January 14, 2021

The Snore Reliever Company, LLC
% Christopher Devine
President
Devine Guidance International, Inc.
4730 South Fort Apache Road; Suite 300
Las Vegas, Nevada 89147

Re: K201719
Trade/Device Name: Vital Sleep
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: November 30, 2020
Received: December 7, 2020

Dear Christopher Devine:

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 Adjodha, M.ChE.
Assistant 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)*
K201719

Device Name
Vital Sleep

Indications for Use *(Describe)*
The Vital Sleep Device is intended as an aid in the reduction of snoring for adults at least 18-years old.

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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K201719

Section Five (5) - 510(k) Summary

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Submitter's Name & Address:	The Snore Reliever Company, LLC Registration Number 3008583502 4201 Tonnelle Avenue, Unit 202 North Bergen, NJ 07047
Contact Person:	Christopher J. Devine, Ph.D. Devine Guidance International, Inc. (702) 917-0585 - mobile
Date Summary Prepared:	December 16, 2020
Device Name:	Vital Sleep Device Classification Name – 872.5570 – Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification:	Class II (special controls)
Special Controls Guidance:	Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea - Guidance for Industry and FDA
Product Code:	LRK
Regulation Number:	872.5570
Regulation Name:	Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Manufacturing Name/Address:	The Snore Reliever Company, LLC 4201 Tonnelle Avenue, Unit 202 North Bergen, NJ 07047

Telephone Number: (646) 316-0918

Predicate Device: K180124 – ZQuiet (Sleeping Well, LLC)

Reference Device(s): K092942 – Vital Sleep (Snore Reliever Company)

1.0 Device Description

The Vital Sleep Device is designed to pull the mandible forward by an adjustable distance, and keep the mouth slightly open during use and reduce snoring. It consists of an arch fitted over the upper teeth and one fitted over the lower teeth. The arches are connected by a flexible hinge that allows a lateral movement (pulling the mandible forward). The arches and hinges form one injection–molded poly-propylene part. In the manufacturing process the semi rigid substrate is over-molded with softer EVA material (*reference Figure 1.0 for the fully assembled, ready-to-fit and use device*).

To fit the mouthpiece to an individual user, the mouthpiece which has been configured for use, is submerged in hot water until EVA material is soft and then placed in the user's mouth. The user gently bites down to create impressions of their teeth in the softened EVA plastic.

Figure 1.0 – Fully-Assembled Vital Sleep Device

2.0 Technological Characteristics

The adjustment mechanism on the right and left of the mouthpiece consists of a #8-32 threaded lug 20 on the lower half and a screw though hole 18. When the mouthpiece is folded for use, screw seat fits within the channel formed by threaded 20. Screw 14 passes through screw seat 18 to thread into Threaded lug 20, additionally acts as a guide channel for screw seat 18. Mouthpiece is folded, and the two screws are installed by rotation clockwise. Once the Screw is threaded through the Lug 20, the snap portion the snap does not allow screws 14 to back out turning counter clockwise if the thread is not engaged.

The buccal sidewall of raised platform 12 has graduation marks, which can be used to gage the travel of indicator mark on the upper half during adjustment. To move the lower half relative to the upper half, a captive Philips head #8-32 screw 14 is rotated clockwise or counterclockwise. The displacement can be gauged by comparing the movement of indicator notches which are molded into the lower half, to blue indicator mark on the upper half of the mouthpiece. The lower arch is adjustable 6 mm forward from the ***resting position***. The customer can adjust to find what offset is most effective for comfort as well as snore reduction (*reference Figure 2.0*).

Note: There are no accessory medical devices associated with the Vital Sleep Device.

