Koncept Innovators, LLC.
% Maureen Garner
President
New World Regulatory Solutions, Inc.
11700 W. Charleston Boulevard Suite 170-390
Las Vegas, Nevada 89135

January 18, 2019

Re: K181099
Trade/Device Name: Bright Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: December 19, 2018
Received: December 21, 2018

Dear Maureen Garner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.18 08:12:19 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181099

Device Name
Bright Guard

Indications for Use *(Describe)*

Bright Guard is a mouth guard intended to protect against grinding and clenching.

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.

510(k) Summary for Bright Guard

K181099

Date of 510(k) Summary Preparation: January 15, 2019

1. Trade (Proprietary) Name: Bright Guard

2. Common Name: Mouth Guard, Over-The-Counter

3. Contact Information

Primary [Regulatory Correspondent]

Contact: Maureen Garner, President
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Secondary [Applicant/Sponsor]

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1619 Executive Avenue
Myrtle Beach, SC 29577 USA

4. Device Classification & Panel

Classification Panel:	Dental
Classification Name:	Unclassified, Pre-Amendment
Product Code:	OBR
Trade/Proprietary Name:	Bright Guard
Common Name:	Mouth Guard

5. Primary Predicate Device: GrindGuardN, K133037;
Reference Device: Rest Assured Extra Comfort Nite Protector Dental Protector, K133423.

6. Device Description

Bright Guard is comprised of a mouth guard, spatula and storage case. The mouth guard is an over-the-counter, flexible and moldable one-piece dental mouth guard, which is used as a barrier between teeth for individuals who grind their teeth. Bright Guard mouth guard is intended to be worn while sleeping. The mouth guard material is conformable to wear, and it can be self-fit by the 'boil and bite' method (submerging in hot water to make the material malleable to fit on the upper teeth of the oral cavity). Bright Guard mouth guard is constructed of 100% Thermoplastic

resin Propylene Elastomer (TPE) material (ethylene-vinyl-acetate) [Elvax]. When heated it forms to the individual's teeth. It is non-flavored and has no color additives. Bright Guard does not contain Bisphenol A (BPA) or phthalates and is free of natural rubber latex. The spatula and storage case are composed of 100% Polypropylene. The materials in Bright Guard are used in various other 510(k) cleared dental mouth guards. The three components (mouth guard, spatula and storage case) are manufactured by injection molding. Bright Guard mouth guard Is provided in one model/size, is reusable by a single individual at least eighteen (18) years of age and is supplied as non-sterile.

7. Indications for Use

Bright Guard is a mouth guard intended to protect against grinding and clenching. For over-the-counter use.

8. Summary of Substantial Equivalence

Bright Guard, like the primary predicate (GrindGuardN, K133037) and reference device (Rest Assured Extra Comfort Nite Protector Dental Protector), cushions the teeth and keeps the upper teeth from contacting the bottom teeth. In this way, Bright Guard, like the predicate and reference device, acts as a protective barrier between teeth.

Bright Guard has the same technical characteristics as the predicate and reference devices, a soft, formable propylene-based elastomer/thermoplastic resin that, by way of the 'boil and bite' method, is fitted to an individual. Both the Bright Guard and predicate device are molded to the upper arches providing a protective barrier between the individual's upper and lower teeth to prevent grinding.

Bright Guard and the predicate device have the same intended use, indications for use and principle of operation.

The table below compares the technological characteristics of Bright Guard and the primary predicate and reference device.

Comparison of Characteristics

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Similarities and Differences**
Trade Name / Brand Name	Bright Guard	GrindGuardN	Rest Assured Extra Comfort Nite Protector Dental Protector	N/A
510(k)#	K181099	K133037	K133423	N/A
Indications for Use	Bright Guard is a mouth guard intended to protect against grinding and clenching.	GrindGuardN is a mouth guard intended to protect against grinding and clenching.	The Rest Assured Extra Comfort Nite Protector Dental Protector is indicated for use for protection against bruxism or night time teeth grinding. The device is intended to reduce damage to teeth and to prevent the noise associated with bruxing or grinding.	Both Bright Guard and the predicate provide a barrier between the upper and lower teeth to prevent bruxism.
Device Description	Flexible, moldable mouth guard used as a barrier between	Flexible, moldable mouth guard used as a barrier between	Flexible, moldable mouth guard used as a barrier between teeth for nighttime teeth grinding.	Both Bright Guard and the predicate use moldable "boil and

