K062333

Attachment 2: 510(k) Summary

510(k) SUMMARY

Steven B. Lamberg, D.D.S.'s Lamberg Sleep Well Device DEC 14 2006

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, D.C. 20004-1109
Phone: 202-637-5794
Facsimile: 202-637-5910

Contact Person: Jonathan S. Kahan

Date Prepared: December 5, 2006

Name of Device /Address of Sponsor

Lamberg Sleep Well Device

Steven B. Lamberg, D.D.S.
140 Main Street
Northport, New York 11768
Phone: 631-261-6014
Facsimile: 631-261-6364

Common or Usual Name

Mandibular advancement device

Classification Name

Anti-snoring device (Product code: LRK)

Predicate Devices

TheraSnore (K973038)
Distar, Inc.

Hawley retainer (Preamendments)
Specialty Appliance Works, Inc.

Trubyte Denture Base Resin System, and Modification to Trubyte Denture Base Resin System
Dentsply International (K011560, K032892)

Intended Use / Indications for Use

The Lamberg Sleep Well device is intended to reduce night time snoring.

The Lamberg Sleep Well device is indicated for use in adults 18 years of age or older in a home or sleep laboratory environment.

Technological Characteristics

The Lamberg Sleep Well device is a one piece, custom-molded device that advances the mandible by 5 mm. The body of the device extends over the upper incisors, and is 2 – 3 mm thick. A central protrusive element hangs down to contact the lingual lower incisors. An Adams clasp is placed to hold the device securely to each of the upper first molars. The appliance ends at the distal of the first molars on the palate.

Principles of Operation

The patient inserts the device into their mouth, seating it against the soft palate, and engages it securely to the upper front molars with the Adams clasps. The central protrusive element hangs down and makes contact with the lingual surface of the mandibular incisors, thus moving the mandible forward by 5 mm. The forward placement of the mandible with respect to the maxilla serves to pull the tongue forward, which directly and indirectly reduces snoring.

Performance Data

No performance data are required in support of this 510(k) notice.

Substantial Equivalence

The Lamberg Sleep Well device is substantially equivalent in intended use and technology to the TheraSnore (K973038). The Lamberg Sleep Well device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Lamberg Sleep Well device and its predicate devices raise no new issues of safety or effectiveness. Thus, the Lamberg Sleep Well device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2006

Steven Lamberg, D.D.S
C/O Mr. Jonathan S. Kahan
Columbia Square
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K062333
Trade/Device Name: Lamberg Sleep Well Device
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: December 7, 2006
Received: December 7, 2006

Dear Mr. Kahan:

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.

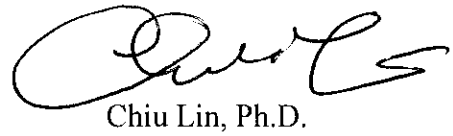
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

Attachment 1:

Indications for Use Statement

510(k) Number: **K062333**

Device Name: Lamberg Sleep Well Device

Indications for Use:

The Lamberg Sleep Well device is intended to reduce night time snoring in adults 18 years of age or older in a home or sleep laboratory environment. The device must be prescribed by a dentist or physician.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Anesthesiology, General Hospital,
Control, Dental Devices

K062333