November 10, 2022

Solbaro Co., Ltd
Jinwook Seo
Regulatory Affair
4th fl. 137, Janggam-ro
Gamgok-myeon, Eumseong-gun, Chungcheongbuk-do 27603
SOUTH KOREA

Re: K222475
Trade/Device Name: Snor Lock
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: August 8, 2022
Received: August 16, 2022

Dear Jinwook Seo:

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222475

Device Name
SNOR LOCK

Indications for Use *(Describe)*
SNOR LOCK is indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep.

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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510(k) SUMMARY K222475

Date: August 8, 2022

1. SUBMITTER

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2. DEVICE

·Trade Name: SNOR LOCK

·Common Name: Antisnoring device

·Classification Name: Device, Anti-Snoring

·Regulation Number 872.5570

·Class: 2

·Classification Product Code: LRK

3. PREDICATE DEVICE

K190058 PureSleep®(OTC use), Sleep Science Partners, Inc.

4. DEVICE DESCRIPTION

The SNOR LOCK is an oral appliance comprised of an upper and lower tray constructed in one piece. The trays engage with the maxillary and mandibular dentition and the device maintains an anterior positioning of the mandible which widens the pharyngeal airway to prevent occlusion.

5. INDICATIONS FOR USE

SNOR LOCK is indicated for use for adults 18 years and above as an aid in the reduction

of snoring during hours of sleep.

6. NON-CLINICAL TESTING

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

Testing institution's method –Appearance, Dimension, Weight / Appearance, pH, Heavy metals, Potassium premanganate reducing substance, Residue on evaporation, Ultraviolet absorption spectrum of extracts

ISO 10993-5 – Cytotoxicity

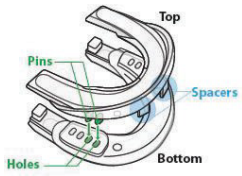
ISO 10993-3 - Genotoxicity (Bacterial Reverse Mutation)

ISO 10993-10 - Guinea Pig Maximization Test for Skin sensitization

ISO 10993-11 – Subchronic toxicity

7. SUBSTANITAL EQUIVALENCE

	Proposed Device	Predicate Device	Discuss/Justify the Differences
510(k) Number	New	K190058	-
Trade Name	SNOR STOP (SNOR LOCK)	PureSleep®(OTC use)	-
Manufacturer	Solbaro Co., Ltd.	Sleep Science Partners, Inc.	-
Common Name	Antisnoring device	Antisnoring device	Equivalent
Classification Name	Intraoral devices for snoring and obstructive sleep apnea	Intraoral devices for snoring and obstructive sleep apnea	Equivalent
Device Class	2	2	Equivalent
Product Code	LRK	LRK	Equivalent
Device Description	The SNOR LOCK is an oral appliance comprised of an upper and lower parts constructed in mouthpiece. The mouthpiece engage with the maxillary and mandibular dentition and the device	The PureSleep® device for Over-the-Counter (OTC) use is an intraoral mandibular repositioning device that increases the pharyngeal space to improve the user's ability to exchange air and to decrease air turbulence, a causative factor in snoring. The device consists of two dental trays designed to conform to the shape of the upper	Equivalent

		maintains an anterior positioning of the mandible which widens the pharyngeal airway to prevent occlusion.	and lower jaws.	
Indication for use		SNOR LOCK is indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep.	PureSleep® (OTC) is indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep.	Equivalent
Indication for use	Prescription Status	OTC	OTC	Equivalent
	Patient Population	Adult persons 18 years of age or older	Adult persons 18 years of age or older	Equivalent
Mode of action		Mandibular repositioning device (MRD) that advances the lower jaw to increase pharyngeal space and alleviate snoring.	Mandibular repositioning device (MRD) that advances the lower jaw to increase pharyngeal space and alleviate snoring.	Equivalent
Environment		During sleep, at home	During sleep, at home	Equivalent
Placement of device		In the mouth, on the lower and upper Jaws	In the mouth, on the lower and upper Jaws	Equivalent
Preparation / Set-up		Connect upper and lower parts per bite type.	Connect upper and lower parts per bite type.	Equivalent
Molding / Fitment		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.	Equivalent
Design				Differences Mandibular advancement of proposed device is fixed in 6mm and

			frame is loacated inside mouthpiece.
	SNOR LOCK is an all-in-one mouthpiece (intraoral device) that is designed to have lower tray anterior to the upper tray. This allows 6mm advancement of mandible and widens pharyngeal space.	Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus allows for custom fitting.	
Adjustments	6 mm of mandibular advancement	• Adjustable jaw advancement position. • Adjustably positions the mandible forward in three positions, 4mm apart anteriorly, while maintaining a 9mm inferior placement for user comfort	Differences Mandibular advancement of proposed device is fixed in 6mm
Single use / Reusable	Single patient, multi-use(reusable)	Single patient, multi-use	Equivalent
Cleaning instructions	Clean/rinse daily with toothbrush & toothpaste. Deep clean once per week with commercial denture cleanser(ex. Polident).	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week.	Equivalent
Sterile	No	No	Equivalent
Materials	Body : ethylene-vinyl acetate copolymer resin Frame : ethylene propylene copolymer, colorant	Polypropylene homopolymer and ethylene vinyl acetate copolymer	Differences SNOR LOCK has additional chemical substances; colorant, ethylene propylene copolymer
Biocompatibility	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged	Equivalent

	prolonged contact duration (>24h to 30 days): cytotoxicity, sensitization, irritation, genotoxicity and subchronic toxicity	contact duration (>24h to 30 days): cytotoxicity, sensitization and irritation	

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

SNOR LOCK has the same Indications for Use and the principle of operations as the predicate device. Even though there is a slight difference in design(mandibular advancement is fixed in 6mm), it does not affect the equivalence and functioning of intended use-reduction of snoring. It has similar physical properties, and demonstrates biocompatibility and performance specifications comparable to the predicate devices.

The chemical compositions might slightly differ from the predicate devices. Additional components are used as frame material and frame colorant. Both devices have used ethylene-vinyl acetate copolymer as base material, which has a major contact with a patient tissue. Additional polymer material used in SNOR LOCK, ethylene propylene copolymer, is a elastomer with established biocompatibility and widely medical use, including surface of infusion bag. Light Brown model(008031) of SNOR LOCK is created by addition of every colorant with the same ratio. By conducting biocompatibility test using this model as a worst case, risk of each product lines with different color are fully assessed. Both SNOR LOCK and predicate deivce are met the requirement of anti-snoring device.

The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that SNOR LOCK is substantially equivalent to the predicate devices.