June 15, 2022

Sleeping Well, LLC
℅ William McLain
President
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, Pennsylvania 17540

Re: K213088
Trade/Device Name: ZQuiet Advance
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: May 13, 2022
Received: May 16, 2022

Dear William Mclain:

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, 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)*
K213088

Device Name
ZQuiet Advance

Indications for Use *(Describe)*
ZQuiet Advance 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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3 510(K) Summary - ZQuiet Advance - K213088

3.1 Submission Owner

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3.2 Submission Correspondent

Mr. William G. McLain
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3.3 Date Summary Prepared

September 23, 2021

3.4 Device Trade Name

ZQuiet Advance

3.5 Device Common Name

Intraoral Device for Snoring

3.6 Device Classification Name

Device, Anti-Snoring, 21 CFR 872.5570, LRK, Class II

3.7 Legally Marketed Device To Which The Device Is Substantially Equivalent

- Predicate Device - PureSleep OTC cleared under K190058
- Reference Device - ZQuiet OTC cleared under K180124

3.8 Description Of The Device

The ZQuiet Advance is an intraoral appliance designed to reduce snoring by advancing the lower jaw. The principal effect of mandibular advancement devices is the protrusion of the lower jaw, thereby widening the upper airway to decrease air turbulence, a causative factor in snoring. This device combines several essential functions: Separate upper and lower dental trays with thermal impression material to engage the upper and lower dentition, a mechanism to provide the forward positioning of the lower jaw relative to the upper jaw in 3 positions determined by the user's bite providing up to +6 mm of possible advancement. The design allows the maintenance of the forward positioning of the lower jaw while allowing minor sagittal and vertical movement. The ZQuiet Advance is a "Boil-and-Bite" device that uses thermal impression resin for device retention. The upper and lower trays are both constructed out of a rigid plastic outer tray to provide the device structure and attachment points for the connecting semi-rigid straps that provide the adjustability. Both the upper and lower trays are lined with material that is moldable when heated in a water bath and provides the ability to conform the device to the individual's teeth.

3.9 Indication for Use

ZQuiet Advance is intended as an aid in the reduction of snoring for adults at least 18 years old.

