August 5, 2019

McKeon Products
% Elizabeth FitzGerald
Director, Regulatory Intelligence
Right Submission LLC
59 High Street
Newton, Massachusetts 02464

Re: K191033
Trade/Device Name: LunaGuard Nighttime Dental Protector
Regulatory Class: Unclassified
Product Code: OBR
Dated: May 7, 2019
Received: May 8, 2019

Dear Elizabeth FitzGerald:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number (if known)
K191033

Device Name

LunaGuard™ Nighttime Dental Protector

Indications for Use (Describe)

The LunaGuard™ Nighttime Dental Protector is indicated for use in protecting the teeth and reducing damage caused by bruxism or nighttime 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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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	Devin Benner CEO McKeon Products 25460 Guenther Warren, MI 48091 USA Telephone: 586-427-7560 devin@macksearplugs.com
Contact:	Elizabeth FitzGerald Director, Regulatory Intelligence Right Submission LLC 59 High Street Newton, MA 02464 USA Telephone: 781-413-7345 elizabeth@rightsubmission.com
Date Summary Prepared:	April 17, 2019

5.2 Name of the Device

Trade Name:	LunaGuard™ Nighttime Dental Protector
Common Name:	Over-the-Counter Dental Guard
Classification Name:	Mouthguard, Over-the Counter
Review Panel:	Dental
Regulation:	Unclassified
Class:	Class II
Product Code:	OBR

5.3 Equivalence Claimed to Predicate Device

The LunaGuard™ Nighttime Dental Protector is equivalent to the Pro Tech Dent (K121272), manufactured by Akervall Technologies Inc..

5.4 Device Description

The LunaGuard™ Nighttime Dental Protector is an over-the-counter, flexible and moldable one-piece dental guard consisting of a lightweight polycaprolactone (PCL) plastic material. This PCL material can diffuse and

absorb grinding forces, along with the microperforations in the mouthguard, to protect the teeth from the grinding and clenching associated with bruxism.

When in place over the upper teeth, the guard maintains separation between upper and lower teeth, reducing noise and damage associated with teeth grinding. It is designed to fit around the teeth with no or minimal space in order to form a barrier between the upper and lower teeth. The lightweight, thin design allows for comfort while sleeping, and does not impede speaking, drinking, or breathing.

The LunaGuard™ material is self-fit by the user using the "boil and bite" method. Once submerged in hot but not boiling water, the dental guard turns clear when it reaches 160 degrees Fahrenheit (71.1 degrees Celsius), indicating readiness to mold. At this point, the user shapes the dental guard around their upper teeth for a snug and user-specific fit.

5.5 Indications for Use

The LunaGuard™ Nighttime Dental Protector is indicated for use in protecting the teeth and reducing damage caused by bruxism or nighttime grinding.

The Indications for Use of the subject device is identical to the Indications for Use of the predicate device, the ProTech Dent.

5.6 Comparison of Technological Characteristics

The LunaGuard™ and the ProTech Dent have the same intended use and indications for use, and are similar in terms of design, materials, method of action, and principles of operation. They are over-the-counter re-moldable dental guards, provided non-sterile for a single user. They are composed of the same polycaprolactone (PCL) plastic material, are the same thickness (1.6 mm), and were found to have similar physical properties as demonstrated by comparative performance testing. Both were found to be biocompatible per ISO 10993.

5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility testing on patient contacting materials was completed in accordance with the requirements of ISO 10993-1: 2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The LunaGuard™ is categorized as a surface device that contacts intraoral (i.e., mucosal, gingival, and palatal) surfaces for limited contact. Results show that the device is biocompatible for its intended use.

Non-Clinical Testing

The physical properties of the LunaGuard™ device were tested against those of the predicate. Comparative testing found the devices to be equivalent with respect to density, hot stage optical microscopy, hardness, melt flow rate, and tensile testing.

5.8 Conclusion

Performance testing and comparison of technological characteristics between the LunaGuard™ and the predicate demonstrate that the LunaGuard™ is substantially equivalent with regard to intended use, operation, function, and technological characteristics.