January 11, 2018

Sleep Specialties, LLC.
James Smith, Ph.D.
Consultant
28591 Springfield Drive
Laguna Niguel, California 92677

Re: K172452
Trade/Device Name: Bruxor™
Regulatory Class: Unclassified
Product Code: OBR
Dated: November 30, 2017
Received: December 4, 2017

Dear James Smith, Ph.D.:

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)*

Device Name
Bruxor™

Indications for Use *(Describe)*

Bruxor™ is intended to protect teeth and reduce the damage caused by bruxing, or night time teeth grinding, and to prevent the noise associated with bruxing and 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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SleepSpecialties

510(k) SUMMARY

Submitted by:

Owner's Name:	James Fallon
Address:	2565 South Las Vegas Blvd., Suite #184 Las Vegas, NV 89109
Contact:	James S. Fallon, Managing Partner
Telephone:	949-702-3797
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Contact Person:

Name	James Smith, Ph.D.
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Date Prepared: January 3, 2018

Trade Name: Bruxor™

Common Name: Mouthguard

Classification Name: Mouthguard, Over-The-Counter

Device Class: Unclassified

Product Code: OBR

Predicate Device: Custom Comfort Nightguard Version 2
(Dentek Oral Care, Inc.)

Predicate 510(k) #: K091660

Reference Device: SnoreRx (K170825; Apnea Sciences Corporation)

Device Description: The Bruxor mouthguard consists of a single *'boil & bite'* tray, fabricated from a thermoplastic resin, that fits over the upper dental arch.

Intended Use: Bruxor™ is intended to protect teeth and reduce the damage caused by bruxing, or night time teeth grinding, and to prevent the noise associated with bruxing and grinding.

Technology Comparison: The technical characteristics of Bruxor are substantially equivalent to the predicate device. The table below compares the technological aspects of the new and predicate device.

Subject Area	Bruxor	Predicate	Differences
Product Code	ORB	ORB	
Product Classification	Unclassified	Unclassified	
Classification Name	Mouthguard, OTC	Mouthguard, OTC	
Proprietary Name	Bruxor™	Custom Comfort Nightguard Version 2	
Technological Features	Intraoral dental tray	Intraoral dental tray	
Intended Use	Aids in the reduction of tooth damage and noise due to bruxing and grinding	Aids in the reduction of tooth damage and noise due to bruxing and grinding	
Indications for Use	Bruxor™ is intended to protect teeth and reduce the damage caused by bruxing, or night time teeth grinding, and to prevent the noise associated with bruxing and grinding.	The Custom Comfort Nightguard Version 2 is indicated for use for 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.	Minor differences in phrasing, however the meaning is equivalent.
Materials	– Formable material (thermoplastic resin)	– Formable tray (thermoplastic resin) – Non-formable base – Non-formable fitting tray	The Bruxor uses a different thermoplastic resin and does not include a non-formable base or fitting tray.
Desirable Characteristics	Home use, heat sensitive / moldable, custom fitted	Home use, heat sensitive / moldable, custom fitted	
Specifications:	– Custom-fitted intraoral device – Covers the upper teeth – Reusable, single-user	– Custom-fitted intraoral device – Covers the upper teeth – Reusable, single-user	
Sterility	Non-sterile	Non-sterile	
Biocompatibility	ISO 10993-1	ISO 10993-1	
Anatomical Sites	Intraoral, during sleep	Intraoral, during sleep	
Human Factors	Standard ‘boil-and-bite’ fitting	Standard ‘boil-and-bite’ fitting	
Compatibility with the environment & other devices	Label warnings against use with certain other dental accessories	Label warnings against use with certain other dental accessories	

Nonclinical Testing	Biocompatibility was established in accordance with ISO 10993 requirements. Device material physical properties included melting point (ISO 3146), density (ISO 1183), and melt flow rate (ISO 1183). Biocompatibility and physical properties of the thermoplastic resin material were previously established through the reference device (K170825). Additional test reports were therefore not submitted as a part of this filing.
Conclusion of Comparison:	Based upon the technological characteristics, materials of construction, and general design considerations, Bruxor has been determined to be substantially equivalent to its predicate device.