

K102118

510(k) Summary

Ranir's Snore Guard Advance

SEP 08 2010

**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: July 27, 2010

Name of Device

Snore Guard Advance

Common or Usual Name/Classification Name

Intraoral Anti-Snoring Device

Predicate Devices

Hays & Meade Anti-Snoring Device (K882303)

Purpose of Submission

The Snore Guard Advance is a modification to the Hays & Meade Anti-Snoring Device.

Intended Use / Indications for Use

The Snore Guard Advance is intended to be used for the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults.

Technological Characteristics

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



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

SEP 08 2010

Re: K102118

Trade/Device Name: Snore Guard Advance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for
Snoring and Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: August 24, 2010
Received: August 24, 2010

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,



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

K102118

Indications for Use Statement

510(k) Number (if known): _____

SEP 08 2010

Device Name: Snore Guard Advance

Indications for Use:

The Snore Guard Advance is indicated for use in the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in adults.


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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