December 13, 2021

Splintek, Inc.
Thomas Brown
Chief Executive Officer (CEO) of Splintek, Inc.
15555 West 108th Street
Lenexa, Kansas 66219

Re: K212706
Trade/Device Name: SleepRight ProRx + Custom Dental Guard, SleepRight ProRx Custom Dental Guard
Regulatory Class: Unclassified
Product Code: OBR, MQC
Dated: November 08, 2021
Received: November 12, 2021

Dear Thomas Brown:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212706

Device Name
SleepRight® ProRx® + Custom Dental Guard

Indications for Use *(Describe)*
• Protection against bruxism or nighttime teeth grinding
• 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.

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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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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510(k) Number *(if known)*
K212706

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
• 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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510(k) Number *(if known)*
K212706

Device Name
SleepRight® ProRx® Custom Dental Guard

Indications for Use *(Describe)*
• Protection against bruxism or nighttime teeth grinding
• 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)

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510(k) Number *(if known)*
K212706

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
• 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)*

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II. 510(k) Summary

This summary of 510(k) 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: Thomas W. Brown

Date Prepared: December 2, 2021

B. Device Trade Name: SleepRight® ProRx® + Custom Dental Guard (K212706)
SleepRight® ProRx® Custom Dental Guard (K212706)

Common Name: Mouthguard

Classification Name: Unclassified (OBR, MQC)

C. Primary Predicate Device: SleepRight® ProRx® Custom Dental Guard (Splintek Inc., K193577)

Reference Predicate Device: SleepRight® ProRx™ Custom Dental Guard (Splintek Inc., K172223)

D. Device Description:

The subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706) are the second-generation guard to the SleepRight® ProRx™ Custom Dental Guard (K172223). Both subject devices (K212706) are completely identical to each other, except for the material that makes up the internal core of each guard. The subject devices (K212706) are both a full occlusal custom formable protector that acts as a barrier between the upper and lower teeth to protect the teeth against bruxism or nighttime teeth grinding. The subject devices (K212706) both contain the exact same horizontal core design with a vertical sectional lattice structure, primarily wrapping around the labial and buccal side of the teeth, as well as around the lingual posterior side of the teeth. The core and lattice are fully encapsulated by a moldable thermoplastic material in both guards. The guards are designed to be fit using the exact same method to heat the guard in hot (not boiling) water until it becomes malleable and can be formed to the consumers upper teeth. To achieve a custom fit, the guard is inserted into the mouth and the side walls/lattice are gently pushed to surround the teeth. The lattice retains the malleable material up against the teeth until the device hardens in approximately four minutes.

E. Performance Data:

The following performance testing was completed for the subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706):

- Comparative evaluation in the materials of construction for the subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706); the primary predicate device, the SleepRight® ProRx® Custom Dental Guard (K193577); and the reference predicate device, the SleepRight® ProRx™ Custom Dental Guard (K172223). See the tests performed below.
    - The subject devices (K212706), the primary predicate device (K193577), and the reference predicate device (K172223) all contain an internal core comprised of materials that are suitable to maintain the structural integrity needed to be overmolded, to withstand the hot (not boiling) water during the fitting process, and to provide protection to the teeth during bruxism; thus, both subject devices are substantially equivalent to both predicate devices.
    - The subject devices (K212706), the primary predicate device (K193577), and the reference predicate device (K172223) all contain the same moldable thermoplastic material that incapsulates the internal core, thus both subject devices are substantially equivalent to both predicate devices.

Test Performed	**Standard**	**Acceptance Criteria Met**
Tensile Strength	ASTM D638	Yes
Flexural Strength	ASTM D790	Yes
Flexural Modulus	ASTM D790	Yes
Elongation	ASTM D638	Yes
Shore D Hardness	ASTM D2240	Yes

- Biocompatibility testing of the subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706). See the biocompatibility testing acceptance criteria below stating that the subject devices (K212706) are biocompatible. The biocompatibility testing supports that both subject devices satisfy the biocompatibility testing acceptance criteria and are substantially equivalent to both predicate devices.

