K093407

510(k) Summary

807.92(c)

JUN 22 2010

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

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

Summary Preparation Date: May 27, 2010

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

Trade Name:	ZQuiet® Mouthpiece
Common/Usual Name:	Anti-Snoring 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) #*
Sleeping Well, LLC	ZQuiet Mouthpiece	K090503

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

The ZQuiet anti-snoring device is a single piece anti-snoring device, which moves the lower jaw forward and helps reduce the likelihood of snoring. This is achieved by covering the upper and lower teeth with a resilient non-toxic thermoplastic elastomer compound. The ZQuiet is easy to wear and simple to use. The single shot manufacturing process incorporates a resilient hinge in the molar area to provide a single piece device.

The anti-snore device comprises an upper member adapted to engage the maxillary dentition of a human and a lower member adapted to engage the mandibular dentition of the human, the upper and lower members being resiliently hinged together.

DEVICE INTENDED USE / INDICATION FOR USE **807.92(a)(5)**

The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults 18 years are older.

Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed Dentist.

Target Population: Adult patients

Environment of Use: Home and sleep laboratories

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

COMPARISON OF SIMILARITIES AND DIFFERENCES		
Item	Modified Device ZQuiet	Predicate Device ZQuiet
K Number	N/A	K090503
Classification Name	Device, Anti-Snoring	Device, Anti-Snoring
Product Code	LRK	LRK
SIMILARITIES		
INTENDED USE		
Indications for Use	The ZQuiet Anti-Snoring device is intended for the treatment of nighttime snoring in adults 18 years or older.	The ZQuiet Anti-Snoring device is intended for the treatment of nighttime snoring in adults.
Intended as an intraoral device	Intended as an intraoral device	Intended as an intraoral device
Intended to reduce snoring or help alleviate snoring	Intended to reduce snoring or help alleviate snoring	Intended to reduce snoring or help alleviate snoring
Indicated for single patient multi use	Indicated for single patient multi use	Indicated for single patient multi use
Indicated for use at home or sleep laboratories	Indicated for use at home or sleep laboratories	Indicated for use at home or sleep laboratories
Prescription device	Prescription device	Prescription device
MATERIALS		
Non-sterile	Non-sterile	Non-sterile
DEVICE DESIGN		
Upper and lower trays	Upper and lower trays	Upper and lower trays
One piece design	One piece design	One piece design
PATIENT USE		
Permits patient to breathe through the mouth	Permits patient to breathe through the mouth	Permits patient to breathe through the mouth
Placed in user's mouth each evening	Placed in user's mouth each evening	Placed in user's mouth each evening
Cleaned daily	Cleaned daily	Cleaned daily
Easily removed from the mouth	Easily removed from the mouth	Easily removed from the mouth
DIFFERENCES		
Device material	Dynaflex G2701-1000-02	Dynaflex G27-0001

NONCLINICAL AND CLINICAL TEST 807.92(b)

ZQuiet® Anti-Snoring Device has been evaluated through *in vitro* tests and animal safety studies. All data is consistent in indicating that this product is safe for use as an anti-snoring device. The materials used in the following studies are identical to the material under review Dynaflex G2701-1000-02. The categories of safety tests and the safety test conclusions are as follows:

Test Performed	Standard/Test Methodology	Results
Agar Diffusion Test (ISO	ISO 10993-5: 1999 "Tests for *in vitro cytotoxicity*	Pass Not considered cytotoxic
Primary Dermal Irritation in Rabbits	Federal Hazardous Substances Act Regulations (16 CFR 1500.41	Pass Not a primary dermal irritant
Guinea Pig Closed Patch Sensitization Test	ISO 10993-10: 2002 Tests for irritation and delayed type hypersensitivity	Pass No sensitizing properties
Oral Mucosal Irritation Study	ISO 10993 – Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity	Under conditions of this study, and based on the Irritation Index the test article was considered to be a minimal irritant.

CONCLUSION 807.92(b)(3)

ZQuiet Anti-Snoring Device is identical to the predicate device in intended use, and design. The material change has been tested according to ISO 10993 and is found safe for the intended use. The ZQuiet Anti-Snoring Device does not raise any new issues concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Sleeping Well, LLC
C/O Yolanda Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

JUN 22 2010

Re: K093407
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: June 4, 2010
Received: June 4, 2010

Dear Ms. Smith:

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.

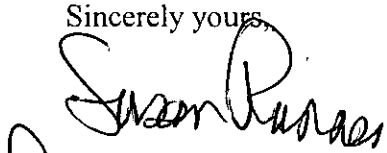
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

K093407

Indications for Use

510(k) Number (if known): _____

Device Name: ZQuiet® Mouthpiece

Indications for Use:

The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults 18 years or older.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

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)

Susan Runner

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

510(k) Number: K093407