K071404

II. 510(k) Summary

AUG 17 2007

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

General Information:

A. Submitted By:

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

Contact Person: Dr. T. J. Brown

Date Prepared: July 25, 2007

B. Device Trade Name: SleepRight® -Select, SleepRight®-Low Profile and SleepRight®-Advance,
SleepRight® - Low Profile Rx and
SleepRight® - Advance Rx

Common Name: Mouthguard/nightguard

Classification Name: Unclassified

C. Predicate Devices: EZ Splint – Power Products / Splintek
The Doctor's® NightGuard – Dental Concepts, LLC

D. Device Description:

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.

E. Prescription Indications for Use:

- Protection against teeth grinding, bruxism & jaw clenching.
- Short-term pain relief from muscle spasm due to occlusal interference.
- For the prevention of chronic tension and TMJ caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

OTC Indications for Use:

The SleepRight® adjustable night guard 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.

F. Comparison of Technical Characteristics to Predicate Device:

Element of Comparison	**Subject Device SleepRight®**	**Predicate EZ Splint**	**Predicate Doctor's NightGuard**
Physical Characteristics **Material** **Select** **Low Profile** **Advance**	 Same Same Elvax Strap Polyurethane and Pellethane bite pads.	Elvax® strap, Polypropylene and Kraton® bite pads	Elvax resin and Elvaloy®
Method of Manufacture	Same	Injection Molded	Injection Molded
Rx or OTC	N/A	Rx	OTC
Reusable	Same	Yes, single consumer	Yes, single consumer
Design	Same as EZ Splint	Partial coverage, preformed oral appliance with adjustable bite pads. No boiling required.	Full coverage of upper arch. Uses boil and bite technology to adjust fit.
Indications for Use	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.	Protection against teeth grinding, bruxism & jaw clenching. Short-term pain relief from muscle spasm due to occlusal interference. For the prevention of chronic tension and TMJ caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Splintek – Power Products
C/O Ms. Melanie K. Hasek, RAC
Senior Project Manager, Regulatory Affairs
PRA International
9755 Ridge Drive
Lenexa, Kansas 66219

Re: K071404
Trade/Device Name: SleepRight® - Select
SleepRight® - Low Profile and SleepRight® - Advance
SleepRight® - Low Profile Rx and SleepRight® - Advance Rx
Regulation Number: Unclassified
Regulation Name: Not Applicable
Regulatory Class: Unclassified
Product Code: MQC and OBR
Dated: July 25, 2007
Received: July 27, 2007

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.

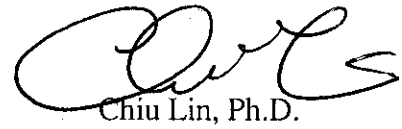
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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 Form

510(k) Number (if known): K071404

Device Name: SleepRight® - Low Profile Rx and SleepRight® - Advance Rx

Indications For Use (Rx):

- Protection against teeth grinding, bruxism and jaw clenching
- Short-term pain relief from muscle spasm due to occlusal interference.
- For the prevention of chronic tension and temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

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

Susan Runner

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

510(k) Number: K071404

I. Indications for Use:

Indications for Use Form

510(k) Number (if known): K071404

Device Name: SleepRight® - Select, SleepRight® - Low Profile and SleepRight® - Advance

Indications For Use (OTC):

The SleepRight® adjustable night guard 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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