November 23, 2020

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

Re: K201484
Trade/Device Name: Somnos Anti-Snoring Mouth Guard
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK, LQZ
Dated: October 15, 2020
Received: October 19, 2020

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/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 -S

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K201484

Device Name
SOMNOS ANTI-SNORING MOUTH GUARD

Indications for Use *(Describe)*
SOMNOS ANTI-SNORING MOUTH GUARD is an over-the-counter mouthguard intended for use in adult persons 18 years of age or older as an aid for the reduction of snoring.

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.

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Section 5: 510(k) Summary
[Compliance with 21 CFR 807.92]

Submission Sponsor
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Date Prepared
October 28, 2020

Type of 510(k) Submission
Traditional

Device Identification

Trade /Proprietary Name:	SOMNOS ANTI-SNORING MOUTH GUARD
Common Name:	Device, Anti-snoring
Classification:	II
FDA Product Code:	LRK
Review Panel:	Dental

Legally Marketed Predicate Device
Primary Predicate Device:
Snore Rx, K170825

This predicate has not been subject to a design-related recall.

Device Description

SOMNOS ANTI-SNORING MOUTH GUARD is comprised of a mouthguard, a spatula and a storage case. The mouthguard is a self-fitting adjustable Mandibular Advancement Device (MAD) removable intraoral anti-snoring device used to reduce nighttime snoring in adult persons18 years of age or older. SOMNOS ANTI-SNORING MOUTH GUARD consists of two customized pre-fabricated single-piece trays that conform to the patient's dentition in the upper and lower jaws. The device functions as a mandibular anterior repositioner, which acts to increase the user's pharyngeal space, resulting in the improvement of the ability to exchange air during sleep. SOMNOS ANTI-SNORING MOUTH GUARD, while *in situ*, moves the lower jaw forward and helps reduce the likelihood of snoring. It is intended to be worn while sleeping. The supplied spatula is used to separate the SOMNOS ANTI-SNORING MOUTH GUARD. SOMNOS ANTI-SNORING MOUTH GUARD is conformable to wear, and it can be self-fitted by the 'boil and bite' method (when heated the device conforms to person's teeth) and allows slight adjustment of the anterior positioning of the jaw to the person's comfort.

SOMNOS ANTI-SNORING MOUTH GUARD is constructed of two (2) preformed and fixed single piece trays composed of Thermoplastic resin Propylene Elastomer (TPE) material, specifically Ethylene-Vinyl-Acetate for the moldable part and Polycarbonate for the rigid part of the device. The spatula and storage case are composed of 100% Polypropylene. The materials in Somnos are commonly used in other 510(k) cleared dental mouth guards for bruxism and anti-snoring. The three components (mouthguard, spatula and storage case) are manufactured by injection molding. They are non-flavored and have no color additives.

SOMNOS ANTI-SNORING MOUTH GUARD is provided in one model/size, is reusable by a single individual who is at least eighteen (18) years of age and is supplied as non-sterile.

Each box of SOMNOS ANTI-SNORING MOUTH GUARD is supplied with the following items:

- (1) Anti-snoring Mouthguard
- (1) Spatula
- (1) Storage case
- (1) Instructions for Use

Indications for Use

SOMNOS ANTI-SNORING MOUTH GUARD is an over-the-counter mouth guard intended for use on adult persons 18 years of age or older as an aid for the reduction of snoring.

Summary of Substantial Equivalence

The intended, indications, and directions for use of SOMNOS ANTI-SNORING MOUTH GUARD are equivalent to those of the predicate device, SnoreRx. The design, manufacturing, and principal of operation are similar to those of the predicate device and do not raise any new issues concerning safety or effectiveness.

Summary of Technological Characteristics

The tables below compare the technological characteristics of SOMNOS ANTI-SNORING MOUTH GUARD and the primary predicate, SnoreRx.

