Description of the device:
The SomnoDent Herbst 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 Herbst is a modification to the SomnoDent Classic (K050592) and SomnoDent Flex (K073004). The labeling is a modification to the SomnoDent G2 (K121340). The SomnoDent Herbst is identical to SomnoDent Classic and SomnoDent Flex, except for differences in the adjustment mechanism (which is a Herbst style titration mechanism). Any differences introduced by these modifications, when compared to the predicate product, do not introduce new safety issues.

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

#### Substantial Equivalence Table

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>SomnoDent Herbst</th>
<th>SomnoDent Classic K050592</th>
<th>SomnoDent Flex K073004</th>
<th>SomnoDent G2 K121340</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended as an intraoral device</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Intended to reduce snoring or help alleviate snoring</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Treatment of mild to moderate obstructive sleep apnea</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Intended for nighttime use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for single patient multiuse</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for use at home or sleep laboratories</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Target population: adults</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Prescription device</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customized fit for each patient (patient specific)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Separate upper and lower tray pieces</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Works by mandibular advancement</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can be adjusted or refit</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Lower jaw adjustment using supplied components</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Permits patient to breathe through mouth</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Upper and lower trays disengage for easy removal</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cleaned and inspected daily by patient</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Substantial equivalence discussion:
The SomnoDent Herbst is considered to be substantially equivalent to the SomnoDent Classic, Flex, and G2 device. The SomnoDent Herbst 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 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 Herbst is identical to SomnoDent Classic, Flex, and G2 except for differences in the adjustment mechanism (which is a Herbst style titration mechanism. The SomnoDent Herbst 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 Herbst style titration 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 Herbst, is as safe, as effective, and performs as well as or better than the predicate devices, the SomnoDent Classic and SomnoDent Flex.
May 17, 2013

Ms. Kathryn A. Jayne
SomnoMed, Incorporated
7460 Warren Parkway, Suite 190
FRISCO TX 75034

Re: K130558
Trade/Device Name: SomnoDent Herbst
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: April 5, 2013
Received: April 17, 2013

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,

Kwame Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure.
Indications for Use

510(k) Number (if known): K130558

Device Name: SomnoDent Herbst

Indications for Use:
The SomnoDent Herbst 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)

(Date: 2013.05.17 11:39:58.041565)

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

510(k) Number: K120558