JUL 2 5 2014
K140777

5 510(k) Summary

5.1 Submission Correspondent and Owner

Mr. Daniel Webster
Vice President
Sleeping Well, LLC
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5.2 Date Summary Prepared

March 25, 2014

5.3 Device Trade Name

ZQuiet-SA

5.4 Device common name

Intraoral Device for Snoring and Obstructive Sleep Apnea

5.5 Device classification name

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

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

Sleeping Well, LLC - ZQuiet - K093407
Sleeping Well, LLC - ZQuiet - K090503
TOMED Dr. Toussaint, GmbH - SomnoGuard - K061688

5.7 Description Of The Device

The ZQuiet-SA oral appliance consists 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 multiple models allowing the dentist to recommend different degrees of mandibular advancement and preference of anterior posts.

5.8 Intended Use

The ZQuiet-SA is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in adults.

5.9 Technological Characteristics

The ZQuiet-SA has identical technical characteristics as the predicate devices. Table 1 contains a description of basic technological characteristics and demonstrates that the proposed and prediate device are identical in terms of how they achieve their intended use.

Table 1: Substantial Equivalence Table Demonstrating Technological Characteristics

Feature	ZQuiet-SA Proposed Device	ZQuiet Cleared Under K090503	ZQuiet Cleared Under K093407	TOMED SomnoGuard - K061688
Basic Design	An upper and lower tray constructed in once piece and joined by a flexible hinge. The device is presented in multiple models which allow for the dentist to recommend the use of anterior posts and different degrees of mandibular advancement.	An upper and lower tray constructed in one piece and joined by a flexible hinge. The device has anterior posts and is presented in one size.	An upper and lower tray constructed in one piece and joined by a flexible hinge. The device has anterior posts and is presented in one size.	One piece design with a "boil and bite" fitting methodology. The SomnoGuard allows the mandible to be advanced 0-5mm.
Differential Mandibular Advancement	0mm, 2mm, 4mm, 6mm	6mm	6mm	0-5mm
Materials	Clear to light blue thermoplastic elastomer compound	Light blue thermoplastic elastomer compound	Light blue thermoplastic elastomer compound	Thermoplastic copolymer.

5.10 Non-Clinical Testing

No additional non-clinical testing was performed for this submission. However, a Risk Analysis was conducted to demonstrate that the risks of the product have been identified and appropriately accounted for.

5.11 Biocompatibility

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

5.12 Clinical Testing

No clinical testing was performed in association with this submission.

5.13 Conclusions

The results of the comparison of design, materials, intended use and technological characteristics demonstrate that the device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 25, 2014

Sleeping Well, LLC
c/o Mr. William McLain
Keystone Regulatory Services, LLC
342 E. Main Street, Suite 207
Leola, PA 17540

Re: K140777
Trade/Device Name: ZQuiet-SA
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: April 25, 2014
Received: April 28, 2014

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary [redacted] ner -S

Erin I. Keith, M.S.
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)*
K140777

Device Name
ZQuiet-SA

Indications for Use *(Describe)*
ZQuiet-SA is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in adults.

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)*

Michael E. Adjodha -S
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