K102475

DEC 7 2012

ZQuiet®

Sleeping Well, LLC
PO Box 1240
Shelburne, VT 05482

510(k) Summary
as required by 21 CFR 807.92(c)

1. Submitter's Identification:

Submitter:	Daniel Webster, Vice President
Address:	Sleeping Well, LLC 5247 Shelburne Rd., #204 PO Box 1240 Shelburne, VT 05482
Telephone: Fax:	(802) 985-3013 (802) 985-9298
Email:	dan@zquiet.com
Correspondent:	(Same As Submitter)
Date of Submission:	August 9, 2012

2. Device Name & Classification:

Device Trade Name:	ZQuiet® Pro-Plus
Common Name:	Intraoral Devices for Snoring and Obstructive Sleep Apnea
Classification Name:	Device, Anti-snoring
Product Code:	LRK
Class:	II
Classification Regulation Number:	21 CFR § 872.5570

3. Device Description:

The ZQuiet® Pro-Plus is an intra oral device used for treating snoring and sleep apnea. It functions to reposition the mandible to increase the patient's pharyngeal space to increase airflow, reduce the vibrations of the soft palate associated with snoring, and/or prevent the collapse of the airway associated with apneic events. The device consists of two (2) custom orthotics; one for the maxillary arch and one for the mandibular arch, made from acrylics widely used and approved for use in the dental industry. The orthotic employs a buccal cam mechanism, consisting of an apposing fin and buttress, that maintains the orthotics in an anteriorized relationship when worn during sleep.

4. Statement of Intended Use:

The ZQuiet® Pro-Plus oral appliance is intended to reduce or alleviate nighttime snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older.

5. Identification of Legally Marketed Predicate Device:

The ZQuiet® Pro-Plus oral appliance is substantially equivalent to other legally marketed devices in the United States, and has the same intended use and technological characteristics as the following predicate device: The SomnoMed MAS RxA (K050592), by SomnoMed Limited.

6. Technological Comparison:

The ZQuiet® Pro-Plus oral appliance utilizes the same technological design features as the predicate device to advance the mandible for the intended use of treating snoring and/or mild to moderate obstructive sleep apnea. Both utilize separate, custom fit, upper and lower dental orthotics. The jaw advancement and relative positioning of the trays is maintained by apposing fin and buttress features, and contain embedded expansion screws for adjustment. Both devices allow vertical jaw movement and enable mouth breathing. The proposed device has one optional design difference that has no relation to the technology associated with the intended use. The upper tray can be made with an omega loop of stainless steel wire located at the anterior midline to relieve palatal stress.

7. Summary of Substantial Equivalence:

The ZQuiet® Pro-Plus oral appliance is substantially equivalent to the SomnoMed MAS RxA. Both devices have the same intended use/indications for use and technology. Both devices are custom made adjustable mandibular repositioning devices fabricated in registered establishments. Both are prescription devices indicated for patients suffering from snoring and/or mild to moderate obstructive sleep apnea. The fundamental scientific technology

of the device is identical to the referenced predicate device, and furthermore, it has been demonstrated in this 510(k) submission that the differences between the ZQuiet® Pro-Plus oral appliance and the predicate device do not raise any questions regarding their safety and effectiveness.

8. Non-Clinical Testing:

Biocompatibility test results are known for this device as well as tests for tear resistance tear strength, tensile strength, elongation yield, and modulus of elasticity.

9. Conclusion

The descriptive characteristics of the ZQuiet® Pro-Plus oral appliance are precise enough to ensure comparability with the predicate when manufactured according to specifications. By comparing designs to the predicate device and the materials used it's concluded that the ZQuiet® Pro-Plus is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 7, 2012

Mr. Daniel Webster
Vice President
Sleeping Well, Limited Liability Company
5247 Shelburne Road, Suite 204
Shelburne, Vermont 05482

Re: K122475
Trade/Device Name: ZQuiet® Pro-Plus Appliance
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: November 2, 2012
Received: November 15, 2012

Dear Mr. Webster:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer

Anthony D. Watson, B.S. M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122475

Device Name: ZQuiet® Pro-Plus Appliance

Indications for Use:

The ZQuiet® Pro-Plus oral appliance is intended to reduce or alleviate nighttime snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

2012.12.06
Susan Runner DDS, MA 13:59:00
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____