May 14, 2026

Koncept Innovators, Inc.
% Maureen Garner
Regulatory Consultant
Newworld Regulatory Solutions, Inc.
11700 W. Charleston Blvd. Suite 170-390
Las Vegas, Nevada 89135

Re: K261134
Trade/Device Name: Dormiva 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: April 6, 2026
Received: April 7, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261134	?
Please provide the device trade name(s).		?

Dormiva Anti-Snoring Mouth Guard

Please provide your Indications for Use below.	?

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

Please select the types of uses (select one or both, as applicable).	[] Prescription Use (21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)	?

General Summary of Submission/Executive Summary K261134

Submission Sponsor

Koncept Innovators, LLC.
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Date Prepared

January 31, 2026

Type of 510(k) Submission

Special(k)

Device Identification

Trade /Proprietary Name:	**Dormiva 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:

SOMNOS ANTI-SNORING MOUTH GUARD, K201484

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

Device Description

Dormiva Anti-Snoring Mouth Guard is comprised of a mouth guard, a spatula and a storage case. The mouth guard is a self-fitting adjustable Mandibular Advancement Device (MAD) removable intraoral anti-snoring device used to reduce nighttime snoring in adult persons 18 years of age or older. The Dormiva Anti-Snoring Mouth Guard consists of two customized pre-fabricated single-piece trays that conform to the person'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. Dormiva 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 spatula supplied is used to separate the Dormiva Anti-Snoring Mouth Guard. Dormiva Anti-Snoring Mouth Guard is comfortable to wear, and it can be self-fitted by the 'boil and bite' method (when heated the device conforms to a person's teeth) and allows slight adjustment of the anterior positioning of the jaw to the person's comfort.

Dormiva 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 Dormiva Anti-Snoring Mouth Guard are the same materials used in the SOMNOS ANTI-SNORING MOUTH GUARD cleared under K201484 and are commonly used in other 510(k)-cleared dental mouth guards for bruxism and anti-snoring. The three components (mouth guard, spatula and storage case) are manufactured by injection molding. They are non-flavored and have no color additives.

Dormiva Anti-Snoring Mouth Guard is provided in three (3) models/sizes (small, medium and large), is reusable by a single person who is at least eighteen (18) years of age and is supplied as non-sterile. Each box of a Dormiva Anti-Snoring Mouth Guard is supplied with the following items:

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

Indications for Use

Dormiva Anti-Snoring Mouth Guard is an over-the-counter mouth guard intended for use in adult persons 18 years of age or older as an aid for the reduction of snoring.

Summary of Substantial Equivalence

Dormiva Anti-Snoring Mouth Guard, like the primary predicate (SOMNOS ANTI-SNORING MOUTH GUARD, K201484), is an intraoral anti-snoring mouth guard device that 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. Both devices, while in *situ*, move the lower jaw forward and help reduce the likelihood of snoring

The intended indications, and directions for use of the Dormiva Anti-Snoring Mouth Guard are equivalent to those of the predicate device, SOMNOS ANTI SNORING MOUTH GUARD. The

materials, manufacturing, and principle of operation are the same as those of the predicate device and do not raise any new issues concerning safety or effectiveness.

COMPARISON TO THE PREDICATE

The purpose of this Special 510(k) submission is to bring to market the device under the proprietary name, Dormiva Anti-Snoring Mouth Guard, now available in three sizes. There have been no changes made to the composition or materials of the device; the only difference is that the mouth guard has been reduced in thickness and is available in small, medium and large. (See table below for specifications.)

Summary of Technological Characteristics

The table below compares the technological characteristics of the Dormiva Anti-Snoring Mouth Guard and the primary predicate, SOMNOS ANTI-SNORE MOUTH GUARD.

