August 23, 2021

SmartGuard Rx Inc.
Brian Larsen
Director
2112 North Hill Field Rd. Suite 2A
Layton, Utah 84041

Re: K200657
Trade/Device Name: SmartGuard Anti-Snore Device
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
Dated: July 14, 2021
Received: July 20, 2021

Dear Brian Larsen:

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,

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200657

Device Name

SmartGuard Anti-Snore Device

Indications for Use *(Describe)*

SmartGuard Anti-Snore Device is indicated for use on adult patients 18 years 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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4.0 Indications for Use: SmartGuard® Anti-Snoring Device is indicated for use on adult patients 18 years or older as an aid for the reduction of snoring.

Indications for Use Comparison for Predicate Devices

SnoreRx K170285: The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Oral Device-s (Snoreeze) K181396: The Oral Device-S is intended to reduce nighttime snoring for adults 18 and older.

Oniris K150566: The Oniris device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults.

Section 5 510(k) Summary

Prepared in accordance to 21 CFR 807.92

Applicant:
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Fax: 855-887-2721
Email: Brian@SmartGuardRx.com

Date Prepared: February 14, 2020

Proprietary Name: SmartGuard® Anti-Snore Device

Common Name: Intra-oral Device for Snoring, Mandibular Advancement Device

Classification Device, Anti-Snoring

Name: Device Class: Class II

Product Code: LRK

Regulation Number: 21 CFR 872.5570

Predicate Device:
Reference Devices:
SnoreRx (k170285)
Snoreeze (k181396)
Orinis (k150566)
SmartGuard Dental Guard (k123161)

DESCRIPTION OF THE DEVICE

The SmartGuard® Anti-Snore Device is an intra-oral device composed of two independent injection molded thermoplastic (Polycarbonate) trays, over molded with thermoforming resin (EVA). One tray is for the maxillary arch, labeled “Upper”, and one tray is fitted to the mandibular arch, labeled “Lower”(Fig1). Both trays are custom fitted by the end user via “Boil-and-Bite” process at home. A molding aid is included in the packaging to assist the user in the customization of the trays. The molding aid is constructed with the same Polycarbonate material as the upper and lower trays, as well as the Advancement Bars.

Once the trays are molded to the user’s teeth, the trays are connected via the insertion of Advancement Bars, which are available in 6 sizes, varying in length by 1mm. The Advancement Bars interlock with the mandibular and maxillary trays and holds the mandible forward which improves the ability to exchange air and decreases air turbulence, a causative factor in snoring (Fig2). Because the trays are independent, the user can articulate vertically (Fig3), allowing for greater airflow and comfort.

As with all listed predicate devices, SmartGuard® Anti-Snore Device is a Mandibular Advancement Device (MAD) and is easily adjusted by the user to allow for **up to 6mm of protrusion.** The user can interchange the various sizes of Advancement Bars to find the size that comfortably advances the mandible and reduces snoring.

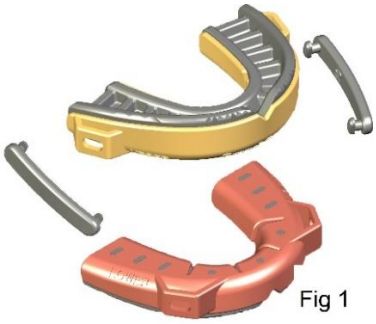
Fig 1

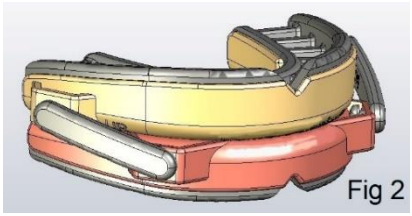
Fig 2

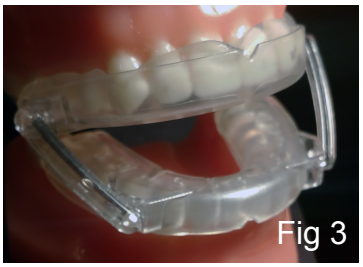
Fig 3

INDICATIONS FOR USE:

SmartGuard® Anti-Snore Device is indicated for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

COMPARISSION OF TECHNOLOGICAL CHARACTERISTICS:

The subject device uses the same or similar technological characteristics as the predicate devices to function as a Mandibular Advancement Device. All devices are substantially equivalent in design, materials, labeling, and function.

As with the predicate devices, SmartGuard® Anti-Snore Device consists of an upper and lower tray constructed with a hard Polycarbonate outer shell and over molded with thermoforming resin which is fitted to the user via “boil and bite” process at home.

See comparison chart below:

Comparison Chart for SmartGuard® Anti-Snore Device and Predicate Devices

		Proposed device	Predicate device	Reference Device	Reference device	Differences - Proposed vs Predicate
Manufacturer		**SmartGuard Rx Inc.**	Apnea Sciences, Inc.	Passion for Life	SAS Oniris	
Device Name		SmartGuard Anti-Snore Device	SnoreRx®	Oral Device S (Snoreeze)	Orinis	
510(k)		K200657	K170825	K181396	K150566	
Class		**Class II**	Class II	Class II	Class II	
Classification	**Reg**	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	
	Product Code	LRK	LRK	LRK	LRK	
	Class. Name	Intraoral Device for Snoring and Obstructive Sleep Apnea	Intraoral Device for Snoring and Obstructive Sleep Apnea	Intraoral Device for Snoring and Obstructive Sleep Apnea	Intraoral Device for Snoring and Obstructive Sleep Apnea	None
Intended use		Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	Intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.	None
Indication for use	**Rx or OTC**	OTC	OTC/RX	OTC/RX	RX	OTC
	Patient population	Adults	Adults	Adults	Adults	None
Cautions,Warnings and Contraindications		Labeling contains all warnings cautions and contraindications contained in FDA guidance documents for Anti-Snore devices	Labeling contains all warnings cautions and contraindications contained in FDA guidance documents for Anti-Snore devices	Labeling contains all warnings cautions and contraindications contained in FDA guidance documents for Anti-Snore devices	Labeling contains all warnings cautions and contraindications contained in FDA guidance documents for Anti-Snore devices	None
Mode of action		Mandibular advancement device (MAD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular advancement device (MAD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular advancement device (MAD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular advancement device (MAD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	None
Environment		During sleep, at home	During sleep at home	During sleep at home	During sleep at home	None
Placement of device		Oral cavity, custom fit to dentition	Oral cavity, custom fit to dentition	Oral cavity, custom fit to dentition	Oral cavity, custom fit to dentition	None

