DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

SomnoDent ALPHA®

Indications for Use *(Describe)*

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.

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510(k) Summary

(As required by 21 CFR 807.92)

SomnoDent ALPHA®

1.0 Submitter

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President-North America
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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

Proposed Candidate	Predicates	Manufacturer	Document Number
SomnoDent ALPHA®	**PRIMARY** = SomnoDent® Fusion	SomnoMed Inc.	K140278
	REFERNCE = TOA/myTAP	Airway Management	K972061

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

Technological Characteristics	Primary Predicate Fusion K140278	Reference Predicate TOA/MyTap K972061	Proposed SomnoDent ALPHA®
Intended Use			
Intended as an intraoral device	Same		
Intended to reduce snoring or help alleviate snoring			
Indicated for use with patients with mild to moderate obstructive sleep apnea			
Intended for night-time use			
Indicated for single patient multiuse			
Indicated for use at home or sleep laboratories			
Target population: adults			
Prescription device			
In use claim	Difference 3-5 Years	Difference Not Stated	Difference 90 days
Design			
Operating Principle - Mandibular Advancement	Same		
Separate upper and lower tray pieces			
Can be adjusted or refit			
Placed in patient's mouth each evening			
Permits patient to breathe through mouth			
Permits patient to talk and drink with appliance in place			
Permits lateral and/or vertical jaw movement			
Upper and lower trays disengage for easy removal from mouth			
Cleaned and inspected daily by patient			
Customized fit for each patient			
Lower jaw adjustment mechanism	Similar Wing/Lug	Difference Dial Adjustment	Similar Wing/Lug Clip Lock
Materials			
Biocompatible tray material	Difference Soft Liner Dental Acrylic (not light cured) Surgical Stainless Steel	Both reference predicate and proposed use a similar Rigid Polycarbonate.	
Heat sensitive impression material for fitting to teeth	N/A	Proprietary Heat Formable Lining	

Performance Specification	Primary Predicate Fusion K140278	Reference Predicate TOA/MyTap K972061	Proposed SomnoDent ALPHA®
Adjustment Range	0-8 mm	Same 0-20 mm	

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.