K063229

510(K) SUMMARY

Ranir Rest Assured™ Nite Protector

DEC 19 2006

The assigned 510(k) number is:_____.

1. **Preparer's Name, Address, Telephone Number, Contact Person, Date of Preparation**

Warner Norcross & Judd LLP
900 Fifth Third Center
111 Lyon Street N.W.
Grand Rapids, Michigan 49503

Contact: Christopher J. Predko

Telephone: (616) 752-2190
Fax: (616) 222-2190

Date Prepared: October 24, 2006

2. **Owner Name, Address, Telephone Number, Fax Number**

Ranir LLC
4701 East Paris Avenue
Grand Rapids, Michigan 49512

Telephone: (616) 698-8880
Fax: (616) 698-0820

3. **Name of the Device**

Rest Assured™ Nite Protector

4. **Common or Usual Name**

Dental Protector/Dental Mouthguard

5. **Classification Name**

Unclassified

6. Predicate Devices

K053580, Dental Concepts LLC, Doctors® Night Guard™
K024261, Dental Concepts LLC, Bite Plate
K014079, Inventive Resources, Inc., Dr. Hayes Bite Guard
K022809, Power Products, Inc.-Splintek, EZ Splint

7. Intended Use

The Rest Assured™ Nite Protector is indicated for protection against bruxism or night time teeth grinding. The device is intended to reduce damage to teeth and prevent noise associated with bruxing or grinding.

8. Device Description/Technological Characteristics

The Rest Assured™ Nite Protector, as packaged, is initially composed of two components: (1) a moldable soft upper component made of Elvax® thermoplastic resin and (2) a hard temporary fitting tray made of biocompatible medical grade Santoprene™. When heated and cooled, the upper Elvax® portion of the mouthguard may be molded to fit the consumer's upper teeth. During the brief fitting process, the Santoprene™ temporary fitting tray maintains the shape of the upper material and prevents the user from biting through the upper material. After the desired fit is achieved, the temporary fitting tray is removed and discarded.

9. Performance Data

No performance data is required for this 510(k) notice.

10. Comparison to Predicates/Substantial Equivalence Conclusion

The Rest Assured™ Nite Protector is as safe and effective as the predicate devices. With respect to physical makeup, the primary (upper) component of the Nite Protector, like the primary components of all four predicate devices, is made of Elvax®, a formable clear thermoplastic copolymer resin. As with the predicates, when heated and briefly cooled, the upper component can be molded to fit the upper teeth. The Nite Protector's secondary base component (the temporary fitting tray) is made of biocompatible medical grade Santoprene™, which has also been determined to be safe and effective for use in FDA cleared medical devices. The Nite Protector has similar intended uses and indications as the predicate devices. Like the Doctor's NightGuard product, the Nite Protector will be available over the counter and contains appropriate labeling and instructions for OTC use. Accordingly, the Rest Assured™ Nite Protector is substantially equivalent to predicate devices with respect to safety and effectiveness.

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

June 25, 2013

Ranir, Limited Liability Company
C/O Mr. Christopher Predko
Attorney
Warner Norcross & Judd, Limited Liability Partnership
900 Fifth Third Center
111 Lyon Street, North West
GRAND RAPIDS MI 49503

Re: K063229
Trade/Device Name: Ranir-Rest Assured™ Nite Protector
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: OBR
Dated: October 24, 2006
Received: October 25, 2006

Dear Mr. Predko:

This letter corrects our substantially equivalent letter of December 19, 2006.

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); 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,

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

K063229

Indications for Use Statement

510(k) Number if known: _____

Device Name: Ranir – Rest Assured™ Nite Protector

Indications for Use:

The Rest Assured™ Nite Protector is indicated for protection against bruxism or night time teeth grinding. The device is intended to reduce damage to teeth and prevent noise associated with bruxing or grinding.

Prescription Use ___ AND/OR Over-The-Counter Use X
(21 C.F.R. 801 Subpart D) (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)

Susan Runner

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

510(k) Number K063229