Sleeping Well, LLC
% Mr. William McLain
President and Principal Consultant
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, Pennsylvania 17540

June 12, 2018

Re: K180124
Trade/Device Name: ZQuiet
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 11, 2018
Received: May 14, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180124

Device Name
ZQuiet

Indications for Use *(Describe)*
ZQuiet 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (K180124)

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3 Date Summary Prepared

May 11, 2018

4 Device Trade Name

ZQuiet

5 Device common name

Intraoral Device for Snoring

6 Device classification name

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

7 Legally Marketed Device To Which The Device Is Substantially Equivalent

- Primary Predicate - ZQuiet , K093407

- Reference Predicate - ZQuiet , K090503
- Reference Predicate - SnoreRx , K170825

8 Description Of The Device

The ZQuiet is an oral appliance comprised of an upper and lower tray constructed in one piece and joined by a flexible hinge. 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. The device is presented in varying protrusive sizes allowing the user to try different degrees of mandibular advancement to reduce snoring.

9 Intended Use

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

10 Technological Characteristics

The proposed ZQuiet has identical technical characteristics to the predicate ZQuiet, K090503. A comparison of technological characteristics is presented in Table 1 below with additional narrative following.

Table 1: Substantial Equivalence Table

Feature	ZQuiet - K180124	ZQuiet - K093407 - Predicate Device (Primary)	ZQuiet - K090503 - Predicate Device (Reference)	SnoreRx - K170825 - Predicate Device (Reference)
Product Code	LKR	LRK	LRK	LRK
Product Classification	Class II	Class II	Class II	Class II
Classification Name	Anti-Snoring Device	Anti-Snoring Device	Anti-Snoring Device	Anti-Snoring Device
Proprietary Name	ZQuiet	ZQuiet	ZQuiet	SnoreRx
Technology - Mode of Action	Mandibular advancement to increase pharyngeal space.	Mandibular advancement to increase pharyngeal space.	Mandibular advancement to increase pharyngeal space.	Mandibular advancement to increase pharyngeal space.
Indication for Use	ZQuiet is intended as an aid in the reduction of snoring for adults at least 18 years old.	The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults 18 years or older.	The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults.	The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.

Table 1: (continued)

Feature	ZQuiet - Proposed Device	ZQuiet - K093407 - Predicate Device (Primary)	ZQuiet - K090503 - Predicate Device (Reference)	SnoreRx - K170825 - Predicate Device (Reference)
Design Principle	An upper and lower tray constructed in one piece and joined by a flexible hinge. The lower tray protrudes the mandible to widen the upper airway.	An upper and lower tray constructed in once piece and joined by a flexible hinge. The lower tray protrudes the mandible to widen the upper airway.	An upper and lower tray constructed in once piece and joined by a flexible hinge. The lower tray protrudes the mandible to widen the upper airway.	An upper and lower tray that are adjustable in 1mm increments. The rigid trays are lined with softer polymer that is molded to take the shape of the upper and lower teeth using a "boil and bite" approach.
Prescription Status	OTC	Prescription	Prescription	OTC
Materials	Thermoplastic Elastomer with Blue Colorant	Thermoplastic Elastomer with Blue Colorant	Thermoplastic Elastomer with Blue Colorant	The materials of construction are unknown.

The following sections provide a more detailed summary of the technological characteristics as compared to the predicate devices.

10.1 Technology - Mode of Action

The proposed and predicate devices are highly similar in terms of technology or mode of action as they are all intraoral devices intended for the purpose of reduction of snoring.

10.2 Indication for Use

Comparison of the Proposed ZQuiet device to the Predicate ZQuiet Devices

While there are minor differences in specific wording, the most substantial difference is in the use of the words "aid in the reduction of snoring" for the proposed device as compared to "treatment of snoring" for the ZQuiet predicates. This change reflects the consumer-oriented focus of reducing snoring as compared to someone who may need to be under a physician's or dentist's care. The proposed and predicate ZQuiet devices are all intended for adults. The proposed and K093407 predicate both additionally indicate that the minimum age of use is 18 years. The K090503 predicate does not mention a minimum adult age of use. The more recently cleared predicate and the proposed device differ in the identification of the device. The proposed device more simply mentions the product name "ZQuiet", where the K093407 predicate describes the product as the "ZQuiet mandibular advancement device". None of the difference described effect the safety or performance of the device. Therefore, there is no negative impact on safety and effectiveness.

