DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 22, 2015

Somnowell, Ltd.
c/o Mr. David Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K150941
Trade/Device Name: Somnowell Mandibular Advancement Appliance (MAA)
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: II
Dated: May 3, 2015
Received: May 7, 2015

Dear Mr. Yungvirt:

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,

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)*

K150941

Device Name

Somnowell Mandibular Advancement Appliance (Somnowell MAA)

Indications for Use *(Describe)*

The Somnowell Mandibular Advancement Appliance (Somnowell MAA) is intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea (OSA) 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (21 CFR 807.92)

510(k) Number K 150941

1	Applicant/Submitter	Somnowell Ltd. Dr. Simon Ash - Managing Director Ideas House Station Estate London E18 1BY United Kingdom Tel: +44 (0) 208 123 0432 Fax: +44 (0) 208 082 5164 Email: simon.ash@somnowell.com		
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura blvd Woodland Hills, CA 91364, USA Phone 213-787-3026 Email: daniela@sterlingmedicalregistration.com		
3	Submission Date	29 March 2015		
4	Device Trade Name	Somnowell MAA		
5	Regulation Description	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (OSA)		
6	Classification	Device Name	:	Device, Anti-Snoring
		Product Code	:	LRK
		Regulation No	:	872.5570
		Class	:	II
		Panel	:	Dental
7	Reason for the Premarket Notification Submission :			New Device
8	Identification of Legally Marketed Predicate Devices :			

- The Somnowell Mandibular Advancement Appliance (Somnowell MAA) is substantially equivalent to K113516 TheraSom-CAST; in terms of intended use, indication for use, technological characteristics and performance.

The predicate devices are a Class II medical device.

9 Device Description :

- The Somnowell Mandibular Advancement Appliance (Somnowell MAA) is a removable intraoral device used for treating night time snoring and mild to moderate obstructive sleep apnea. It consists of two customized fabricated chrome cobalt (Vitallium 2) frameworks that conform to the patient's dentition in the upper and lower jaws and are connected bilaterally via a stainless steel telescoping Herbst device. The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. This mechanical protrusion acts to improve the patient's ability to breathe during sleep without obstruction of the pharyngeal airway. The device is customized according to the prescription of the prescribing dentist for each patient. It has an adjustment mechanism enabling the amount of mandibular advancement to be set or altered by the dentist. The maximum protrusion and allowable increments of adjustment are 5mm.

10 Intended use :

- The Somnowell Mandibular Advancement Appliance (Somnowell MAA) is intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older.

11 Performance Standards or Special Controls :

- Recognized Consensus Standard: ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- FDA guidance document: Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

12 Substantial Equivalence :

Substantial Equivalent Table	Somonwell MAA	TheraSom-CAST
510K		**K113516**
Company Name	Somnowell Ltd	FAMILY DENTAL SERVICES, P.C.
Product Code	LRK	LRK
Classification	Class II	Class II
Indication for Use	The Somnowell Mandibular Advancement Appliance (Somnowell MAA) is intended for the treatment of night time snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older.	The TheraSom-CAST is used to reduce or alleviate the occurrence of snoring and/or for the treatment of mild to moderate obstructive sleep apnea (OSA) in patients 18 years of age or older.
Reusable / Single Use	Reusable	Reusable
Environment Use	Indicated for use at home or sleep laboratories	Indicated for use at home or sleep laboratories
Target population	Adults patients	Adults patients
Prescription Device/ OTC	Prescription Device	Prescription Device
Design	Customized device Compromised from upper and lower trays. Upper and lower tray unhook for easy removal from mouth.	Customized device Compromised from upper and lower trays. Upper and lower tray unhook for easy removal from mouth.
Connection of trays	Herbst mechanism Stainless steel	Locking mechanism Stainless steel tension springs.
Functionality	The device functions as a mandibular repositioner, maintaining the lower jaw in a forward position during sleep. To be Placed in patient mouth each evening Easily removed by patient. Permits patients to breathe through mouth.	The device functions as a mandibular repositioner, which acts to improve the patient's ability to breathe without obstruction of the pharyngeal airway. To be Placed in patient mouth each evening Easily removed by patient. Permits patients to breathe through mouth.
Adjustment	It has an adjustment mechanism enabling the amount of mandibular	The springs may vary in lengths and may be moved to adjust the relative positions of the

	advancement to be set or altered using titration key. The maximum protrusion and allowable increments of adjustment are 5mm.	upper and lower components so as to set the distance of the mandibular advancement. The maximum protrusion and allowable increments of adjustment are 5mm.
Cleaning Instructions	Daily cleaning by patient	Daily cleaning by patient
Used Raw Material for Upper and Lower Trays	Chrome Cobalt	Chrome Cobalt
Used Raw Material for fixation parts	Stainless Steel	Stainless Steel
Provided Sterile/ Non Sterile	Non Sterile	Non Sterile

