510(k) Summary

SPONSOR
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
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
Legally Marketed Equivalent Device
Company: Sleeping Well, LLC
Product: ZQuiet Mouthpiece
510(k) # K090503

DEVICE DESCRIPTION
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
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)

<table>
<thead>
<tr>
<th>K Number</th>
<th>N/A</th>
<th>K090503</th>
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<tbody>
<tr>
<td><strong>Classification Name</strong></td>
<td>Device, Anti-Snoring</td>
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<td><strong>Product Code</strong></td>
<td>LRK</td>
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**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 use**
- Intended as an intraoral device
- Intended to reduce snoring or help alleviate snoring
- Indicated for single patient multi use
- Indicated for use at home or sleep laboratories
- Prescription device

**Device Design**
- Non-sterile

**Device Details**
- Upper and lower trays
- One piece design

**Patient Use**
- Permits patient to breathe through the mouth
- Placed in user’s mouth each evening
- Cleaned daily
- Easily removed from the mouth

**Device Material**
- Dynaflex G2701-1000-02
- Dynaflex G27-0001
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:

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Test Details</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Dermal Irritation in Rabbits</td>
<td>Federal Hazardous Substances Act Regulations (16 CFR 1500.41)</td>
<td>Pass Not a primary dermal irritant</td>
</tr>
<tr>
<td>Guinea Pig Closed Patch Sensitization Test</td>
<td>ISO 10993-10: 2002 Tests for irritation and delayed type hypersensitivity</td>
<td>Pass No sensitizing properties</td>
</tr>
<tr>
<td>Oral Mucosal Irritation Study</td>
<td>ISO 10993 – Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity</td>
<td>Under conditions of this study, and based on the Irritation Index the test article was considered to be a minimal irritant.</td>
</tr>
</tbody>
</table>

**CONCLUSION**

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

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" (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 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
Indications for Use

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)

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

510(k) Number: K093407