Comparison Chart for SmartGuard® Anti-Snore Device and Predicate Devices

	Proposed device	Predicate device	Reference Device	Reference device	Differences - Proposed vs. Predicate
Manufacturer	**SmartGuard Rx Inc.**	Apnea Sciences, Inc.	Passion for Life	SAS Oniris	
Device Name	SmartGuard Anti-Snore Device	SnoreRx®	Oral Device S (Snoreeze)	Orinis	
510(k)	K200657	K170825	K181396	K150566	
Molding / Fitting	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth.	Proposed device is molded one arch at a time and is adjustable to arch shape.
Design	Consists of an upper and lower tray. Outer shell provides with structural support and over mold is softer material that is heat sensitive and thus allows for custom fitting.	Consists of an upper and lower tray. Outer shell provides with structural support and over mold is softer material that is heat sensitive and thus allows for custom fitting.	Consists of an upper and lower tray. Outer shell provides with structural support and over mold is softer material that is heat sensitive and thus allows for custom fitting.	Consists of an upper and lower tray. Outer shell provides with structural support and over mold is softer material that is heat sensitive and thus allows for custom fitting.	None
Adjustments	Anterior advancement of the mandible is increased as the user chooses interconnecting bars varying in length by 1mm with up to 6 sizes to chose from. Allowing up to 6 mm of protrusion.	Squeeze mouthpiece in a 'C' position and adjust. • The upper and lower trays are adjustable in 1mm increments up to 6mm.	Advancement of the relative position of the trays by the use of screw adjustment to obtain a fixed advancement up to 6 mm	Oniris device comes with 9 connectors of varying length. Enables up to 11mm of protrusion.	Proposed device is adjustable as user chooses Advancement Bars, varying by 1mm in length. The upper and lower trays are only connected by the bars which allows vertical articulation and comfort.
Single Use / Reusable	Single user, multi-use	Single user, multi-use	Single user, multi-use	Single user, multi-use	None
Cleaning instructions	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	None
Sterile	No	No	No	No	None
Materials	Polycarbonate and ethylene vinyl acetate copolymer	Polycarbonate resin Ethylene vinyl acetate copolymer	Polycarbonate resin Ethylene vinyl acetate copolymer	Polycarbonate resin Ethylene vinyl acetate copolymer	None
Biocompatibility	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (> 24h to 30 days): cytotoxicity, sensitization and irritation	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (> 24h to 30 days): cytotoxicity, sensitization and irritation	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (> 24h to 30 days): cytotoxicity, sensitization and irritation	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (> 24h to 30 days): cytotoxicity, sensitization and irritation	None

Biocompatibility

The predicate and subject devices are considered to be external communicating devices of permanent exposure (>30 days) per ISO 7405 and surface-contacting devices (mucosa) of permanent contact (>30 days) per ISO 10993-1. There are no new materials being used in the proposed device. Materials utilized for the SmartGuard® Anti-Snore Device are identical to the primary materials used in the predicate devices for the same intended use. Both the predicate and SmartGuard® Anti-Snore Device are made from polycarbonate and EVA.

The SmartGuard® Anti-Snore Device complies with the FDA guidance document "Use of International Standard ISO 10993 Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Use of Fourier Transform Infrared (FTIR) Spectroscopy was used to identify the identity of the hard shell material of the subject device (PC) as well as the predicate devices.

The liner material (EVA) is identical to the material used in the previously cleared device marketed by the submitter (K123161).

The materials used in the subject device in its final finished form are identical to the predicate devices in formulation, processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

As all materials used in the device are used in many other currently marketed medical devices, no additional biocompatibility testing was conducted.

Risk Analysis and Usability Engineering

SmartGuard Rx Inc conducted a risk analysis on the proposed device in accordance with ISO 14971:2007 and by considering the issues raised in the FDA guidance document "*Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea*" (November 12, 2002). All identified risks have been addressed through device design, verification/validation or through labeling and instructions for use provided to the consumer.

A Human Factors and Usability Engineering (HFE/UE) study was performed of the SmartGuard® Anti-Snore Device in accordance to FDA guidance document "*Applying Human Factors and Usability Engineering to Medical Devices*" issued on Feb 3, 2016. The summary report for the Usability Test is contained in section 21. The results of the UE test verified the proposed device labeling, including directions for use, warnings, contraindications and indications are easily understood by the lay person and validated the ease of customizing the device for personal use at home.

NON-CLINICAL BENCH TESTING

The device materials were tested for various physical properties including Tensile Modulus (ISO 527) Flexural Modulus and Flexural Strength (ISO 178), and Water Absorption (ISO 62). All materials met device specifications.

CLINICAL TESTING

No clinical testing was performed in association with this submission.

CONCLUSION:

The results of the comparison of design, intended use, technological characteristics, materials, and labeling demonstrate the subject device is substantially equivalent in safety and effectiveness to the legally marketed predicate devices and does not introduce any new risks.