K090503

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Sleeping Well, LLC
Company Address	PO Box 1240 Shelburne, VT 05482
Telephone:	802-985-3013 888-978-4389
Fax:	
Contact Person:	Daniel A. Webster

MAR 1 0 2009

Summary Preparation Date: January 20, 2009

DEVICE NAME **807.92(a)(2)**

Trade Name:	ZQuiet® Mouthpiece
Common/Usual Name:	Anti-Snoring Device/Mandibular Advancement Device
Classification Name:	Device, Anti-snoring
Regulation Number:	CFR21 872.5570
Product Code:	LRK
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Tomed Dr. Toussaint GmbH.	Anti-Snoring/Sleep Apnea Device	K061688

DEVICE DESCRIPTION **807.92(a)(4)**

The ZQuiet ® Mouthpiece is an Anti-Snoring device consisting of :

- Two trayed plates fitted in front and between the upper and lower teeth and gums and integrated with each other with the same material as the upper and lower plates.
- The device is made of Thermoplastic elastomer
- May be used as supplied

DEVICE INTENDED USE **807.92(a)(5)**

The ZQuiet Anti-Snoring device is intended for the treatment of nightime snoring in adults.

Target Population: Adult patients

Environment of Use: Home and sleep laboratories

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Similarities		
Device	**New Device ZQuiet®**	**Predicate Device SomnoGuard Series**
K Number		K061688
Classification Name	Device, Anti-Snoring	Device, Anti-Snoring
Product Code	LRK	LRK
INTENDED USE		
Mandibular Advancement device	Yes	Yes
Intended as an intraoral device	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes
Indicated for single patient multi use	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes
Prescription device	Yes	Yes
MATERIALS		
Device material	Thermoplastic elastomer	Thermoplastic elastomer
Non-sterile	Yes	Yes
THEORY OF OPERATION		
Advancement of lower jaw to open upper airway	Yes	Yes
DEVICE DESIGN		
Ready-to-Use	Yes	Yes
Upper and lower trays	Yes	Yes
One piece design	Yes	Yes
Ready-to-use device	Yes	Yes
PATIENT USE		
Permits patient to breathe through the mouth	Yes	Yes
Placed in user's mouth each evening	Yes	Yes
Cleaned daily	Yes	Yes
Easily removed from the mouth	Yes	Yes
DIFFERENCES		
Boil and Bite fitting	No	Yes
Indicated for use with patients with mild to moderate OSA	No	Yes

Substantial Equivalence Discussion
ZQuiet Anti-Snoring Device is similar to the predicate device in intended use, materials and design and does not raise any new issues concerning safety and effectiveness.

NONCLINICAL AND CLINICAL TEST **807.92(b)**

SAFETY and EFFECTIVENESS

BIOCOMPATIBILITY
Non-Clinical Performance Data
ZQuiet® Anti-Snoring Device has been evaluated for safety through *in vitro* tests and animal safety studies.

CONCLUSION **807.92(b)(3)**
ZQuiet® Anti-Snoring Device is similar to the predicate device in intended use, materials and design and does not raise any new issues concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sleeping Well, LLC
C/o Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

MAR 1 0 2009

Re: K090503
Trade/Device Name: ZQuiet® Mouthpiece
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: February 20, 2009
Received: February 25, 2009

Dear Mr. 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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090503

Device Name: ZQuiet® Mouthpiece

Indications for Use:

The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090503