OCT 17 2003

Attachment 4
Revised 7/16/03

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is K022809

1. **Submitter's Identification:**

Power Products, Inc. - Splintek
3325 Wyoming Street
Kansas City, Missouri 64111
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Date Summary Prepared: August 6, 2002

2. **Name of the Device:**

Classification Name: Device, Jaw Repositioning

Common Name: Oral Occlusal Appliance or splint

Proprietary Name : EZ Splint and EZ Splint PM

Classification/Panel: These devices have not been classified. The Dental device panel will review this submission. The product code that has been assigned is LQZ.

3. **Predicate Device Information:** These devices are substantially equivalent in design and intended use to the Dr. Hays Bite Guard, K104029, as well as the NTI Tension Suppression System, K010876. Both predicates are used by the patient

to assist in the treatment and management of bruxism, teeth-grinding, and associated mandibular muscle tension and pain.

4. **Device Description:** The devices are constructed of a thermal sensitive Elvax strap and polypropylene and Kraton® bite pads. The bite pads may be adjusted for the individual patient. Although the two products look similar, the EZ-Splint PM has an anatomically contoured shape for maximum cheek retention and stability during sleep, The EZ-Splint was designed as small as possible for speech and maximum flexibility when used in conjunction with dental and orthodontic work. The EZ-Splint's narrow shape makes it favorable for daytime use.

5. **Intended Use:** 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 temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth.

6. **Comparison to Predicate Devices:** Please refer to the following chart.

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FEA URE	EZ-SPLINT EZ-SPLINT PM	Dr. HAYS BITE GUARD	NTI TENSION SUPPRESION SYST.
Indic ition for Use	• Protection against teeth grinding, bruxism and jaw clenching. • Short-term pain relief from muscle spasm due to occlusal interferer.ce. • For the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth.	Same	Same and for the prophylatic treatment of migraine pain.
Des gn	Adjustible, pre-formed oral appliance. The bite pads may be moved to adjust to the patient to prevent contact of posterior teeth and to provide a resilent break in the teeth clenching cycle.	Full mouth appliance that is custom molded by the practioner for the patient.	Customized by the practioner for the patient, fitted over the two maxillary central incisors with a dome shaped protrusion which extends lingually to prevent posterior of canine tooth contact
Ma erials	Elvax strap, Polypropelene and Kraton bites pads	Lexan and Elvax	Polycarbonate
Me hod of Ma ufacture	Injection molded	Dental laboratory molded	Injection molded
Pr scription Device	Yes	Yes	Yes
Re isable	Yes, single patient	Same	Same
Me hod of de infection	Warm water, soap, and toothbrush	Same	Same

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Non clinical tests were not performed.

8. **Discussion of Clinical Tests Performed:**

Clinical tests were not performed

. **Conclusions:**

The EZ-Splint and the EZ-Splint PM are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2003

Power Products, Incorporated-Splintek
C/O Ms. Carolann Kotula
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K022809
Trade/Device Name: EZ-Splint & EZ Splint PM
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MQC
Dated: July 30, 2003
Received: July 31, 2003

Dear Ms. Kotula:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Splintek-PPI
EZ-Splint; EZ-Splint PM
K022809

K022809

Attachment 3
Revised 7/16/03

510(k) Number (if known): K022809

Device Name: EZ-Splint; EZ-Splint PM

Indications For Use:

- 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 temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth.

(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

510(k) Number: K022809

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**