DEC 30 2005

K052862

510(k) Summary
Full Breath Sleep Appliance – AB (Anterior Bite)
Full Breath Sleep Appliance – ABB (Anterior Bite with Bumps)

Applicant

Bryan Keropian DDS
18607 Ventura Blvd., Suite 206
Tarzana, CA 91356

Product Name

Full Breath Sleep Appliance – AB (Anterior Bite)
Full Breath Sleep Appliance – ABB (Anterior Bite with Bumps)

Proposed Product Code

LQZ

Proposed Device Classification

Jaw Repositioning Device

Contact Person

Bryan Keropian DDS
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510(k) Application Preparation

Bryan Keropian, DDS

K052862

510(k) Summary (continued)

This is a simple enhancement to the design of the Quiet Night & Quiet Night MA (K032410). It incorporates the Quiet Night and the NTI (K010867) anterior discluding element for bruxism and control of vertical dimension and anterior mandibular advancement for reduction/elimination of snoring. It also has the posterior trans-palatal bar to prevent the tongue from sealing against the palate and reducing snoring, and restrains the tongue from up and back movement. The tongue restraint has resulted in reduced AHI/RDI's and reduction of ODI's.

DEVICE SPECIFICATIONS

The Full Breath Sleep Appliance is a custom fabricated device typically by a professional dental laboratory and delivered by a dentist.

PREDICATE DEVICE COMPARISON TABLE:

Product Name	Full Breath Sleep Appl.	Quiet Night Quiet Nt. MA	NTI Tension Suppression System	Breathe EZ Anti-Snoring Device	Sleepbite	Dr. B's Mouthpiece
510(k)	Pending	K032410	K010876	K022891	K103808	K991948
Product Code	LQZ	LQZ	LQZ	LRK	LRK	LRK
Indicated Use	Treatment of Mild & Mod. OSA -- Treatment of Snoring -- Prevent Bruxism	Prophylactic treatment of medically diagnosed migraine pain -- Prevent Bruxism	Prophylactic treatment of medically diagnosed migraine pain -- Prevent Bruxism	Treatment of snoring -- Prevent Bruxism	Treatment of snoring -- Prevent Brusxism	Treatment of snoring -- Prevent Bruxism
Method of Delivery	By prescription	By prescription	By prescription	By prescription	By prescription	By prescription

INDICATIONS FOR USE

1. An oral appliance to be used for the treatment of mild and moderate Obstructive Sleep Apnea.
2. For the treatment of snoring.
3. For the prevention of bruxism.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2005

Dr. Bryan Keropian
Bryan Keropian DDS A Professional Corporation
18607 Ventura Boulevard, Suite 206
Tarzana, California 91356

Re: K052862
Trade/Device Name: Full Breath Sleep Appliance-ABCAnterior Bite)
Full Breath Sleep Appliance-ABB (Anterior Bite with Bumps)
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LQZ
Dated: October 11, 2005
Received: October 11, 2005

Dear Dr. Keropian:

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

K052862

FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use

510(k) Number (if known): K052862

Device Name: Full Breath Sleep Appliance – ABC (Anterior Bite)
Full Breath Sleep Appliance – ABB (Anterior Bite with Bumps)

Indications for Use:

1) An oral appliance to be used for the treatment of mild and moderate Obstructive Sleep Apnea
2) For the treatment of snoring
3) For the prevention of bruxism.

Angela Blackwell for MSR

Division of Surgery, General Hospital,
Infection Control, Dental Devices

510(k) K052862

Prescription Use ✓
(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)