3.10 Technological Characteristics

The proposed ZQuiet Advance has identical technical characteristics to the PureSleep OTC cleared under K190058. Table 1 below summarizes the overall technological characteristics between the proposed, predicate, and reference devices.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Device Proprietary Name	ZQuiet Advance	PureSleep OTC	ZQuiet OTC	Not applicable
Manufacturer	Sleeping Well, LLC	Sleep Science Partners, Inc.	Sleeping Well, LLC	Not applicable
510(k) Number	K213088	K190058	K180124	Not applicable
Classification Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570	The classification regulation is identical among the proposed, predicate, and reference devices.
Classification Name	Intraoral Device for Snoring and Obstructive Sleep Apena	Intraoral Device for Snoring and Obstructive Sleep Apena	Intraoral Device for Snoring and Obstructive Sleep Apena	The classification name is identical among the proposed, predicate, and reference devices.
Labeling				
Indications for Use	Intended as an aid in the reduction of snoring for adults at least 18 years old.	Indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep.	Intended as an aid in the reduction of snoring for adults at least 18 years old.	There are minor definitions in wording of the indication for use, however, they are all indicated for the reduction of snoring in adults 18 years and above.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Rx or OTC	OTC	OTC	OTC	The proposed, predicate, and reference devices are all indicated for OTC use.
Patient Population	Adults	Adults	Adults	There are no differences among the proposed, predicate, and reference device related to the patient population. They are all indicated for adult use.
Labeling	Language, visuals and structure are based on FDA guidance documents and closely resemble the predicate device labeling for which an HFE/UE study was conducted concluding that the device is clinically safe for OTC use.	Language, visuals and structure are based on FDA guidance documents and designed for OTC use. An HFE/UE study supported the conclusion that the device is clinically safe for OTC use.	Labeling designed for OTC use with the same contraindications and warnings.	The instructions for use are similar among the proposed, predicate, and reference devices in that they all are formatted for OTC use and contain instructions, contraindications, warning, precautions, and instructions for sizing and fitting the device. They differ in the particulars associated with assembly of the respective products.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Clinical Conditions Impacting Safe and Effective Use	Presence of: loose restorations, missing anterior or posterior teeth, malocclusion, undercuts, limited fine motor skills, central sleep apnea, any severe respiratory disorder, history of jaw pain or temporomandibular disorder (TMD), loose, sore or damaged teeth, loose caps, dental implants withing the last 3 months, orthodontia or dentures, sore or bleeding gums, advanced periodontal disease. Use under 18 years of age.	Presence of: central sleep apnea, chronic asthma, emphysema, COPD or any other serious breathing or respiratory disorder; loose, damaged or weakened teeth, loose or damaged fillings or caps; abscess, mouth sores, bleeding gums or severe gum disease; dental implant within the last 3 months, braces, full dentures or sleep using another dental appliance; diagnosis of temporomandibular joint disorder (TMD), symptoms of TMD such as clicking, popping, grating or locking of your jaw or jaw pain when you open your mouth, yawn or chew; jaw or tooth pain from clenching your jaw or grinding your teeth. Use under 18 years of age.	Not included as the reference device is not included for a labeling comparison.	Both the proposed and predicate devices contain references to loose restorations, missing anterior or posterior teeth, malocclusion, undercuts, central sleep apnea, any severe respiratory disorder, history of jaw pain or temporomandibular disorder (TMD), loose, sore or damaged teeth, loose caps, dental implants withing the last 3 months, orthodontia or dentures, sore or bleeding gums, advanced periodontal disease. Use under 18 years of age. The predicate device does not mention the presence of malocclusions, undercuts, or limited fine motor skills.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
		Technology		
Mode of Action	Mandibular advancement to increase pharyngeal space to alleviate snoring.	Mandibular advancement to increase pharyngeal space to alleviate snoring.	Mandibular advancement to increase pharyngeal space to alleviate snoring.	There are no difference among the proposed, predicate, and reference devices related to mode of action. They are all mandibular advancement devices.
Environment	Home use, during sleep.	Home use, during sleep.	Home use, during sleep.	There are no difference among the proposed, predicate, and reference devices related to the environment of use. They are all for home use during sleep.
Placement of Device	In the mouth, on the lower and upper jaw.	In the mouth, on the lower and upper jaw.	In the mouth, on the lower and upper jaw.	There are no difference among the proposed, predicate, and reference devices related to the placement of the device. They are all placed in the mouth, on the lower and upper jaw.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Preparation / Set-Up	Connect upper and lower parts per bite type.	Connect upper and lower parts per bite type.	None. Prefabricated mouthpiece selected per bite type.	Both the proposed and predicate device consist of separate upper and lower trays that are connected based on the bite type. See comments on Design below for additional details. The reference device is dissimilar to proposed device in that the top and bottom trays arrive at the customer in once piece. Bite type directs the user to select a properly dimensioned mouth piece. There is no assembly for the reference device.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Molding / Fitment	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins.	None.	The proposed and predicate device are identical in terms of the method to fit the device to the user. They both rely on a "boil-and-bite" method where resin is softened via heating and and an impression is made based on the user biting into the soft material. The reference device differs from the proposed device in that the reference device does not require molding. The device size is selected based on the user's bite type.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Design	Consists of upper and lower trays, each with a rigid outer shell with the tray of the shell lined with thermal impression material that allows for customer fitting. The thermal impression material mates with the anterior teeth. Trays are connected by semi-rigid side straps that are used to determine the amount of mandibular advancement.	Consists of upper and lower trays, each with a rigid outer shell withe the tray of the shell lined with thermal impression material that allows for customer fitting. Trays are connected by interlocking pins and holes the with the pin/hole selection determining the amount of mandibular advancement.	Consists of upper and lower non-custom open trays connected by a resilient hinge.	Both the proposed and predicate devices consist of upper and lower trays. They differ in that the proposed device only has impression material to mate with the posterior teeth. They also differ in the method of connection. The proposed device uses straps with lengths selected based on bite types. The predicate device uses notches selected based on bite types. The reference device requires no adjustment since the entire device is a singe piece and size is selected based on bite type.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Adjustments	Adjustable jaw advancement positions based on bite type. Adjustably positions the mandible forward in three positions up to +6 mm maximum advancement.	Adjustable jaw advancement positions based on bite type. Adjustably positions the mandible forward in three positions.	Mouthpiece with 2 varying levels of advancement selected per bite type. Similar jaw advancement levels up to +6 mm maximum advancement.	While the methods of adjustment differ based on the Design table entry above, the range of adjustment among the proposed, predicate, and reference devices is the same in that up to 6 mm of advancement is available.
Single Use / Reusable	Single user, multi-use.	Single user, multi-use.	Single user, multi-use.	There are no differences among the proposed, predicate, and reference devices related to use/reuse. They are all reusable for a single user.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Cleaning Instructions	Clean/rinse daily with toothbrush and toothpaste or with oral appliance cleaning solution.	Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets.	Clean/rinse daily with toothbrush and toothpaste or with oral appliance cleaning solution.	The proposed, predicate, and reference devices are all similar in that instructions for daily cleaning are provided. Additionally, they all recommend the use of a toothbrush and toothpaste. Regarding the use of cleaning solutions, the proposed and reference devices are identical in their recommendation. The proposed and predicate devices differ only in the recommended use of cleaning tablets for the predicate device.
Sterility	Non-sterile	Non-sterile	Non-sterile	The proposed, predicate, and reference devices are identical regarding sterility status. They are all non-sterile.