Summary of Equivalence: The Somnowell MAA is considered to be substantially equivalent to K113516 TheraSom-CAST in terms of intended use, indication for use, technological characteristics and performance.

Similar to its predicate device the Somnowell MAA is a customized device, consists of two parts, upper and lower trays. Somnowell MAA uses chrome cobalt (Vitallium 2) which is the same as its predicate device K113516 TheraSom-CAST. The used chrome cobalt (Vitallium 2) has been cleared for marketing within K970205. The chrome cobalt (Vitallium 2) casted framework is substantially equivalent to the cast framework used in dentures used prior to 1976. The dental alloy framework provides strength to the device.

The Somnowell MAA in similar to its predicate device is adjustable using titration keys and a screw which enables the jaw to be brought forward in small advancements.

The difference it that Somnowell MAA uses side placement of buccal locking mechanism - Herbst mechanism, (which can be found in other appliances such as SomnoDent Herbst K130558); and the predicate device K113516 TheraSom-CAST uses locking mechanism of tension springs. This difference raises no safety and/or effectiveness issues as has been demonstrated by bench testing.

The Somnowell MAA shares the same technological characteristics as its predicate device and raises no new issues of safety or effectiveness, thus, the Somnowell MAA is considered to be substantially equivalent to its predicate devices.

Risk Assessment was conducted with accordance to ISO 14971 2007. The risk assessment raised all potential risks involved with the use of the device, used raw materials, performance, contraindications, warnings and risks to health. The main risks to health generally associated with the use of Somnowell MAA, as in similar to its predicate device and other intraoral devices for snoring and/or obstructive sleep apnea, are as follow:

- Intraoral gingival, palatal, or dental soreness
- Temporomandibular Joint (TMJ) Dysfunction Syndrome
- Obstruction of oral breathing
- Loosening or flaring of lower anterior teeth or general tooth movement

Instructions for use addresses these risks by identifying the used raw material, contraindications, warning, precautions and the recommendation on follow up visitation.

The Somnowell MAA shares the same intended use, raw material, design, technological characteristics, warnings, contraindications as its predicate devices and raises no new safety and/or effectiveness issues, thus, the Somnowell MAA is considered to be substantially equivalent to its predicate devices.

Performance Testing

Non Clinical Testing - Bench testing were carried out : Static Arch-Compression Test and Resistance to fracture and distortion. No used standards. These tests intended to simulate the mechanical force applied by during normal use of the appliance. The Somnowell appliance is not intended to be worn during mastication of food. Test results have demonstrated that Somnowell MAA is capable of withstanding the applied horizontal forces without distortion or fracture, and that the fixing part joints were capable of withstanding the applied horizontal forces without distortion or breakage. Test results have proven that the device performance and its intended use are as safe and as effective as its predicate devices. The Somnowell MAA shares the same intended use, raw material, design, technological characteristics as its predicate devices and raises no new safety and/or effectiveness issues, thus, the Somnowell MAA is considered to be substantially equivalent to its predicate devices.

Biocompatibility Cytotoxicity Test was carried out with accordance to ISO 10993-5. Results have demonstrated that no evidence of causing cell lysis or toxicity is related to Somnowell used raw material. Test results have proven that in similar to the predicate devices, no risk is

raised by the used raw material of Somnowell MAA. The Somnowell MAA shares the same intended use, raw material, design, technological characteristics as its predicate devices and raises no new safety and/or effectiveness issues, thus, the Somnowell MAA is considered to be substantially equivalent to its predicate devices.

Clinical testing - No clinical data is included in this submission.

Conclusion:

Somnowell MAA shares similarity with its predicated devices in terms of intended use, indication for use, raw material, technological characteristics and performance, as also has been demonstrated by bench testing, risk assessment and substantial equivalent table. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus Somnowell MAA is as safe and as effective for its intended use and performs as well as the predicate devices and thus considered to be substantially equivalent to its predicate devices.