K100545

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II. 510(k) Summary JUN - 4 2010

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

General Information:

A. Submitted By:

Splintek, Inc.
3325 Wyoming St
Kansas City, MO 64111
Tel: 816-531-2008
Fax: 816-531-1968

Contact Person: Dr. T. J. Brown

Date Prepared: May 27, 2010

B. Device Trade Name: SleepRight® Original

Common Name: Mouthguard

Classification Name: Unclassified

C. Predicate Devices: SleepRight® -Low profile

D. Device Description:

An adjustable protector that provides a barrier between the upper and lower posterior teeth. The flexible connecting strap provides 5 adjustments for the bite pads.

E. OTC Indications for Use:

The SleepRight® Original is indicated for the protection against bruxism or night time teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Cautions: Do not use if you are under 18 years of age; have TMJ; have teeth or jaw pain; or if the dental guard is broken or damaged. Do not use as an athletic mouth guard. Do not use for more than 12 hours in a 24 hour period. Not for use with dentures, braces or other dental appliances. Do not use for more than 3 months from initial use without consulting your dentist. Ask a dentist before use if you have loose fillings, loose caps, or unfilled cavities; jaw clicking or pain, teeth pain, face pain; difficulty chewing; mouth sores; gum disease or bleeding gums; or serious respiratory problems. While using the product, see your dentist at least

every 6 months. Stop use and see a dentist if you develop loose teeth or a change in your bite; experience pain or other irregularity; the product easily falls out of your mouth or causes you to gag; you develop bleeding gums, soreness, or other reaction inside your mouth.

F. Comparison of Technical Characteristics to Predicate Device:

Element of Comparison	**Subject Device SleepRight® Original**	**Predicate SleepRight® -Low profile**
510(k) Number	K100545	K071404
Device Description:	An adjustable protector that provides a barrier between the upper and lower posterior teeth. The flexible connecting strap provides 5 adjustments for the bite pads.	An adjustable protector that provides a barrier between the upper and lower posterior teeth. The flexible connecting strap provides 4 adjustments for articulating bite pads.
Physical Characteristics Material	Elvax® strap, Polypropylene bite pads	Elvax® strap, Polypropylene and Kraton® bite pads
Thermal Safety	Same	Warm water (not boiling) is recommended for fitting.
Method of Manufacture	Same	Injection Molded
Rx or OTC	OTC	Rx and OTC
Reusable	Same	Yes, single patient
Sterile	Same	No
Method of Disinfection	Same	Cool water, mouthwash or toothpaste.
Design	Same except bite pads do not articulate	Partial coverage, preformed oral appliance with adjustable bite pads. No boiling required.
Compatibility with Environment & Other Devices	Same	Biocompatible materials used.
Indications for Use **OTC**	Same	Protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.
Target Population	Same	Individuals over the age of 18 who clench and grind their teeth.
Where used	Same	For home use.
Flavored	No	Yes

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

JUN - 4 2010

Power-Products-Incorporated-Splintek
C/O Ms. Melaine Hasek
Senior Regulatory Affairs Manager
PRA International
9755 Ridge Drive
Lenexa, Kansas 66219

Re: K100545
Trade/Device Name: SleepRight® Original
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: May 28, 2010
Received: June 1, 2010

Dear Ms. Hasek:

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

K100545

I. Indications for Use:

Indications for Use Form

510(k) Number (if known): _____

Device Name: SleepRight Original

Indications For Use [Over The Counter (OTC)]:

The SleepRight Original is indicated for the protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use _____ *(Part 21 CFR 801 Subpart D)* *AND/OR* *Over-The-Counter Use* X *(21 CFR 801 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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