Splintek, Inc.
Samantha Schroeder
Research and Development Chemist
15555 West 108th Street
Lenexa, Kansas 66219

November 17, 2017

Re: K172223
Trade/Device Name: SleepRight® ProRx® Custom Dental Guard
Regulatory Class: Unclassified
Product Code: OBR, MQC
Dated: October 18, 2017
Received: October 19, 2017

Dear Samantha Schroeder:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172223

Device Name
SleepRight® ProRx® Custom Dental Guard

Indications for Use *(Describe)*

The SleepRight® ProRx® Custom Dental 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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172223

Device Name
SleepRight® ProRx® Custom Dental Guard

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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II. 510(k) Summary

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.
15555 West 108th Street
Lenexa, KS 66219
Tel: 816-531-2008
Fax: 816-531-1968

Contact Person: Samantha Schroeder

Date Prepared November 16, 2017

B. Device Trade Name: SleepRight® ProRx® Custom Dental Guard

Common Name: Mouthguard

Classification Name: Unclassified (OBR, MQC)

C. Primary Predicate Device: ProTech Dent® (Akervall Technologies, K121272)
Reference Predicate Device: SleepRight® -Advance (Splintek Inc., K071404)

D. Device Description:

The SleepRight® ProRx® Custom Dental Guard is a full occlusal custom formable protector that provides a barrier between the upper and lower teeth. Contains a hard core material enveloped by a moldable thermoplastic. The guard is heated in hot (not boiling) water until it becomes malleable and then formed to the consumers upper teeth. To achieve a custom fit, the guard is inserted into the mouth and the side walls are gently pushed up to surround the teeth. The material hardens in roughly one minute. The SleepRight® ProRx® Custom Dental Guard has a tensile strength of 29 Mpa and a Shore D hardness value comparable to the primary predicate device, the ProTech Dent®.

E. Performance Data:

The following performance testing was completed for the SleepRight® ProRx® Custom Dental Guard:

- Comparative evaluation of the physical properties of the materials of construction of the SleepRight® ProRx® Custom Dental Guard and the primary predicate device, the ProTech Dent®.

- Comparative wear and abrasion resistance testing of the SleepRight® ProRx® Custom Dental Guard and the primary predicate device the ProTech Dent®.
- Biocompatibility testing
    - Cytotoxicity (ISO 10993 – 5)
    - Sensitization and Irritation (ISO 10993 – 10)

F. OTC Indications for Use:

The SleepRight® ProRx® Custom Dental 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 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 temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

G. Comparison of Technical Characteristics to Predicate Device:

Element of Comparison	**Subject Device SleepRight® ProRx®**	**Primary Predicate ProTech Dent®**	**Reference Predicate SleepRight® -Advance**
510(k) Number	K172223	K121272	K071404
Physical Characteristics Material	Thermoplastic Polymer - Polycaprolactone	Thermoplastic Polymer - Polycaprolactone	Elvax Strap Polyurethane and Pellethane bite pads.
Method of Manufacture	Injection Molded	Injection Molded	Injection Molded
Rx or OTC	Rx and OTC	OTC	Rx and OTC
Reusable	Yes, single consumer.	Yes, single consumer.	Yes, single consumer.
Design	Adjustable preformed oral device.	Adjustable preformed oral device.	Partial coverage, preformed oral appliance with adjustable bite pads.

Element of Comparison	Subject Device SleepRight® ProRx®	Primary Predicate ProTech Dent®	Reference Predicate SleepRight® -Advance
510(k) Number	K172223	K121272	K071404
Indications for Use **OTC** **Rx**	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. 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 temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.	The Akervall Technologies mouthguards (ProTech Dent®) are indicated for use in protecting the teeth and reduce damage caused by bruxism or nighttime grinding.	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 temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

H. Conclusion:

The SleepRight® ProRx® Custom Dental Guard has the same indications for use, same materials of construction, same technological characteristics, and the same principals of operation as the predicate devices ProTech Dent® (K121272) and SleepRight® -Advance (K071404). Therefore, the SleepRight® ProRx® Custom Dental Guard is substantially equivalent to the predicate devices.