MAY 2 8 2002

K020893

Dennis R. Bailey, D.D.S.

Fellow, Academy of General Dentistry - Fellow, International College of Dentists - Diplomate, American Board of Orofacial Pain
President, Sleep Disorders Dental Society (1998-1999) - Credentialed by the Certification Board of the Sleep Disorders Dental Society

GENERAL DENTIST: PRACTICE RESTRICTED TO
CRANIOFACIAL PAIN & RELATED HEADACHE DISORDERS,
OROFACIAL PAIN & TEMPOROMANDIBULAR JOINT DISORDERS,
INTRAORAL APPLIANCE THERAPY FOR SNORING & RELATED BREATHING DISORDERS,
ORTHODONTICS

Premarket Notification [510(k)] Summary

Contact Person: Dennis R. Bailey, DDS

Date Prepared : March 7, 2002

Name of the Device: NOrAD

Trade Name: NOrAD

Common Name: Mandibular repositioning appliance (device)

Classification Name: Device, Anti-Snoring and to Manage Sleep Apnea

Substantial Equivalence is being made to other "boil and bite" or "boil and fit" devices, specifically the Silencer Custom and the TAP, as well as a custom fit Device (EMA) that uses an elastic module to secure the upper and lower as well as reposition the jaw and are advocated for the management of snoring and sleep apnea.

Description of the Device: This device has a hard outer component with heat sensitive material contained within that component. The heat sensitive material is softened and is what fits the appliance to the patient's teeth for securing the appliance in place. Hooks for conventional Orthodontic elastics exist on the outer component for the purpose of attaching the elastics to prevent the mandible from retruding. The upper component has two (2) hooks and the lower component has one (1) hook. This allows for various methods of elastic

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placement depending on the need(s) of the patient. There is ramping on both the upper and the lower to facilitate and guide the mandible forward when the patient is in occlusion. These ramps also provide a posterior stop for support of the mandible. The appliance also provides for full coverage of the dentition to prevent any tooth movement or occlusal changes. The teeth at the anterior of the appliance allow for indexing of the appliance at a position most acceptable to the patient during wear and allows the patient to determine the most effective jaw position for repositioning dependent on sleep position. The teeth index in such a way to allow for freedom of movement of the jaw during sleep while remaining in an indexed position.

Intended Use: This device is intended for the reduction and management of sleep apnea, as well as snoring.

Technologic Characteristics: Compared to the Silencer Custom, the EMA and the TAP appliance the NOrAD appliance does not hold or lock the jaw into a set position while also repositioning the mandible. The NOrAD allows for free movement both vertically as well as laterally and to some degree horizontally. This allows the patient the ability to move the jaw during sleep without inducing increased muscle activity.

Substantial Equivalence is based on non-clinical data. In addition the literature supports the historical significance of oral devices that reposition the

jaw and reduce and mange snoring as well as sleep apnea. Pancer et al described this in an article published in the journal CHEST in 1998, where they concluded that mandibular repositioning appliances were 95% successful in reducing and/or controlling snoring and were 83% effective in managing sleep apnea. In addition the American Academy of Sleep Medicine (formerly the American Sleep Disorders Association) published in 1995 their Standards of Practice and Guidelines which demonstrated that oral appliances were effective in the management of snoring and mild to moderate sleep apnea.

Based on clinical data, it is demonstrated in a variety of articles that looked at oral appliances and their use for the treatment of snoring and sleep apnea, oral appliance therapy is an effective means by which these conditions can be managed. This effectiveness is embraced from a variety of aspects including safety, convenience and cost.

In conclusion, a number of studies have shown improvement of the airway utilizing imaging associated with the use of oral appliances (also referred to as Oral Airway Dilators), which aids in the management and reduction of Snoring and sleep apnea.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2002

Dr. Dennis R. Bailey
7901 East Belleview Avenue, Suite 200
Englewood, Colorado 80111

Re: K020893
Trade/Device Name: NOrAD
Regulation Number: None
Regulation Name: Intra-Oral Mandibular Repositioner
Regulatory Class: Unclassified
Product Code: LRK
Dated: March 7, 2002
Received: March 19, 2002

Dear Dr. Dennis R. Bailey:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020893

510(k) Number (if known):

Device Name: NOrAD

Indications For Use:

The NOrAD device (appliance) is indicated for use in patients who are snorers or have mild to moderate obstructive sleep apnea that has been medically diagnosed or are intolerant to nasalCPAP and wish to reduce and manage their condition while sleeping.

The device may be used in individuals who have had an overnight sleep study and do not have apnea or have mild to moderate obstructive sleep apnea and their physician has recommended the appliance. The device may also be indicated for a patient that snores and may have obstructive sleep apnea but their physician does not feel a sleep study is indicated and has recommended or referred the patient for appliance therapy. In many instances the decision will have been made after consultation has occurred between the dentist and the physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020893