K112879

JAN 27 2012

510(k) SUMMARY

Ranir, LLC's
Rest Assured Ready to Wear Nite Protector

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

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Date Prepared: January 9, 2012

Name of Device and Name/Address of Sponsor

Rest Assured Ready to Wear Nite Protector

Ranir, LLC
4701 East Paris Avenue SE
Grand Rapids, MI 49512

Common or Usual Name

Nightguard

Classification Name

Mouthguard, Over-the-Counter

Classification Product Code

OBR

Predicate Devices

Ranir, LLC's Rest Assured Generation II Dental Protector (K091792)
Ranir, LLC's Grind No More Version 2 (K091175)
Splintek – Power Products Inc.'s SleepRight No Boil Dental Guard (K071404)

Purpose of the Special 510(k) notice

The Rest Assured Ready to Wear Nite Protector is a modification to Ranir's Rest Assured Night Generation II Dental Protector (K091792).

Notably, the Rest Assured Ready to Wear is the same device as the Rest Assured II, with five minor differences: (1) the Rest Assured Ready to Wear is a posterior, occlusive mouthguard, whereas the Rest Assured II is a fully occlusive mouthguard; (2) the Rest Assured Ready to Wear is to be worn on either the mandibular or maxillary teeth, while the Rest Assured II is for maxillary teeth only; (3) while the Rest Assured II is fitted using the "boil and bite" technique, the Rest Assured Ready to Wear is fitted via adjustable bite plates without boiling; (4) the Rest Assured Ready to Wear is made of ELVALOY, ELVAX, and polypropylene, while the Rest Assured II is made from ELVAX and Dynaflex; and (5) labeling modifications to provide appropriate user fitting instructions.

Intended Use

The Rest Assured Ready to Wear Nite Protector is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

The Rest Assured Ready to Wear Nite Protector is a posterior-occlusive nightguard, comprised of two molar bite pads connected by a buccal retaining strap. The device is fit to the user's mouth by adjusting the bite plates along the retaining strap.

Substantial Equivalence

The company's Rest Assured Ready to Wear has the same intended use and indications for use as the previously cleared predicate devices, the Rest Assured II, the Grind No More 2, and the SleepRight. In addition, the Rest Assured Ready to Wear has similar technological characteristics and principles of operation to the Rest Assured II, the Grind No More 2, and the SleepRight. Although there are minor differences between the Rest Assured Ready to Wear and the Rest Assured II, namely in the use of the device on the posterior portion of the mandible only, the change in the design and function of the adjustable bite plates, the change in materials, and the limited labeling changes, these minor differences do not raise new questions of safety or efficacy. The posterior-only occlusial design and use of the device on mandibular teeth are common to other cleared mouthguards, such as the previously cleared SleepRight and Grind No More 2 devices. The adjustable nature of the device is also supported by the SleepRight predicate. Although the materials used in the device have changed, each of the materials comprising the Rest Assured Ready to Wear are common to other cleared medical devices, including the named predicates. Finally, the limited labeling changes only provide appropriate instructions on how to fit the device properly and do not affect device safety or

effectiveness. Thus, the Rest Assured Ready to Wear is substantially equivalent to the claimed predicate devices.

Performance Testing

A risk analysis for the subject device was performed per ISO 14971 and ISO 7405 was adhered to in the evaluation of biocompatibility of device materials.

In addition, the company performed wear testing on the subject device to evaluate the wear resistance (i.e., Alabama-type wear testing) of the device in comparison to various over-the-counter FDA-cleared predicate night guards. The wear resistance of the evaluated night guard material was comparable to the tested predicate devices with no abnormal evaluations.

Next, a third party testing laboratory tested the device to establish that the subject device was comparable to an identified predicate device with similar design. The third party laboratory verified that the subject device is comparable to the predicate device and can be used on the mandibular or maxillary teeth with the adjustable bite plates similar to the predicate device design.

Lastly, a 20 subject user study was conducted to verify that the limited labeling changes for device use were effective and well understood by the 20 subjects. Greater than 80% of the tested subjects agreed that the adjustable bite pads were acceptable and 95% of the subjects approved of the overall fitting process and fit their device correctly.

In sum, the above summarized bench testing and user study results confirm that the Rest Assured Ready to Wear is substantially equivalent to the claimed predicate devices in intended use, device design, safety and effectiveness.

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

JAN 2 7 2012

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

Re: K112879
Trade/Device Name: Rest Assured Ready to Wear Nite Protector
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: December 28, 2011
Received: December 28, 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

Indications for Use Statement

510(k) Number (if known): K112879

Device Name: Rest Assured Ready to Wear Nite Protector

Indications for Use:

The Rest Assured Ready to Wear Nite Protector is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

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