Similarities Between Subject and Predicate Devices

Trade Name / Brand Name	**Subject Device**	**Primary Predicate Device**
	SOMNOS ANTI-SNORING MOUTH GUARD	SnoreRx
510(k)#	K201484	K170825
Indications for Use	SOMNOS ANTI-SNORING MOUTH GUARD is intended for use in adult persons 18 years of age or older as an aid for the reduction of snoring.	SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.
Device Description	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space. Adjustment of the relative position of the trays by the use of latch adjustment to obtain a fixed advancement.	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space. Adjustment of the relative position of the trays by the use of latch adjustment to obtain a fixed advancement.
Patient Population	Adult persons 18 years of age or older	Adult patients 18 years of age or older
Duration of Use	Single patient, multi-use	Single patient, multi-use
Desirable Characteristics	Home use, heat sensitive/moldable position [Boil and Bite Method (Heat & Bite Self-Fit)], adjustable jaw advancement	Home use, heat sensitive/moldable position [Boil and Bite Method (Heat & Bite Self-Fit)], adjustable jaw advancement
Rx or OTC	OTC	OTC
Specifications -Mechanical	-Repositions mandible-anteriorly up to 6 mm	-Repositions mandible-anteriorly up to 6 mm
Method of Manufacturing	Injection Molding	Injection Molding
Biocompatibility	Biocompatible Materials Used – ISO 10993	Biocompatible Materials Used – ISO 10993
Specifications: -Physical -Use	 -Custom-fitted intraoral device -Reusable	 -Custom-fitted intraoral device -Reusable
Sterility	Non-Sterile	Non-Sterile
Materials	-Ethylene Vinyl Acetate copolymer -Polycarbonate resin No Flavor; No Color Additives	-Ethylene Vinyl Acetate copolymer -Polycarbonate resin No Flavor; No Color Additives

Differences Between Subject and Predicate Devices

Trade Name / Brand Name	**Subject Device**	**Primary Predicate Device**
	SOMNOS ANTI-SNORING MOUTH GUARD	SnoreRx
Accessories Provided	"Spatula" for handling devices during molding steps	"Fitting Tray" for handling device during molding stept
Total allowed molding attempts	1	3
Replacement recommended	6 months	8 to 12 months

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 are minor and do not raise questions of safety or effectiveness. It is on this basis that SOMNOS ANTI-SNORING MOUTH GUARD is substantially equivalent to the cited predicate device.

Summary of Performance Data

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

The following functional performance tests were conducted on SOMNOS ANTI-SNORING MOUTH GUARD in accordance with FDA Recognized Consensus Standard, ISO 20795-2 Dentistry – Base polymers – Part 2: Orthodontic base polymers:

- Hardness, Water Sorption and Solubility Testing;
- Spatula & Mouth guard Boiling/Cooling Water Testing;
- Flexural Strength & Flexural Modulus;
- Fracture Toughness; and
- Optical Microscopy (OM).

A biocompatibility assessment was conducted using SOMNOS ANTI-SNORING MOUTH GUARD as a final finished device in accordance with International Standard ISO 10993-1:2009 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 SOMNOS ANTI-SNORING MOUTH 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

Koncept Innovators conducted a risk analysis on SOMNOS ANTI-SNORING MOUTH GUARD in accordance with ISO 14971, taking into account the issues raised in the FDA Guidance Document, "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea -Guidance for Industry and FDA." With respect to perceivable conditions in which the device would be subjected to a worst-case environmental of human error scenario, Koncept Innovators believes the outcomes of these risks are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form. The identified potential risks have been addressed through device design or with communication with the user through the instructions for use. SOMNOS ANTI-SNORING MOUTH GUARD uses a STOP BANG questionnaire on the labeling to assess the risks of sleep apnea and contains appropriate warnings and labeling for the device to be used without a prescription. SOMNOS ANTI-SNORING MOUTH GUARD is not indicated for obstructive sleep apnea.

SOMNOS ANTI-SNORING MOUTH GUARD relied on biocompatibility and functional performance testing as the basis for non-clinical data. The non-clinical testing performed demonstrated that the SOMNOS ANTI-SNORING MOUTH GUARD is substantially equivalent to the predicate device, SnoreRx.

Statement of Substantial Equivalence

SOMNOS ANTI-SNORING MOUTH GUARD has the same intended use and indications for use as the predicate, SnoreRx. Any minor differences in the technological features of the subject device when compared to the predicate device have been successfully evaluated through safety and performance testing and other verification and validation activities such that the information submitted to the FDA demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. SOMNOS ANTI-SNORING MOUTH GUARD, as designed by and manufactured for Koncept Innovators, Inc. has been determined to be substantially equivalent to the predicate device, SnoreRx.