SomnoMed
Dental • Sleep • Medical

MAY 3 0 2012

510(k) Summary (21 CFR 807.92)

510(k) Number: K121340

Submission Owner:	SomnoMed, Inc. 7460 Warren Parkway Suite 190 Frisco, TX 75034 Phone: 888-447-6673 Fax: 972-377-3404 Email: kjayne@somnomed.com
Official Correspondent:	Kathryn A. Jayne

Date Prepared:	February 15, 2012
Trade Name:	SomnoDent® G2
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:	K073004, SomnoDent Flex

Description of the device:

The SomnoDent G2 device 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 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 G2 is a modification to the SomnoDent Flex (K073004). The SomnoDent G2 is identical to SomnoDent Flex, except for differences in the adjustment mechanism (which is an addition of a material of construction, which is biocompatible), and a change in adjustable range from 6 to 10mm. Any differences introduced by these modifications, when compared to the predicate product, do not introduce new safety issues.

Indications for Use:

The SomnoDent G2 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 G2	SomnoDent Flex K073004
Intended Use		
Intended as an intraoral device	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes
Treatment of mild to moderate obstructive sleep apnea	Yes	Yes
Intended for nighttime use	Yes	Yes
Indicated for single patient multiuse	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes
Target population: adults	Yes	Yes
Prescription device	Yes	Yes
Design		
Customized fit for each patient	Yes	Yes
Separate upper and lower tray pieces	Yes	Yes
Works by mandibular advancement	Yes	Yes
Can be adjusted or refit	Yes	Yes
Lower jaw adjustment using supplied components	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes
Upper and lower trays disengage for easy removal	Yes	Yes
Cleaned and inspected daily by patient	Yes	Yes
Material		
Trays constructed from a soft lining material adhered to a hard surface acrylic	Yes	Yes
Advancement mechanism constructed of surgical grade stainless steel	No	Yes
Advancement mechanism constructed of biocompatible, medical grade polycarbonate	Yes	No

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Substantial equivalence discussion:
The SomnoDent G2 is considered to be substantially equivalent to the SomnoDent Flex device. The SomnoDent G2 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 SomnoDent G2 is identical to SomnoDent Flex, except for differences in the adjustment mechanism (which is an addition of a material of construction, which is biocompatible), and a change in adjustable range from 6 to 10mm. 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, bench testing was conducted on the advancement mechanism to ensure the device performed as intended and is safe and effective. Testing included a mechanical force test to simulate bruxism, which was determined worst case use, to ensure the wings functioned as designed and withstood appropriate pressures. The results indicated that the subject device performs as well or better than the predicate device. Mechanical testing was conducted on the winglet bond of the subject device. Testing results indicate that the bonds withstand applicable pressures, ensuring the device is safe and effective. In addition, comparative testing around the coupling mechanism was conducted between the subject and predicate devices. 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 G2, is as safe, as effective, and performs as well as or better than the predicate device, the SomnoDent Flex.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Somnomed Inc.
C/O Mr. Jeff D. Rongero
Responsible Third Party Official
Underwriters Laboratories
12 Laboratory Drive
Research Triangle, North Carolina 27709

MAY 30 2012

Re: K121340
Trade/Device Name: SomnoDent G2
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: May 21, 2012
Received: May 25, 2012

Dear Mr. Rongero:

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" (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,

for

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

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Indications for Use

510(k) Number (if known):

Device Name: SomnoDent G2

Indications for Use:

The SomnoDent G2 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)

Susan Runner

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

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