Table 1: Substantial Equivalence Table

Feature	**Proposed Device - ZQuiet Advance (K213088)**	**Predicate Device - PureSleep OTC (K190058)**	**Reference Device - ZQuiet OTC (K180124)**	**Comments on Similarities and Differences**
Materials	Polypropylene, Ethylene Vinyl Acetate Copolymer, and Acetal Homopolymer	Polypropylene homopolymer and ethylene vinyl acetate copolymer	Thermoplastic elastomer	The material among the proposed, predicate, and reference devices are different. They are similar in that they have all been selected based on providing a device that facilitates meeting its intended use.
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. Material testing provided by the device manufacturer.	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (>24h to 30 days): cytotoxicity, sensitization and irritation. The source of the biocompatibility data is unknown.	Meets ISO 10993-1 for a surface device contacting mucosal membrane for a prolonged contact duration (>24h to 30 days): cytotoxicity, sensitization and irritation. Material testing provided by the device manufacturer.	The proposed, predicate, and reference devices are similar in that testing was presented that demonstrated the materials are biocompatible for their intended use. The source of testing differs in that the proposed device testing was provided by the material manufacturer where the reference device was provided by the device manufacturer.

3.11 Non-Clinical Testing

Non-clinical testing consisted of strap compression testing, physical properties testing, and a Human Factors Evaluation. The results of compression testing of the straps used to support the advancement of the mandible were compared to straps utilized in devices with a similar design. Physical properties testing was conducted by the material manufacturer. The Human Factors Study concluded that the identified risks associated with critical tasks were adequately mitigated.

3.12 Biocompatibility

Biocompatibility testing was conducted by the device manufacturer and was demonstrated to meet the requirements described in the guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"', Dated September 4, 2020 for mucosal membrane contacting devices with permanent duration.

3.13 Clinical Testing

No clinical testing was performed in association with this submission.

3.14 Conclusions

The results of the comparison of design, labeling, materials, intended use and technological characteristics demonstrate that the proposed ZQuiet Advance is as safe and effective as the legally marketed predicate devices. Therefore, Sleeping Well, LLC concludes that the proposed ZQuiet Advance is as safe and effective as, and therefore substantially equivalent to, the identified predicate devices.