September 20, 2016

SomnoMed Inc.
c/o Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Milburn, NJ 07041

Re: K162306
Trade/Device Name: SomnoDent ALPHA®
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: LRK
Dated: September 2, 2016
Received: September 6, 2016

Dear Dave Yungvirt:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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

The SomnoDent ALPHA is temporarily intended as an aid in the reduction of simple night time snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) Summary  
(As required by 21 CFR 807.92)  
SomnoDent ALPHA®

1.0 Submitter  
SomnoMed, Inc.  
7460 Warren Parkway, Ste. 190  
Frisco, TX 75034  
Telephone: 972-377-3400  
Fax: 469-200-7855  

Official Contact  
Kien Nguyen  
President-North America  
Telephone: 972-377-3400, Ext. 101  
Email: knguyen@somnomed.com

2.0 Date Prepared  
March 29, 2016

3.0 Device Identification  
Proprietary Names: SomnoDent ALPHA®  
Common Name: Device, Anti-Snoring  
Classification Name: Intraoral device for snoring and Intraoral devices for snoring and obstructive sleep apnea  
Device Classification: Class II  
Product Code: LRK  
Regulation Number: 21 CFR 872.5570

4.0 Legally Marketed Predicate Device  

<table>
<thead>
<tr>
<th>Proposed Candidate</th>
<th>Predicates</th>
<th>Manufacturer</th>
<th>Document Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SomnoDent ALPHA®</td>
<td>PRIMARY = SomnoDent® Fusion</td>
<td>SomnoMed Inc.</td>
<td>K140278</td>
</tr>
<tr>
<td></td>
<td>REFERNCE = TOA/myTAP</td>
<td>Airway Management</td>
<td>K972061</td>
</tr>
</tbody>
</table>

The SomnoDent ALPHA is substantially equivalent to the predicates listed above, currently in commercial distribution.

5.0 Device Description  
The SomnoDent ALPHA is a device that functions as a mandibular repositioner, which acts to increase the patient’s pharyngeal space during sleep. The increase in the patient’s pharyngeal space improves their ability to exchange air during sleep. The device consists of two generic splints, which fit over the upper and lower teeth. The lower splint is held in a protrusive position by an advancement mechanism. The device advances the mandible in the sagittal plane to increase the patient’s pharyngeal space during sleep and reduce the apnea symptoms.

6.0 Intended Use  
The SomnoDent ALPHA is temporarily intended as an aid in the reduction of simple night time snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older.
## 7.0 Comparison to the Predicate

<table>
<thead>
<tr>
<th>Technological Characteristics</th>
<th>Primary Predicate Fusion K140278</th>
<th>Reference Predicate TOA/MyTap K972061</th>
<th>Proposed SomnoDent ALPHA®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Intended as an intraoral device</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Intended to reduce snoring or help alleviate snoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indicated for use with patients with mild to moderate obstructive sleep apnea</td>
<td></td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Intended for night-time use</td>
<td></td>
<td></td>
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<tr>
<td>Indicated for single patient multiuse</td>
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<td></td>
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<tr>
<td>Indicated for use at home or sleep laboratories</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Target population: adults</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In use claim</td>
<td>Difference 3-5 Years</td>
<td>Difference Not Stated</td>
<td>Difference 90 days</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating Principle - Mandibular Advancement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separate upper and lower tray pieces</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Can be adjusted or refit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placed in patient’s mouth each evening</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Permits patient to breathe through mouth</td>
<td></td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Permits patient to talk and drink with appliance in place</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Permits lateral and/or vertical jaw movement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper and lower trays disengage for easy removal from mouth</td>
<td></td>
<td></td>
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<tr>
<td>Cleaned and inspected daily by patient</td>
<td></td>
<td></td>
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<tr>
<td>Customized fit for each patient</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Lower jaw adjustment mechanism</td>
<td>Similar Wing/Lug</td>
<td>Difference Dial Adjustment</td>
<td>Similar Wing/Lug Clip Lock</td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biocompatible tray material</td>
<td>Difference Soft Liner Dental Acrylic (not light cured) Surgical Stainless Steel</td>
<td>Both reference predicate and proposed use a similar Rigid Polycarbonate.</td>
<td></td>
</tr>
<tr>
<td>Heat sensitive impression material for fitting to teeth</td>
<td>N/A</td>
<td>Proprietary Heat Formable Lining</td>
<td></td>
</tr>
</tbody>
</table>
8.0 Performance Testing
To demonstrate substantial equivalence risk management [ISO 14971:(R)2010, biocompatibility [ISO 10993-1:(R)2013; 10993-5:(R)2014; and 10993-10:2010], and bench performance testing was conducted to ensure the device performed as intended and is safe and effective. During risk management and performance testing, no new risks were identified. The risk management concluded that the SomnoDent ALPHA is state of the art with acceptable risks.

The testing on the adjustment mechanism demonstrates that the wing/lug, clip lock mechanism can withstand the applicable forces within the mouth, ensuring the device is safe and effective. In addition, the biocompatibility evaluation and testing to ISO 10993 demonstrated that the device is a non-sensitizer, non-irritant and is non-cytotoxic.

The primary Fusion predicate is made according to an individual bite record to establish a baseline for mandibular adjustment, a larger adjustment range is not clinically necessary. The Fusion is usually produced at 60-70 percent of maximum starting protrusion, and then the adjustment mechanism allows further adjustments. For a one size fits all customizable device (ALPHA/MyTap), a larger adjustment range is necessary to establish a starting protrusion position and still allow for therapeutic adjustment. Since the customizable devices have the same adjustment range and mandibular advancement is already a proven treatment option for snoring and sleep apnea, no additional clinical testing is necessary to support substantial equivalence.

The SomnoDent ALPHA has a similar intended use as its primary and reference predicates, except that it is used temporarily. The temporarily intended use claim does not impact equivalence, as the device enables clinicians to determine if a patient is a good candidate for a mandibular repositioner with a shorter in use claim prior to prescribing a similar device with a longer in use claim. The ALPHA intended use is conservative and supported by biocompatibility and in-use bench testing. Simulated in-use testing was completed with mechanical cyclic force testing during performance testing to support the in use claim.

9.0 Conclusion
The SomnoDent ALPHA device is as safe and as effective for its intended use and performs as well as the predicate devices. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.