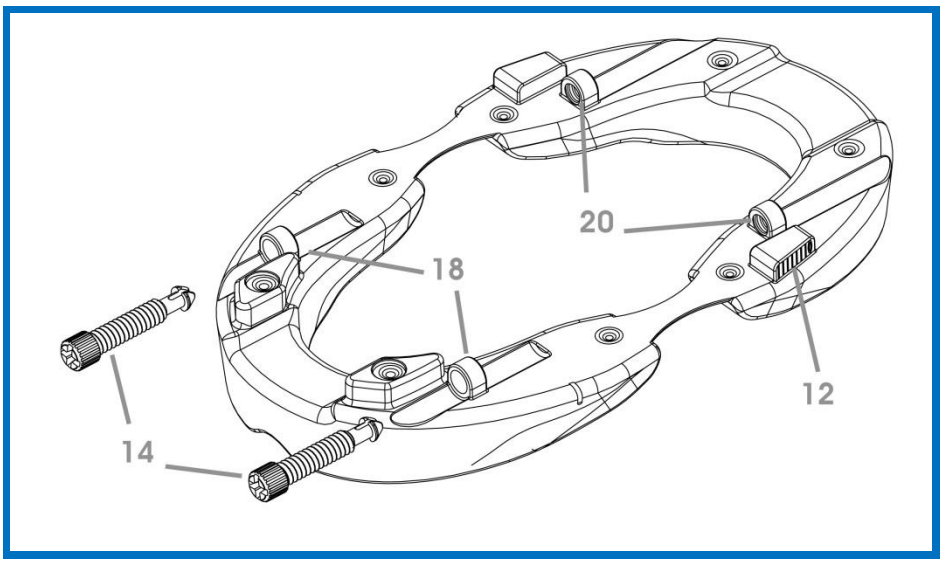

***Figure 2.0 – User Adjustments** (Folding, Threaded Lugs, Screws, & Adjustment Markings)*

3.0 Indications for Use

The Vital Sleep Device is intended as an aid in the reduction of snoring for adults at least 18-years old.

4.0 Prescriptive Statement

The Vital Sleep Device is intended for over the counter (OTC) utilization; "Over-The-Counter Use (21 CFR 801 Subpart C)"

5.0 Discussion(s) Regulatory History, Change in Prescription Status & Change in Materials

5.1 Regulatory History

The reference predicate device (Vital Sleep – first generation) was cleared by FDA on 13 Jan 2010 (K092942). This device remains on the market today. The next generation Vital Sleep Device (this abbreviated 510(k) application K201719) has never been submitted for clearance previously. The next generation device is identical to the first generation device with just one change, composition of materials (resins).

Additionally, a change from prescription to over-the-counter (OTC) use is being requested to align with current products in commercialization.

5.2 Prescription Status

- There are essentially two (2) elements driving the need for filing an abbreviated 510(k) for the Vital Sleep Device: (a) a change in the prescription status from prescription required to OTC; and (b) a change in materials used.
- The proposed Vital Sleep device is intended to be sold over-the-counter. Therefore, the product labeling has been revised to reflect the elimination of prescribing information. The warning statements placed into the Vital Sleep User Manual remain consistent with the reference predicate device (Vital Sleep) and the predicate device (ZQuiet).

  "**Over-The-Counter Use (21 CFR 801 Subpart C)**"

- The predicate ZQuiet (K180124) has received clearance for over-the-counter use. Premised on the design and construction of the Vital Sleep Device coupled with the successful testing of the device in accordance with ISO 10993 requirements and labeling identical to the predicate; the Vital Sleep Device will be safe and effective as an OTC product.

5.3 Change of Materials

Additionally, the change in materials (*similar plastics generally accepted as safe in medical device applications*) employed in the construction of the Vital Sleep Device will not negatively impact product performance, safety or efficacy. To ensure the materials used do not adversely impact the user, the Snore Reliever Company

performed applicable ISO 10993 testing. Testing was performed at recognized and qualified testing laboratories (Nelson Labs & Toxikon). The testing results reflected a pass on all tests performed. A detailed summary can be found in Section 15 of the Abbreviated 510(k).

6.0 Substantial Equivalency Discussion

The proposed Vital Sleep Device has identical technical characteristics to the predicate device (Vital Sleep – K092942) and the identical over-the-counter (OTC) claim as the reference predicate device (ZQuiet – K180124). A comparison of technological characteristics is delineated within Table 5.0 (Substantial Equivalence Comparison Table).

