include instructions for heating, cooling, and setting time in the labeling.

Contraindications

You should include the following contraindications in your labeling. The device is contraindicated for patients who:

- have central sleep apnea
- have severe respiratory disorders
- have loose teeth or advanced periodontal disease
- are under 18 years of age.

Warnings

You should include the following warnings in your labeling. Use of the device may cause:

- tooth movement or changes in dental occlusion
- gingival or dental soreness

⁶ Although final labeling is not required for 510(k) clearance, final labeling must also comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

- pain or soreness to the temporomandibular joint
- obstruction of oral breathing
- excessive salivation.

Precautions

You should include the following precaution: Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

Patient Labeling

Patient labeling should be clear, accurate, and provide complete use and care instructions for the patient. Information on patient labeling is available in the guidance entitled, “Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers,” issued April 19, 2001, <http://www.fda.gov/cdrh/ohip/guidance/1128.html>.