K113022

JUN 1 1 2012

Section 5.0 510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Sleep Science Partners, Inc.
Submitter's Address:	900 Larkspur Landing Circle, Suite 207 Larkspur, CA 94939
Telephone:	415-272-7777
Fax:	415-925-1575
Contact Person:	Heather Flick
Date Prepared:	October 7, 2011
Device Trade Name:	PureSleep
Device Common Name:	Antisnoring device
Device Classification Name:	Intraoral devices for snoring and obstructive sleep apnea
Device Classification:	Class II
Product Classification:	872.5570
Product Code	LRK

Summary of Substantial Equivalence:

The proposed PureSleep is substantially equivalent to the currently marketed PureSleep device (formerly known as SnoreMaster - K954128) and the SomnoGuard (K061688).

Device Description:

PureSleep is an intraoral mandibular repositioning device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea in adults. It advances the lower jaw and tongue forward so the airway will remain open during sleep. The PureSleep device has three adjustments for forward mandibular advancement, 4mm apart anteriorly, while maintaining a 9mm inferior placement for patient comfort.

The PureSleep device is formed to the upper and lower teeth similar to an athletic mouth guard. When boiled, the outer resin holds its shape, while the inner resin softens, which adapts to the teeth when bitten. To prepare for the fitting, the upper and lower components are attached at the proper setting depending on the patient's bite, using either the two holes closest to the front of the device, the center holes, or the two holes closest to the back of the device. The device is boiled in water for one minute, allowed to cool for 14 to 18 seconds. Holding the mouth open and lower jaw forward, the patient places the PureSleep device in the mouth and bites down firmly for 45 seconds. Upon removal of the device, excess material can be trimmed for greater comfort. The device can be re-boiled up to three times to achieve the best impression.

PureSleep is simple to fit and does not require impressions or lab-fabrication. As such, it is a more economical and timesaving alternative to more costly lab-fabricated mandibular advancement devices.

Intended Use:

PureSleep is an intraoral mandibular repositioning device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea in adults.

Technological Characteristics Compared to Predicate:

A comparison of the technological characteristics of the proposed PureSleep and the predicate devices has been performed. The results of this comparison demonstrate that the proposed PureSleep device is equivalent to the predicate devices.

Performance Data:

With the exception of the molding resin used for the upper intraoral piece, the design of the proposed PureSleep device is identical to the currently marketed PureSleep (formerly known as SnoreMaster K954128), cleared in October 2, 1995. Biocompatibility testing was performed, according to ISO 10993 Parts 5 and 10, on the proposed device and all tests met specification. The mechanism of action remains the same. Published literature and the cleared predicate devices justify the rationale for expanding the intended use to treat mild to moderate obstructive sleep apnea.

Published Literature

The PureSleep indications for use have been expanded to include, "treat mild to moderate sleep apnea in adults." This expanded claim is based on the fact that the PureSleep mechanism of action has not changed since the original and cleared FDA product submission K954128 and on published scientific studies that have shown mandibular repositioning devices effective in treating snoring and mild to moderate obstructive sleep apnea.

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

Ms. Heather Flick
Vice President and Chief Legal Counsel
Sleep Science Partners, Inc.
900 Larkspur Landing Circle, Suite 207
Larkspur, California 94939

JUN 11 2012

Re: K113022
Trade/Device Name: PureSleep
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, 2012
Received: June 7, 2012

Dear Ms. Flick:

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,

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

Section 4.0 Indications for Use

510(k) Number (if known): K113022

Device Name: PureSleep

Indications for Use:

PureSleep is an intraoral mandibular repositioning device used during sleep to reduce snoring and treat mild to moderate obstructive sleep apnea in adults.

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

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

510(k) Number: K113022