Comparison of Technological Characteristics of Subject and Predicate Devices

	Subject Device	Predicate Device	Similarities
Trade Name / Brand Name	**Dormiva Anti-Snoring Mouth Guard**	**SOMNOS ANTI-SNORING MOUTH GUARD**	N/A
510(k)#	TBD	K201484	N/A
Indications for Use	Dormiva Anti-Snoring Mouth Guard is an over-the-counter mouth guard intended for use in adult persons18 years of age or older as an aid for the reduction of snoring.	SOMNOS ANTI-SNORING GUARD is an over-the-counter mouth guard intended for use in adult persons 18 years of age or older as an aid for the reduction of snoring.	Same
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.	Same
Patient Population	Adult persons18 years of age or older	Adult persons 18 years of age or older	Same
Duration of Use	Single person, multi-use	Single person, multi-use	Same
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	Same
Rx or OTC	OTC	OTC	Same
Specifications -Mechanical	-Repositions mandible-anteriorly up to 6 mm	-Repositions mandible-anteriorly up to 6 mm	Same
Method of Manufacturing	Injection Molding	Injection Molding	Same
Biocompatibility	Biocompatible Materials Used --	Biocompatible Materials Used –	Same

	Subject Device	Predicate Device	Similarities
	ISO 10993	ISO 10993	
Specifications -Physical -Use	-Custom-fitted intraoral device -Reusable	Custom-fitted intraoral device -Reusable	Same
Sterility	Non-Sterile	Non-Sterile	Same
Materials	-Ethylene Vinyl Acetate copolymer -Polycarbonate resin No Flavor; No Color Additives	-Ethylene Vinyl Acetate copolymer -Polycarbonate resin No Flavor; No Color Additives	Same
Tray Design	Pre-formed and fixed	Pre-formed and fixed	Same
Accessories Provided	"Spatula" for handling devices during molding steps	"Spatula" for handling devices during molding steps	Same
Total allowed molding attempts	3	4	Same
Replacement recommended	6 months	6 months	Same

Differences Between Subject and Predicate Devices

	Subject Device	Predicate Device
Trade Name / Brand Name	Dormiva Anti-Snoring Mouth Guard	Somnos Anti-Snoring Mouth Guard
Models/Sizes Available	Three sizes available: small, medium, large	One size available
Dimensions	**Small** • Height 25.5 mm • Depth 37.0 mm • Inner width 21.8 mm • Outer Width 54.7 mm **Medium** • Height 25.5 mm • Depth 39.0 mm • Inner width 26 mm • Outer Width 58.7 mm **Large** • Height 25.5 mm • Depth 42.9 mm • Inner width 29.8 mm • Outer Width 63 mm **Spatula** • Length 47.5 mm • Width 11.0 mm (17 mm flare at base) • Thickness 2.25 mm	**One Size** • Height 27.7 mm • Depth 42.6 mm • Inner width 32.1 mm • Outer Width 67.6 mm **Spatula** • Length 73.0 mm • Width 14.30 mm to 22.3 mm Thickness 1.60 mm

	Subject Device	**Predicate Device**
Trade Name / Brand Name	Dormiva Anti-Snoring Mouth Guard	Somnos Anti-Snoring Mouth Guard

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 Special 510(k), there are no differences between the subject device and the cited predicate other than introduction of three new sizes with varied dimensions/thickness. It is on this basis that the Dormiva 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 same functional performance tests conducted on the Somnos Anti-Snoring Mouth Guard in accordance with FDA Recognized Consensus Standard, ISO 20795-2 Dentistry – Base polymers – Part 2: Orthodontic base polymers apply to the Dormiva Anti-Snoring Mouth Guard. They are as follows:

- 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. This biocompatibility assessment is the same for the Dormiva Anti-Snoring Mouth Guard device.

The following biocompatibility performance tests were conducted on Somnos Anti-Snoring Mouth Guard and apply to the Dormiva Anti-Snoring 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 DORMIVA 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. Dormiva 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. Dormiva Anti-Snoring Mouth Guard is not indicated for obstructive sleep apnea.

Dormiva Anti-Snoring Mouth Guard relied on biocompatibility and functional performance testing as the basis for non-clinical data. The non-clinical testing performed is the same as that used to demonstrate substantial equivalence of the SOMNOS ANTI-SNORING MOUTH GUARD.

Statement of Substantial Equivalence

The Dormiva Anti-Snoring Mouth Guard has the same intended use and indications for use as the predicate, SOMNOS ANTI-SNORING MOUTH GUARD. All technological features of the subject device when compared to the predicate device are the same and 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. Dormiva Anti-Snoring Mouth Guard, as designed by and manufactured for Koncept Innovators, LLC. has been determined to be substantially equivalent to the predicate device, SOMNOS ANTI-SNORING MOUTH GUARD. The Dormiva Anti-Snoring Mouth Guard is available in three (3) sizes, and the mouth guard thickness has been reduced. All labeling has been updated.