K103004

FEB 25 2011

510(k) Summary

Ranir's Snore Guard

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

Ranir, LLC
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Grand Rapids, MI 49512
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Contact Person: Jeff Fisher

Date Prepared: December 13, 2010

Name of Device

Snore Guard

Common or Usual Name/Classification Name

Intraoral Anti-Snoring Device

Predicate Devices

Snore Guard Advance (K102118)
SleepRight Original (K100545)

Purpose of Submission

The Snore Guard is a modification to the Snore Guard Advance.

Intended Use / Indications for Use

The Snore Guard is indicated for use in the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults 18 years of age or older.

Technological Characteristics

The Snore Guard consists of a mouthguard worn on the maxilla, connected to an occlusal stop (called an "occlusal ramp"), which contacts the patient's mandibular incisors. Both the maxillary tray and the occlusal ramp are custom fitted using a "boil-and-bite" process.

Substantial Equivalence

The Snore Guard has the same intended use and similar indications, principles of operation, and technological characteristics as Snore Guard. The minor differences in the Snore Guard's technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Snore Guard is substantially equivalent to its identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Ranir, LLC
C/O Mr. Gerard J. Prud'homme
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

FEB 25 2011

Re: K103004
Trade/Device Name: Snore Guard
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: February 17, 2011
Received: February 17, 2011

Dear Mr. Prud'homme:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103004

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Snore Guard

Indications for Use:

The Snore Guard is indicated for use in the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults 18 years of age or older.

Prescription Use __X__ (Per 21 C.F.R. 801.109) AND/OR Over-The-Counter Use____ (Per 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)

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

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