Table 5.0 – Substantial Equivalence Comparison Table

Item	Feature	Vital Sleep (This Submission)	Vital Sleep (K092942) Reference Predicate	ZQuiet (K180124) Predicate	Equivalency Discussion
1	Product Code	LRK	LRK	LRK	Identical
2	Product Classification	II	II	II	Identical
3	Regulation	872.5570	872.5570	872.5570	Identical
4	Technology – Mode of Action	Mandibular advancement to increase pharyngeal space.	Mandibular advancement to increase pharyngeal space.	Mandibular advancement to increase pharyngeal space.	Identical
5	Indications for Use	The ZQuiet Device is intended as an aid in the reduction of snoring for adults at least 18-years old.	The Vital Sleep mandibular advancement device is intended for the treatment of nighttime snoring in adults	The ZQuiet Device is intended as an aid in the reduction of snoring for adults at least 18-years old.	Identical to the predicate
6	Product Design Principles	The device is designed to pull the mandible forward by an adjustable distance, and keep the mouth slightly open	The device is designed to pull the mandible forward by an adjustable distance, and keep the mouth slightly open	An upper and lower tray constructed in one piece and joined by a flexible hinge. The lower tray protrudes the	Identical to reference predict and Similar to the predicate with the exception that SRC employed more granularity

Item	Feature	Vital Sleep (This Submission)	Vital Sleep (K092942) Reference Predicate	ZQuiet (K180124) Predicate	Equivalency Discussion
		during use and reduce snoring. It consists of an arch fitted over the upper teeth and one fitted over the lower teeth. The arches are connected by a flexible hinge that allows a lateral movement (pulling the mandible forward).	during use. It consists of an arch fitted over the upper teeth and one fitted over the lower teeth. The arches are connected by a flexible hinge that allows a lateral movement (pulling the mandible forward).	mandible to widen the upper airway.	in their principles of design
7	Prescription	OTC	Prescription	OTC	Identical to the predicate
8	Materials	The arches and hinges form one injection–molded poly-propylene part. During the manufacturing process, the semi- rigid substrate is over-molded with softer EVA material	The arches and hinges form one injection–molded black delrin part. In the manufacturing process the semi rigid substrate is over-molded with softer EVA material	Thermoplastic Elastomer with Blue Colorant	Similar to the predicate & reference predicate
9	Testing Performed	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Identical to the predicate & reference predicate
10	Width	63mm	64mm	[redacted]	Similar to the reference predicate
11	Length	50mm	51mm		Similar to the reference predicate
12	Height	29mm	28mm		Similar to the reference predicate
13	Air Gap	6mm	6mm		Similar to the reference predicate

7.0 Special Controls

The application of special controls was in accordance with; "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea - Guidance for Industry and FDA." Sections six (6) through eight (8) of the Guidance Document describe the agency's recommendations for complying with the Special Controls requirements. Compliance with Special Controls was achieved through:

- The identification of risk and the risk mitigation activities pursued;
- Biocompatibility testing;
- Labeling in accordance with 21 CFR, Part 801 requirements; and
- Warning statements placed into the User Manual.

7.1 Control of Materials

In support of control the quality of finished devices, all procured materials are submitted to receiving inspection, which includes the clear identification of the material received and a copy of the material certification provided by the supplier.

8.0 Conclusion Statement

The documented evidence complied during the inspection of raw materials, ISO 10993 testing, and comparison made versus the predicate and reference predicate devices for design, materials, intended use, and technical properties demonstrate that the Vital Sleep Device is as safe and effective as the legally marketed predicate devices. Product packaging and labeling were created considering 21 CFR, Part 801 and FDA Guidance Document – Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Guidance for Industry requirements. Additionally, the product labeling has been revised to

provide sufficient granularity in support of the over-the-counter use for the Vital Sleep Device. Therefore, the Snore Reliever Company, LLC concludes that the proposed Vital Sleep Device is substantially equivalent to the predicate devices depicted within this summary report.