**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 18, 2015

SomnoMed, Inc.
c/o Kien T. Nguyen, Ph.D., MBA
President – North America
7460 Warren Parkway, Suite 190
Frisco, Texas, 75034

Re: K150369
Trade/Device Name: SomnoDent® with Micro-Recorder
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: PLC
Dated: May 19, 2015
Received: May 19, 2015

Dear Dr. Nguyen:

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 yours,

Tina Kiang -S

for 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

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)*

K150369

Device Name

SomnoDent® with Micro-Recorder

Indications for Use *(Describe)*

The SonmoDent® intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Optionally, if the DentiTrac® micro-recorder is completely embedded into the SomnoDent® device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac® System.

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.**





PSC Publishing Services (301) 443-6740 EF

# 510(k) Summary

(As required by 21 CFR 807.92)

# SomnoDent® with Micro-Recorder

## 1.0 Submitter

SomnoMed, Inc.
7460 Warren Parkway, #190
Frisco, TX 75034
Telephone: 972-377-3400
Fax: 972-377-3404

**Official Contact**

Kien Nguyen, Ph.D., MBA
President – North America
Telephone: 972-377-3400, Ext. 101
Email: knguyen@somnomed.com

## 2.0 Date Prepared

June 16, 2015

## 3.0 Device Identification

| | |
|---|---|
| Proprietary Names: | SomnoDent® with Micro-Recorder |
| 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: | PLC |
| Regulation Number: | 21 CFR 872.5570 |

## 4.0 Legally Marketed Predicate Device

| Candidate(s) | Predicate | Manufacturer | Document Number |
|---|---|---|---|
| SomnoDent® with Micro-Recorder | SomnoDent® Fusion Classic, SomnoDent® Fusion Flex | SomnoMed, Inc. | K140278 |

The SomnoDent® with Micro-Recorder is substantially equivalent to the SomnoDent® Fusion Classic and Flex products listed above, currently in commercial distribution.

## 5.0 Device Description

The SomnoDent family of intraoral devices consists of the following models: Classic, Flex, G2, Herbst Advance, and Fusion. The devices 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 devices are patient specific (they are customized for each patient) and have an adjustable coupling mechanism enabling the amount of mandibular advancement to be set by the sleep dentist at the time of fitting the device. The devices can then be adjusted by the sleep dentist to control the treatment to find the best possible adjustment.

This submission adds the option for any clinician to decide to incorporate a DentiTrac® micro-recorder embedded into a SomnoDent® to record a patient's compliance to the prescribed oral appliance therapy in combination with the DentiTrac® System. This option can be incorporated into the family member models listed above. During scheduled visits, the data within the DentiTrac® can be uploaded to a web application for cloud-based reporting and tracking using a DentiTrac® Base Station at the clinician's office. The DentiTrac® micro-recorder monitors the wear time through the oral temperature, as well as tracks movements and head position. The inclusion of the embedded DentiTrac® micro-recorder provides additional information when used in combination with the DentiTrac® System, but does not impact the operating principles or safety of the SomnoDent®.

## 6.0 Intended Use

The SomnoDent® intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Optionally, if the DentiTrac® micro-recorder is completely embedded into the SomnoDent® appliance, the micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac® System.

## 7.0 Comparison to the Predicate

| Technological Characteristics | Predicate SomnoDent® Fusion K140278 | Proposed SomnoDent® Family with DentiTrac® Micro-Recorder |
|---|---|---|
| **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 (Flex retention)<br><br>No (Classic retention) | Yes (Flex retention)<br><br>No (Classic retention) |
| Advancement mechanism constructed of surgical grade stainless steel | Yes | Yes |
| **DentiTrac® Micro-recorder embedded into SomnoDent®** | **No** | **Yes** |

The addition of the DentiTrac Micro-Recorder to the SomnoDent device does not change the intended use of the SomnoDent device for the treatment of night time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. Based on how the DentiTrac Micro-Recorder is embedded inside the SomnoDent device, the patient will not be physically exposed to the micro-recorder. The DentiTrac Micro-Recorder is completely sealed under a layer of acrylic within the SomnoDent device. Furthermore, the size, position and location of the embedded DentiTrac Micro-Recorder in the SomnoDent device does not increase any risk to patient safety as there is ample space in the patient's oral cavity to accommodate the additional volume.

## 8.0 Performance Testing

The SomnoDent® family of devices with DentiTrac® micro-recorder are identical to the predicate devices with the exception of the addition of the DentiTrac® micro-recorder. Since the characteristics of the SomnoDent® did not change, no new clinical performance data was necessary to substantiate this change. Risk assessments and non-clinical testing demonstrated that EMC and electrical safety, biocompatibility, and software elements were assessed and tested. The data is reported in master file, MAF2557. Process validation was generated from SomnoMed to ensure that the SomnoDent® devices can be repeatedly and reliably embedded and retain the Quality Control functionality of SomnoDent® and the DentiTrac®.

## 9.0 Conclusion

Based on the similarities in the primary intended use, principles of operation, functional design, established materials and medical use, and the information presented in the summary and in Masterfile MAF2557, the conclusions demonstrate that the SomnoDent® family members with an embedded DentiTrac® micro-recorder are as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.