

K113326



510(k) Summary

JUN 27 2012

1. Purpose of the 510(k) Notice

OraLabs requests this 510(k) as it is a new device.

2. Submitter's Information – Name, Address, Telephone Number, Contact Person and Date Prepared

OraLabs, Inc.
Gary Schlatter, CEO
18685 East Plaza Drive
Parker, CO 80134
Phone:(303) 783-9499, Extension 3202
Fax: (303) 783-5759
www.oralabs.com

This summary was amended on 06/21/12 and any questions shall be addressed to:

Teresa Purdue
Quality Assurance Director
18685 East Plaza Drive
Parker, CO 80134
Phone:(303) 783-9499, Extension 3249
Fax: (303) 783-5759
www.oralabs.com

3. Device Name

- Proprietary name - Oral-B plus *Scope Outlast* Nighttime Dental Guard
- Common Name of Device – Dental Guard (Over-the-Counter)
- Classification Name – Unclassified
- Classification Product Code – OBR
- Review Panel - Dental

To my knowledge FDA has not classified this device.

4. Devices to Which Substantial Equivalence is Claimed:

OraLabs claims equivalence to Dentek's Custom Comfort Dental Guard, 510(k) Number K083400.

Dentek Oral Care, Inc.
307 Excellence Way
Maryville, TN 37801



Phone: (865) 983-1300
Facsimile: (865) 983-2444
Registration Number: 2938386
Product Code: OBR

5. Device Description

Description of device – a mouthguard constructed of a propylene-based elastomer. The target area is the oral cavity of individuals that suffer from bruxism, nighttime teeth grinding.

The device works by molding the thermoplastic resin to the individual's mouth. The thermoplastic resin can be molded after submerged in boiling water via the microwave. The molded thermoplastic resin is worn at to reduce damage to the teeth and to prevent the noise associated teeth grinding.

OraLabs Oral-B plus *Scope Outlast* Nighttime Dental Guard is intended for individuals age 18 and older. Thermoplastic can be molded to fit all sizes.

Technology

The Oral B Nighttime Dental Guard plus *Scope Outlast* and the predicate device rely on the same technology for performance.

Physical State

The dental mouthguard in its physical state is composed of the following ingredients:

- Propylene-based elastomer
- Flavor

This presents a soft propylene-based elastomer that is molded to the individual's teeth.

Technical Method

The dental mouthguard is a removable appliance that is fitted to the teeth by taking an impression of the teeth when in a heated state.

Scientific Concepts

The OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard is based on the scientific concept of a physical barrier placed between the individual's teeth while they sleep. The barrier is intended to reduce damage to the teeth as the upper and lower teeth contact each other. In addition, the physical barrier is intended to reduce the noise associated with bruxing or grinding.

6. Technological Characteristics

OraLabs Oral-B plus *Scope Outlast* Nighttime Dental Guard and the predicate device share the same scientific concept, a physical barrier placed between the upper



and lower teeth. Both devices use a soft, formable material that, when heated, fits to the individual's teeth.

OraLabs Oral-B plus *Scope Outlast* Nighttime Dental Guard uses a propylene based elastomer.

OraLabs Oral-B plus *Scope Outlast* Nighttime Dental Guard incorporates flavor with the nighttime dental guard. It does not change the functional characteristics in any way.

The OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard has passed biocompatibility testing listed for a medical device. As such, it is safe for an individual to use for a prolonged amount of time.

7. Performance Data:

- **ISO 10993-12:2007 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials**
- **ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity**
- **ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Test for Irritation and Skin Sensitization, Pages 11-14, Pages 18-26**
- **ISO 10993-11: 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity**

8. Comparison Statements

OraLabs Oral-B plus *Scope Outlast* Nighttime Dental Guard has the addition of flavor to the propylene-based elastomer. This allows the individual wearing the device to have a mint-flavored sensation upon use.

The addition of flavor does not change the physical barrier characteristics from the predicate device, **Dentek's Custom Comfort Dental Guard**.

Our device provides a physical barrier and is effective, safe, and substantially equivalent for use by individuals that experience night time teeth grinding.

A comparison table is included as an attachment to this section.

9. Non-Clinical Data

OraLabs relied on Biocompatibility testing as the basis for non-clinical data. The testing performed indicates the dental guard is safe for individuals to use.



The biocompatibility testing performed on the OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard included the tests listed below:

- MEM Elution Using L-929 Mouse Fibroblast Cells (ISO) (Cytotoxicity)
- Guinea Pig Maximization Sensitization Test (ISO) (Method for Biomaterial Extracts) – Per Extract
- Intracutaneous Irritation Test (ISO) (3 Rabbits) – Per Extract
- Acute Systemic Injection Test (ISO) – Per Extract
- SubChronic (14-day) Intravenous Toxicity Study in Non-Swiss Webster Mice (14 Repeat Dose Exposure) (includes hematology & clinical chemistry) (GLP)

OraLabs researched literature for the symptoms and potential issues of “bruxism”. Two sources we used were Stedmans Medical Dictionary and the Merck Manual. Research states that grinding can lead to jaw pain and other problems. A nighttime dental guard is a product that allows consumers to provide a barrier between their upper and lower teeth during periods in which they grind their teeth.

10. Indications for Use

The Oral B plus *Scope Outlast* Nighttime Dental Guard is an Over-the-Counter dental guard indicated for the protection against bruxism - the nighttime clenching and grinding of the teeth.

It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated with teeth grinding.

11. Conclusion

The biocompatibility testing objectively concludes that the OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard is safe for consumers.

Dental guards have been used by several manufacturers to provide a protective barrier between the consumer’s upper and lower teeth.

OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard has many of the same characteristics as the other devices, a soft, formable propylene-based elastomer that is fitted to individuals 18 years or older.

OraLabs Oral B plus *Scope Outlast* Nighttime Dental Guard is as safe and effective as the **Dentek’s Custom Comfort Dental Guard**.



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

JUN 27 2012

Ms. Teresa Purdue
Quality Assurance Director
Oralabs, Incorporated
18685 East Plaza Drive
Parker, Colorado 80134

Re: K113326

Trade/Device Name: Oral B plus Scope Outlast Nighttime Dental Guard
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: OBR
Dated: June 1, 2012
Received: June 4, 2012

Dear Ms. Teresa Purdue:

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

K113326

Indications for Use Statement

510(k) Number (if known) K113326

Device Name: Oral B plus *Scope Outlast* Nighttime Dental Guard

Indications for Use:

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It is intended for use in the mouth at night to reduce damage to the teeth and to prevent the noise associated teeth 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)



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

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