Comparison of the Proposed ZQuiet Device to the SnoreRx, K170825

The proposed ZQuiet device has an indication of use that states"ZQuiet is intended as an aid in the reduction of snoring for adults at least 18 years old." The predicate SnoreRx device has an indication for use that states "The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring." There are no differences in the patient population and in the function which is aiding in the reduction of snoring. Therefore, there is no negative impact on safety and effectiveness related to the indications for use.

10.3 Design Principle

Comparison of the Proposed ZQuiet device to the Predicate ZQuiet Devices

The proposed and predicate ZQuiet devices are identical in design with the only difference being the degree of mandibular advancement. Both of the predicate devices had 6mm of mandibular advancement. The proposed ZQuiet has 2mm and 6mm of mandibular advancement to give the user the opportunity to find a device that works with their particular anatomy. The degree of mandibular advancement does not exceed the original cleared 6mm. Therefore, the proposed ZQuiet device is substantially equivalent to the predicate device in

terms of the basic design and mandibular advancement and there is no negative impact on safety and effectiveness.

Comparison of the Proposed ZQuiet Device to the SnoreRx, K170825

The proposed ZQuiet device and predicate SnoreRx device are designed differently, but function similarly. The proposed device is molded in one piece from a material that is sufficiently stiff to retain the lower mandible in position throughout the night yet sufficiently pliable to allow small degrees of lateral movement of the mandible and remain comfortable for the user. To achieve different degrees of mandibular advancement, ZQuiet uses different molds to manufacture devices with different dimensions.

The predicate SnoreRx device uses a rigid outer tray and that contains a soft polymer that the user molds to the shape of their teeth using a boil and bite approach. The SnoreRx device uses an intra-device ratcheting mechanism to adjust the degree of mandibular advancement.

Despite the difference in the approach to achieving the degree in mandibular advancement, the end result is the same. The mandible is advanced and the pharyngeal space is increased. Therefore, there is no negative impact on safety and effectiveness.

10.4 Prescription Status

The proposed ZQuiet is intended to be sold over-the-counter. Therefore, the product labeling has been modified to eliminate prescribing information. There have been no changes related to warnings or contraindications. The proposed product labeling now includes the STOP-Bang screening questionnaire in order to advise the user to consult a physician before product use if responses indicate a potential presence of sleep apnea or respiratory disorder. The predicate SnoreRx, K170825 has a clearance for over-the-counter use. Sleeping Well believes that through the redesign of the packaging by placing the warnings and precautions prominently on the outer packaging and instructions for use, and by providing the STOP-Bang Questionnaire to alert the user for the potential presence of complicating factors, the labeling is as safe and as effective as the OTC predicate, K170825. Therefore, there is no negative impact on safety and effectiveness.

10.5 Materials

The proposed ZQuiet device will be made with either clear or blue-tinted thermoplastic elastomer. These materials are identical to those referenced in the two Sleeping Well predicate devices with the following exception. Sleeping Well, LLC intends to be able to vary the amount of tint to aid in product differentiation. The proposed and predicate ZQuiet devices, are therefore, considered to be substantially equivalent in terms of materials and there is no negative impact on safety and effectiveness.

A comparison to the predicate SnoreRx is not possible because the materials of con-

struction are unknown.

11 Non-Clinical Testing

Non-clinical testing was not performed for this submission. However, Sleeping Well conducted a risk analysis on the device in accordance with ISO 14971:2007 and by 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". All identified risks have been addressed through device design or through communication with the user through the instructions for use.

12 Biocompatibility

Since the materials and methods of manufacture are identical to the materials and/or the base materials utilized in the K093407 and K090503 predicates, no additional biocompatibility testing was conducted.

13 Clinical Testing

No clinical testing was performed in association with this submission.

14 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices. The packaging and labeling has been redesigned to provide sufficient information to the consumer to ensure the safe and effective over-the-counter use of the proposed device. Therefore, Sleeping Well, LLC concludes that the proposed ZQuiet is substantially equivalent to the identified predicate devices.