Dockstader
ORTHODONTIC LAB, INC.

510(k) Summary

April 23, 2008

JUN 12 2008

Dockstader Orthodontic Lab, Inc.
340 West Cromwell
Fresno, CA 93711

Establishment Registration Number: **SBD070202**
510(k) Number: **K072731**

Contact Person: Michael C Bausman
Telephone: (559) 439-5160
Fax: (559) 439-8147

Device

Trade Name:	EndSnor™
Common Name:	Anti-Snoring/Sleep Apnea Device
Classification Name:	Device, Anti-Snoring
Product Code:	LRK
Class:	II
Regulation Number:	872.5570

Description of Device: The EndSnor™ device is a dentist prescribed one-piece anti-snoring/sleep apnea appliance, custom-fit to patients' teeth by a professional dentist. It consists of an acrylic upper and lower posterior bite registration with an acrylic overlay of the posterior teeth, finished to the buccal/lingual height of contour for retention. If needed, the dentist may request stainless steel ball clasps, commonly used in the fabrication of orthodontic appliances, be added for more retention. Four expansion screws, commonly used in the fabrication of orthodontic appliances, are set in the acrylic to allow for mandibular readjustment. Mandibular adjustments are made by turning each screw equally. A labial supporting bar, commonly used in the fabrication of orthodontic appliances, is used to bridge the anterior gap in order to allow for less obstruction of the airway, and to remove the occurrence of loosening or harming of lower anterior teeth.

Intended Use Statement: The EndSnor™ appliance, a dentist prescribed mandibular repositioning (MRP) device, is worn during sleep and is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea. Before a dentist prescribes an EndSnor™ appliance for treatment, it is recommended that the patient receive a medical examination including a sleep study diagnosis, and a dental examination including cephalometric and tomography analysis to determine the need for an EndSnor™ appliance.

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510(k) Summary

Identification of Legally Marketed Device, (predicate) for Substantial Equivalence:
Name: Adjustable PM Positioner
K Number: K955503
Date Cleared: 02/08/1996

Technological Characteristics Summary:
Similarities between both devices are the following:

- Indications for use
- Function (MRP) – Mandibular Repositioning Device
- Single Patient
- Multi-Use
- Prescription Device
- Custom Fabricated (Fit) from Common Orthodontic Appliance Materials
- Adjustable
- Environment – Home/Sleep Laboratories
- Removable
- Non Sterile

Comparison to Predicate Device

Attribute	EndSnor™	Adjustable PM Positioner
Use:		
Intended as a Dentist prescribed intraoral device	YES	YES
Intended to reduce or help snoring and minor to moderate obstructive sleep apnea	YES	YES
Intended for use with patients 18 years or older who snore or have minor to moderate obstructive sleep apnea	YES	YES
Indicated for single patient multi-use	YES	YES

Comparison to Predicate Device cont:

Attribute	EndSnor™	Adjustable PM Positioner
Use cont:		
Indicated for use at home or sleep laboratories	YES	YES
Design:		
Custom fit for each user	YES	YES
Mandible can be advanced with buccal expansion screws	YES	YES
Expansion screw placement on buccal for unobstructed airway passage	YES	YES
Permits user to breath through mouth, opens the airway	YES	YES
Acrylic fits over upper and lower posterior teeth	YES	YES
Anterior Acrylic connector over upper and lower anterior teeth	NO	YES

Comparison to Predicate Device cont:

Attribute	EndSnor™	Adjustable PM Positioner
Design cont:		
Anterior connector on labial using dental lingual bar for orthodontic splints	YES	NO
Prevents grinding of teeth	YES	YES
Easily removed from mouth	YES	YES
Placed in users mouth each evening	YES	YES
Cleaned daily	YES	YES
Materials:		
Dental expansion screws for mandibular adjustment	YES	YES
Non-Sterile	YES	YES
Acrylic	YES	YES
Heat-sensitive acrylic	NO	YES
Retention clasps for retention if needed	YES	NO
Dental lingual bar for splints	YES	NO

Differences Between EndSnor™ and Adjustable PM Positioner, a Marketed Predicated Device

Differences are:

- EndSnor™ has 4 buccal expansion screws instead of 2 for mandible advancement.
- A labial supporting dental lingual bar for orthodontic splints is used to bridge the anterior gap on the labial instead of acrylic over the anterior upper and lower teeth, thus creating less obstruction of the airway and to remove the occurrence of loosening or harming of lower anterior teeth. The labial supporting dental lingual bar is placed so there isn't any contact with the lower or upper anterior teeth.
- EndSnor™ is made of cold cure splint acrylic that is commonly used in dental labs for orthodontic splint fabrication. The Adjustable PM Positioner is made of a heat sensitive acrylic.
- The dentist can chose to add retention clasps if needed for retention of the EndSnor™ appliance in the mouth. These commonly used orthodontic retainer clasps are Ball Clasps. These are made of stainless steel wire commonly used in the fabrication of orthodontic appliances.

Safety and Efficacy:

- The EndSnor™ device is similar to the Adjustable PM Positioner, a marketed predicated device, both are mandibular repositioning devices (MRP) and both are similar in design and function. The difference between the EndSnor™ and the Adjustable PM Positioner, a predicated device, are minor and do not raise any new safety concerns or risks.
- Literature supports the historical significance of oral devices that reposition the mandible and reduce and mange snoring as well as mild to moderate sleep apnea.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2008

Mr. Michael C. Bausman
Chief Executive Officer
Dockstader Orthodontic Lab, Incorporated
340 West Cromwell
Fresno, California 93711-6113

Re: K072731
Trade/Device Name: EndSnor™
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices For Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: April 25, 2008
Received: April 25, 2008

Dear Mr. Bausman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072731

Device Name: EndSnor™

Intended Use Statement: The EndSnor™ appliance, a dentist prescribed mandibular repositioning (MRP) device, is worn during sleep and is indicated for persons 18 years or older, who wish to reduce the incidence of snoring and/or mild to moderate obstructive sleep apnea. Before a dentist prescribes an EndSnor™ appliance for treatment, it is recommended that the patient receive a medical examination including a sleep study diagnosis, and a dental examination including cephalometric and tomography analysis to determine the need for an EndSnor™ appliance.

Prescription Use ___X___. (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072731