Test Performed	Standard	Acceptance Criteria	Acceptance Criteria Met
Cytotoxicity (in vitro)	ISO 10993-5:2009	Cell morphology graded greater than 2 is considered to have a cytotoxic effect	Yes
Sensitization (in vivo)	ISO 10993-10:2010	Any skin reaction scores greater than the scores received by the negative control group, were considered to represent sensitization	Yes
Irritation (in vivo)	ISO 10993-10:2010 ISO 10993-23:2021	The requirements are met if the difference between the test article extract average score and the control average score is 1.0 or less and the test does not fail at any observation period	Yes

- Comparative wear and abrasion resistance testing of the subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706); and the DenTek™ Professional-Fit™ Dental Guard (Pro-Fit).
    - The longevity of the guards was evaluated by comparing the number of "bruxing" cycles that the guards could withstand before failure. The data demonstrated that both subject devices (K212706) lasted an order of magnitude longer than the Pro-Fit.
    - The abrasion results in the subject devices (K212706) are comparable to the primary predicate device (K193577) and to the reference predicate device (K172223) as all subject devices and predicate devices lasted an order of magnitude longer than the Pro-Fit and are therefore substantially equivalent.

F. Over-the-Counter (OTC) Indications for Use:

- Protection against bruxism or nighttime teeth grinding
- Reduce damage to the teeth and to prevent the noise associated with bruxing or grinding

Prescription (Rx) Indications for Use:

- Protection against teeth grinding, bruxism, and jaw clenching
- Short-term pain relief from muscle spasm due to occlusal interference
- 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® + (K212706)**	**Subject Device SleepRight® ProRx® (K212706)**	**Primary Predicate SleepRight® ProRx® (K193577)**	**Reference Predicate SleepRight® ProRx™ (K172223)**
510(k) Number	K212706	K212706	K193577	K172223
Physical Characteristics Material	Thermoplastic Polymer-Polycaprolactone	Thermoplastic Polymer-Polycaprolactone	Thermoplastic Polymer-Polycaprolactone	Thermoplastic Polymer-Polycaprolactone
Method of Manufacture	Injection Molded	Injection Molded	Injection Molded	Injection Molded
OTC or Rx	OTC and Rx	OTC and Rx	OTC and Rx	OTC and Rx
Reusable	Yes, single consumer	Yes, single consumer	Yes, single consumer	Yes, single consumer
Design	Adjustable pre-formed oral device	Adjustable pre-formed oral device	Adjustable pre-formed oral device	Adjustable pre-formed oral device
Indications for Use **OTC**	Protection against bruxism or nighttime teeth grinding. Reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	Protection against bruxism or nighttime teeth grinding. Reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	Protection against bruxism or nighttime teeth grinding. Reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	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.
Rx	Protection against teeth grinding, bruxism, and jaw clenching. Short-term pain relief from muscle spasm due to occlusal interference. 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.	Protection against teeth grinding, bruxism, and jaw clenching. Short-term pain relief from muscle spasm due to occlusal interference. 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.	Protection against teeth grinding, bruxism, and jaw clenching. Short-term pain relief from muscle spasm due to occlusal interference. 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.	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 subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706) are the second-generation guard to the SleepRight® ProRx™ Custom Dental Guard (K172223). The subject devices, the SleepRight® ProRx® + Custom Dental Guard (K212706) and the SleepRight® ProRx® Custom Dental Guard (K212706) have the same indications for use, similar materials of construction, same technological characteristics, and the same principals of operation as the primary predicate device, the SleepRight® ProRx® Custom Dental Guard (K193577) and the reference predicate device, the SleepRight® ProRx™ Custom Dental Guard (K172223). Therefore, both subject devices are substantially equivalent to the predicate devices.