K133423

DEC 20 2013

Ranir.

4701 East Paris Avenue SE
Grand Rapids, MI 49512 U.S.A.
Telephone 616-698-8880
Fax 616-698-0820

Attachment 8

510(k) Summary

K133423

DEC 20 2013

Ranir.

4701 East Paris Avenue SE
Grand Rapids, MI 49512 U.S.A.
Telephone 616-698-8880
Fax 616-698-0820

510(k) SUMMARY
Ranir, LLC's
Rest Assured Extra Comfort Nite Protector Dental Protector

1.

Submitter's Name:	**Ranir, LLC**
Address:	4701 East Paris Avenue SE Grand Rapids, MI 49512
Telephone Number:	Phone: (616) 698-8880 ext. 1278 Facsimile: (616) 222-0710
Contact Person:	Paula Bojsen, Global Regulatory Compliance Manager
Date Prepared:	October 30, 2013

2. Device Name:

Proprietary or Trade Name:	Rest Assured® Extra Comfort Nite Protector (Model BRX-220013) [Private Labeler Name] Extra Comfort Nite (or "Night") Protector [Private Labeler Name] Nite (or "Night") Protector [Private Labeler Name] Dental Protector
Common or Usual Name:	Dental protector Nightguard
Classification Name:	Mouthguard, Over-the-Counter
Product Code:	OBR

3. Predicate Devices:

Ranir, LLC's Rest Assured® Ready to Wear Nite Protector	(K112879)
Ranir, LLC's Rest Assured® Generation II Dental Protector	(K091792)
Prestige Brand's The Doctor's Advanced Comfort Night Guard	(K073220)

Ranir.

4701 East Paris Avenue SE
Grand Rapids, MI 49512 U.S.A.
Telephone 616-698-8880
Fax 616-698-0820

4. **Device Description**
The Rest Assured Extra Comfort Nite Protector is indicated 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 teeth grinding.

5. **Purpose of the Special 510(k) notice.**
The Rest Assured® Extra Comfort Nite Protector is a modification to Ranir's Rest Assured® Generation II Night Protector (K091792).

6. **Intended Use:**
The Rest Assured® Extra Comfort Nite Protector is indicated for use for protection against bruxism or night time teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

7. **Technological Characteristics:**
The Rest Assured® Extra Comfort Nite Guard is an occlusive nightguard, fitted to the consumer by the "boil and bite" method. Similarly, the predicate devices are occlusive nightguards fitted by the "boil and bite" method"; therefore, the Rest Assured® Extra Comfort Nite Guard is technologically similar to the predicate devices.

8. **Performance Testing**:
The Rest Assured® Extra Comfort Nite Guard complies with the following recognized consensus standards:
   - ISO 14971:2007, Medical devices - Application of risk management to medical devices
   - ISO 7405:2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
   - ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
   - ISO 10993-3:2003, Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
   - ISO 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
   - ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
   - ISO 10993-11:2010, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
   - ISO 10993-17:2002, Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances

Ranir

4701 East Paris Avenue SE
Grand Rapids, MI 49512 U.S.A.
Telephone 616-698-8880
Fax 616-698-0820

Ranir contracted with the North American Science Associates, Inc. ("NAMSA") to conduct comprehensive biocompatibility testing on the finished Rest Assured® Extra Comfort product, and NAMSA concluded that the combination of Elvax® and Elvaloy® used in the final Rest Assured® device demonstrated appropriate biocompatibility for its intended use and duration of exposure. This testing is similar and produced similar results as compared to the Gen II predicate device.

Comprehensive biocompatibility testing conducted by NAMSA was for cytotoxicity, oral mucosal irritation, acute systemic toxicity, sensitization, material mediated pyrogenicity, leachables / extractables characterization, systemic toxicity, and genotoxicity. It was found that the material combination is biocompatible for the intended use and anticipated duration of use, and there are no leachables / extractables that pose a safety risk.

The Rest Assured® Extra Comfort Nite Guard was compared to the Doctor's Advance Comfort Night Guard and evaluated for physical characteristics, workmanship, performance, and hazards by third party testing. Ranir's Rest Assured® Extra Comfort Nite Guard was found to be comparable to this predicate device.

Simulated wear testing, and boil and bite testing, was also conducted on the Rest Assured® Extra Comfort Nite Guard. These tests confirm that the modifications with respect to the predicate Gen II device do not impact structural integrity.

All verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

9. Substantial Equivalence

The Rest Assured® Extra Comfort Nite Guard possesses the same indications for use, technological characteristics, and principles of operation as the predicate devices (the currently marketed Ranir, LLC's Rest Assured® Generation II Dental Protector (091792), Rest Assured® Ready to Wear Nite Protector (K112879), and The Doctor's Advanced Comfort Fit Nightguard (K073220). The minor technological differences between the Rest Assured® Extra Comfort Nite Protector and the predicate devices raise no new questions of safety or effectiveness. Thus, the Rest Assured® Extra Comfort Nite Protector is substantially equivalent. All materials used are in the predicate devices, in different mixtures/combinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 20, 2013

Ranir, LLC
Ms. Paula Bojsen
Global Regulatory Compliance Manager
4701 East Paris Avenue SE
Grand Rapids, MI 49512

Re: K133423
Trade/Device Name: Rest Assured® Extra Comfort Nite Protector (Model BRX-220013)
Regulation Number: Unclassified
Regulation Name: Mouthguard Over-The-Counter
Regulatory Class: Unclassified
Product Code: OBR
Dated: September 17, 2013
Received: September 20, 2013

Dear Ms. Bojsen:

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 contact 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. 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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Rest Assured® Extra Comfort Nite Protector

Indications for Use *(Describe)*
The Rest Assured® Extra Comfort Nite Protector is indicated 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 teeth grinding.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Susan Runner DDS MA
Mary S. Runner -S
2013.12.18
08:37:11 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."