May 8, 2019

SomnoMed Inc.
℅ Dorene Markwiese
Director Regulatory Affairs and Quality Assurance
SonoMed Inc.
820 Civic Center Dr.
Santa Clara, California 95050

Re: K183443
Trade/Device Name: SomnoDent Avant
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK, LQZ
Dated: January 28, 2019
Received: February 7, 2019

Dear Dorene Markwiese:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K183443

Device Name: SomnoDent Avant

Indications for Use:

The SomnoDent Avant is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary (21 CFR 807.92)

510(k) Number: K183443

Submission Owner:	SomnoMed, Inc. 6513 Windcrest Drive Suite 100 Plano, TX 75024 Phone: 888-447-6673 Email: dmarkwiese@somnomed.com
Official Correspondent:	Dorene Markwiese
Date Prepared:	May 6, 2019
Trade Name:	SomnoDent® Avant
Common Name:	Intraoral device for snoring and mild to moderate obstructive sleep apnea (OSA)
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulation Number:	21 CFR 872.5570
Product Code:	LRK / PLC
Class:	II
Panel:	Dental
Primary Predicate:	K073004, SomnoDent Flex
Reference Devices	Narval CC (K113201) MicrO2 OSA Device (K133683)

Description of the device:
The SomnoDent Avant device is an intraoral device used for treating Snoring and Sleep Apnea. The device 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 is customized for each patient and has an adjustable coupling mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. The SomnoDent Avant is a modification to the SomnoDent Flex (K073004). The SomnoDent Avant is identical to SomnoDent Flex, except for differences in the adjustment mechanism (strap set material), and a change in adjustable range from -1.0mm to +8.0mm.

Indications for Use:
The SomnoDent Avant is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

510(k) Summary

Substantial Equivalence:

Substantial Equivalence Table

	SomnoDent Avant	PRIMARY PREDICATE SomnoDent Flex (FDA K073004)	REFERENCE Narval CC (FDA K113201)	REFERENCE MicrO2 OSA Device (FDA K133683)
				
Materials				
Tray	PMMA	PMMA	Polyamide	PMMA
Soft Liner	SMH B-Flex	SMH B-Flex	(none)	(none)
Advancement Mechanism	Polyamide	PMMA, Stainless Steel	Polyamide	PMMA
Intended Use				
Indication for Use	The SomnoDent Avant is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age and older.	The SomnoMed MAS Flex "S" is intended to reduce or alleviate night time snoring and mild to moderate Obstructive Sleep Apnea (OSA).	The Narval CC is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The MICRODENTAL, Inc. MicroO2 is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Intended as an intraoral device	Yes	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes	Yes
Treatment of mild to moderate obstructive sleep apnea	Yes	Yes	Yes	Yes
Intended for night-time use	Yes	Yes	Yes	Yes
Indicated for single patient multi-use	Yes	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes	Yes
Target population: adults	Yes	Yes	Yes	Yes
Prescription device	Yes	Yes	Yes	Yes
Design				
Customized fit for each patient	Yes	Yes	Yes	Yes
Works by mandibular advancement	Yes	Yes	Yes	Yes

Connected upper and lower tray pieces	Yes	No	Yes	No
Manufacture technology	Uses computer-aided design (CAD) and manufactured using CNC machining	Uses hand-made manufacture on dental models	Uses computer-aided design (CAD) and manufactured using selective laser sintering	Uses computer-aided design (CAD) and manufactured using CNC machining

510(k) Summary

Substantial Equivalence Discussion:
The SomnoDent Avant is considered to be substantially equivalent to the SomnoDent Flex device. SomnoDent Avant is an oral appliance used for the treatment of snoring and mild to moderate Obstructive Sleep Apnea (OSA). The SomnoDent Avant and predicate device function 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 devices are customized for each patient and have an adjustable coupling mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.

The device consists of two trays customized to fit over the upper and lower teeth and the lower tray is held in a protrusive position by an advancement mechanism consisting of a strap attached to an upper anterior guide and two lower fixing elements. The device advances the mandible in the sagittal plane to increase the patient's pharyngeal space during sleep and reduce the apnoeic symptoms.

SomnoDent Avant is retained to the teeth by a polymeric material (called SMH B-Flex) which forms a soft, flexible lining between the teeth and dental acrylic. This material continuously engages the undercut along the entire arch on both labial and lingual sides. This polymeric material, SMH B- flex, is the same material previously cleared by FDA under K073004.

SomnoDent Avant is adjusted by switching out the strap for another strap with a different length. This adjustment may be required to fine-tune treatment, increase comfort or to ensure ongoing effectiveness as the patient's anatomy adapts.

The device has a device specific special control guidance document entitled "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA."

The SomnoDent Avant is identical to SomnoDent Flex, except for differences in the adjustment mechanism (strap set material), and a change in adjustable range, i.e., increments of 1mm, from -1.0mm to +8.0mm, and the additional Avant Strap Sets. Any differences introduced by these modifications, when compared to the predicate product, do not affect substantial equivalence.

Summary of Non-Clinical Testing:
Bench testing of the new adjustment mechanism and evaluation of the additional strap set material confirms substantial equivalence of the SomnoDent Avant to the predicate device.

- Biocompatibility Evaluation per FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
    - Conducted Cytotoxicity, Sensitization and Irritation biocompatibility testing per ISO 10993-5 and ISO 10993-10
- Evaluation of material conformance to ISO 20795-1 Dentistry – Polymers – Part 1 – Denture Base Polymers
- Risk Analysis of the modification per ISO 14971

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, it is concluded that the SomnoDent Avant is substantially equivalent to the predicate devices.