	Subject Device	Primary Predicate Device	Reference Device	Similarities and Differences
	teeth for nighttime teeth grinding.	teeth for nighttime teeth grinding.		bite" technology to provide a custom fit.
Molding Method	Boil and Bite Method (Heat & Bite Self-Fit)	Boil and Bite Method (Heat & Bite Self-Fit)	Boil and Bite Method (Heat & Bite Self-Fit)	Both Bright Guard and the predicate use moldable "boil and bite" technology to provide a custom fit.
Rx or OTC	OTC	OTC	OTC	Both Bright Guard and the predicate device are indicated for over-the-counter use.
Method of Manufacturing	Injection Molding	Injection Molding	Injection Molding	Both Bright Guard and the predicate are manufactured by injection molding.
Biocompatibility	Biocompatible Materials Used	Biocompatible Materials Used	Biocompatible Materials Used	Both Bright Guard and the predicate use biocompatible materials tested according to ISO 10993.
Sterility	Non-Sterile	Non-Sterile	Non-sterile	Both Bright Guard and the predicate are supplied non-sterile.
Contact Material	Thermoplastic resin Propylene Elastomer: ethylene-vinyl-acetate [Elvax] No Flavor; No Color Additives	Thermoplastic resin Propylene Elastomer: polycalprolactone No Flavor; No Color Additives	Thermoplastic resin Propylene Elastomer: ethylene-vinyl-acetate [Elvax and Elvaloy] No Flavor; No Color Additives	Both Bright Guard and the predicate are composed of flavorless, colorless thermoplastic elastomer resins designed for dental mouth guards
Location of Use	Upper Arch Teeth	Upper Arch Teeth	Upper Arch Teeth	Both Bright Guard and the predicate are placed on the upper arch teeth.
Wear Time	Four (4) months wear time until replacement with new mouth guard Worn during sleeping for no more than twelve (12) hours per day.	Six (6) –eight (8) months wear time until replacement with new mouth guard Not stated on IFU	For more than thee (3) months for initial use without consulting dentist. See dentist every 6 months thereafter while using this product. Not stated in IFU	Bright Guard is worn for 4 months while the predicate can be worn over a 6 to 8 month period.
Molding Time	In hot water time: 15-20 seconds; Mouth molding time: 20-25 seconds	In hot water time: 10 seconds; Mouth molding time: 20 seconds	60 seconds in boiling water; 30 seconds to mold in mouth	The predicate has a 10 second shorter boil time and the same bite time to complete molding.

The table above identifies a few minor differences between the subject device and the cited predicate and reference devices. The wear time and molding time are similar to the subject device. The contact material for the subject and reference devices is ethylene-vinyl-acetate;

polycaprolactone for the primary predicate. Though not identical, the contact materials for all three devices cited are moldable thermoplastic elastomer resins that are used in other 510(k)-cleared dental mouth guards that share the same intended use as the subject device.

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent when it has the same intended use and same or similar technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), any difference between the subject device and the cited predicate and reference devices are minor and do not raise questions of safety and effectiveness. It is on this basis that Bright Guard is substantially equivalent to the cited predicate device.

9. Summary of Performance Data

There were no clinical tests performed or provided in this submission.

The following functional non-clinical performance tests were conducted on Bright Guard:

- Hardness, Water Sorption and Solubility Testing; and
- Spatula & Mouth guard Boiling/Cooling Water Testing

A biocompatibility assessment was conducted using Bright Guard mouth guard as a final finished device in accordance with International Standard ISO 10993:2009 Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process and FDA's Guidance Document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", June 16, 2016.

The following biocompatibility performance tests were conducted on Bright Guard:

- **In Vitro Cytotoxicity Test** using **ISO 10993-5:2009** Test Method - MTT Method MEM with 10%FBS extract
- **Skin Sensitization Test** using **ISO 10993-10:2010** Test Method – Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract
- **Skin Sensitization Test** using **ISO 10993-10:2010** Test Method – Guinea Pig Maximization Test Sesame Oil Extract
- **Oral Mucosal Irritation Test** using **ISO 10993-10:2010** Test Method – Hamster 0.9% Sodium Chloride Extract
- **Oral Mucosal Irritation Test** using **ISO 10993-10:2010** Test Method – Hamster Sesame Oil Extract

Bright Guard relied on biocompatibility and functional performance testing as the basis for non-clinical data. The non-clinical testing performed demonstrated that the Bright Guard mouth guard is substantially equivalent to the predicate device.