SomnoMed
Dental • Sleep • Medical

510(k) Summary (21 CFR 807.92)

JUN 20 2014

510(k) Number: K140278

Submission Owner:	SomnoMed, Inc. 7460 Warren Parkway Suite 190 Frisco, TX 75034 Phone: 888-447-6673 x106 Fax: 972-377-3404 Email: kjayne@somnomed.com
Official Correspondent:	Kathryn A. Jayne
Date Prepared:	January 31, 2014
Trade Name:	SomnoDent® Fusion
Common Name:	Intraoral device for snoring and mild to moderate obstructive sleep apnea (OSA)
Classification Name:	Device, Anti-Snoring
Regulation Number:	21 CFR 872.5570
Product Code:	LRK
Class:	II
Panel:	Dental
Predicate Devices:	K050592, SomnoDent Classic K073004, SomnoDent Flex K121340, SomnoDent G2 K130558, SomnoDent Herbst

Description of the device:
The SomnoDent Fusion is an intraoral device intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. 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 patient specific (it 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 Fusion is a modification to the SomnoDent Classic (K050592), SomnoDent Flex (K073004), SomnoDent G2 (K121340) and SomnoDent Herbst (K130558). The SomnoDent Fusion is identical to SomnoDent Classic, SomnoDent Flex, SomnoDent G2, and SomnoDent Herbst except for differences in the adjustment mechanism. Any differences introduced by these modifications, when compared to the predicate product, do not introduce new safety issues.

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

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Substantial Equivalence:

Substantial Equivalence Table

	SomnoDent Fusion	SomnoDent Classic K050592	SomnoDent Flex K073004	SomnoDent G2 K121340	SomnoDent Herbst K130558
Intended Use					
Intended as an intraoral device	Yes	Yes	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes	Yes	Yes
Treatment of mild to moderate obstructive sleep apnea	Yes	Yes	Yes	Yes	Yes
Intended for nighttime use	Yes	Yes	Yes	Yes	Yes
Indicated for single patient multiuse	Yes	Yes	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes	Yes	Yes
Target population: adults	Yes	Yes	Yes	Yes	Yes
Prescription device	Yes	Yes	Yes	Yes	Yes
Design					
Customized fit for each patient (patient specific)	Yes	Yes	Yes	Yes	Yes
Separate upper and lower tray pieces	Yes	Yes	Yes	Yes	Yes
Works by mandibular advancement	Yes	Yes	Yes	Yes	Yes

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	SomnoDent Fusion	SomnoDent Classic K050592	SomnoDent Flex K073004	SomnoDent G2 K121340	SomnoDent Herbst K130558
Can be adjusted or refit	Yes	Yes	Yes	Yes	Yes
Lower jaw adjustment using supplied components	Yes	Yes	Yes	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes	Yes	Yes	Yes
Upper and lower trays disengage for easy removal	Yes	Yes	Yes	Yes	Yes
Cleaned and inspected daily by patient	Yes	Yes	Yes	Yes	Yes
Material					
Trays constructed from a soft lining material adhered to a hard surface acrylic	Yes (Flex retention) No (Classic retention)	No	Yes	Yes (Flex retention) No (Classic retention)	Yes (Flex retention) No (Classic retention)
Advancement mechanism constructed of surgical grade stainless steel	Yes	Yes	Yes	No	Yes

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Substantial equivalence discussion:
The SomnoDent Fusion is considered to be substantially equivalent to the SomnoDent Classic, Flex, G2, and Herbst device. The SomnoDent Fusion and predicate devices 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 patient specific (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 SomnoDent Fusion is identical to SomnoDent Classic, Flex, G2, and SomnoDent Herbst except for differences in the adjustment. The SomnoDent Fusion will be available in one of two material types, acrylic (identical to SomnoDent Classic) or soft lining adhered to acrylic (SomnoDent Flex). Any differences introduced by these modifications, when compared to the predicate product, do not introduce new safety issues.

Summary of Testing:
To demonstrate substantial equivalence, testing was conducted on the advancement mechanism to ensure the device performed as intended and is safe and effective. Mechanical testing was conducted on the calibration mechanism of the subject device. Testing results indicate that the mechanism withstands applicable pressures, ensuring the device is safe and effective. The testing concluded that the advancement of the subject device is substantially equivalent to the predicate device with regards to mechanical performance. Testing demonstrates that the subject device, the SomnoDent Fusion, is as safe, as effective, and performs as well as or better than the predicate devices, the SomnoDent Classic, SomnoDent Flex, SomnoDent G2, and SomnoDent Herbst.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 20, 2014

SomnoMed, Incorporated
Ms. Kathryn Jayne
Regulatory Affairs/Quality Assurance Manager
7460 Warren Parkway, Suite 190
Frisco, TX 75034

Re: K140278
Trade/Device Name: SomnoDent Fusion Classic, Somnodent Fusion Flex
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, 2014
Received: June 5, 2014

Dear Ms. Jayne:

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 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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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 on last page.

510(k) Number *(if known)*
K140278

Device Name
SomnoDent Fusion

Indications for Use *(Describe)*
The SomnoDent® Fusion is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
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