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

March 21, 2016

SAS Oniris
Mr. Thibault Vincent
CEO
704 Avenue Roger Salengro
Chaville, 92370
France

Re: K150566
Trade/Device Name: Oniris
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: February 8, 2016
Received: February 10, 2016

Dear Mr. Vincent:

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" (21 CFR 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)*
K150566

Device Name
ONIRIS

Indications for Use *(Describe)*
The Oniris device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults.

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.

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510(k) Summary
K150566

Device Trade Name : Oniris

Submitter:
SAS Oniris
147 avenue Paul Doumer
92500 RUEIL-MALMAISON
FRANCE

Phone: +33 1 47 16 17 17
Fax: +1 47 16 20 11

Contact person: Thibault Vincent

Device Common Name : Mandibular advancement device

Date summary prepared : 18/03/2016

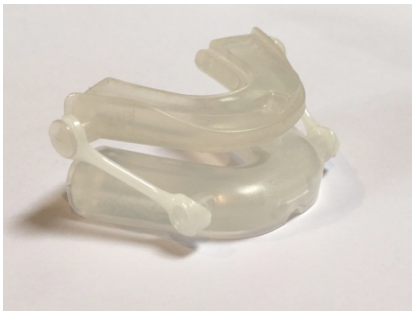
Device Classification Name : Intraoral Devices for snoring and obstructive sleep apnea

Device classification : Class II
Product Classification : 872.5570
Product Code : LRK

Predicate devices:

Primary predicate :
SomnoGuard® SP Soft**.** K121761
Reference predicates :
Zquiet® Mouthpiece. K093407
SomnoGuard Series (SomnoGuard, 2.0, AP, and AP Pro). K061688

Description of the device :
The Oniris Mandibular advancement device is an intraoral device for use during up to 8 hours of sleep, and composed of two injection molded thermoplastic trays overmoulded with thermoforming resin and customized to fit over the patient's teeth. The trays are attached and articulated through interconnecting rods to allow for mandibular advancement in relation to the maxilla up to 11 mm of protrusion. Mandibular advancement is the mechanism of action to increase upper airway opening to reduce snoring and mild to moderate sleep apnea.



The Oniris device is formed to upper and lower teeth without the need of taking a patient's dental impressions. Oniris device is a "boil-&-bite" device, the trays are customizable.
This mandibular advancement device maintains performance for 12 to 24 months depending on its conditions of use and maintenance as well as the patient's salivary composition.

Oniris mandibular device is proposed in two sizes to be adapted to different sizes of jaw (size 1 and size 2 in the same box). The practitioner/dentist has to choose the most comfortable size for the patient.

Intended use:
The Oniris device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults.

Technological characteristics compared to predicates
The principle of mandibular advancement for treatment of snoring/or obstructive sleep apnea is well known and there are a number of predicate devices. The advancement of the lower jaw, enables opening the upper airway and reduce snoring.
The Oniris Mandibular advancement device has the same technical characteristics as the primary predicate devices as summarized in table. Reference predicates supports substantial equivalence for the protrusion up to 11 mm and the possibility to mouth breath during device wearing.

	Oniris mandibular advancement K150566	SomnoGuard® SP Soft K121761 **Primary predicate**	Zquiet ® K093407 **Reference predicate**	SomoGuard AP® K061688 **Reference predicate**
Indications for use	The Oniris device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults.	The SomnoGuard® **SP** Soft is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea **(OSAS)** in adults.	The ZQuiet mandibular advancement device is intended for the treatment of nighttime snoring in adults 1 8 years are older.	The SomnoGuard series of mandibular advancement devices is intended for the treatment of night-time snoring and mild to moderate obstructive sleep apnea (OSAS) in adults.
Dental impressions	« Boil & bite » appliance	« Boil & bite » appliance		« Boil & bite » appliance :
Mandibular advancement	**Oniris Device** comes with 9 connectors of different length enables up to 11mm protusion	**SomnoGuard® SP Soft** with 6 connectors of different length enables up to 10 mm protusion	**ZQuiet®** employs a buccal cam mechanism	**SomnoGuard AP** comprises two-part titratable enables up to 12 mm protusion.
Sterility	Non sterile	Non sterile	Non sterile	Non sterile
Design	Two independent thermoplastic trays linked to each other by a coupling protrusion mechanism.	Two independent thermoplastic trays linked to each other by a coupling protrusion mechanism.	Upper and lower dental orthotics with a buccal cam mechanism.	**SomnoGuard AP** consists of two independent thermoplastic trays, both parts are linked to each other by a coupling protusion mechanism
Single patient use	X	X	X	X
Cleaned with water and toothbrush daily	X	X	X	X
Interchangeable rods	Fixed by pressure on lower tray; angular rotation on pin tray	Fixed by pressure on lower and upper tray.		

The thermoplastic material used for tray is different, and the connecting mechanism of interchangeable rods Oniris device presents some differences compared to the primary predicate. The difference consists on larger shape stopper on lower tray to decrease the possibility of rod detachment. A slot has been added on the shape stopper to facilitate the fitting by pressure. The change of this rod is possible after angular rotation of the rod along its axis. This angular rotation is impossible to reproduce when wearing in mouth, and is a security to avoid detachment of rod during wearing.
On upper tray the rod is fitting like a key system, the rod rotate around the axis in order to reach the functional location, while the rod is fixed by pressure on the lower tray primary predicate.

The submission includes physical property specifications for materials used in the fabrication of the device, including density, tensile strain, tensile modulus, impact strength, softening temperature, melt flow rate, and Vicar Softening Point.

Clinical Data
In a one arm pilot study investigating the use of Oniris device in patients with moderate sleep apnea demonstrated a reduction of apnea index, hypopnea index and oxygen desaturation index and was subjectively evaluated by patients to provide positive impact on snoring, morning fatigue and sleep quality.

Conclusions :
The Oniris device function is a similar manner to other comparative predicate devices and the intended use is the same. All are prescription devices indicated for patients suffering from snoring and/or mild to moderate obstructive apnea.
The information in this 510(k) submission demonstrate the Oniris device are substantially equivalent to the predicate devices. Fundamental scientific technology of the device is identical to the referenced predicate device. Rationale discussion on design differences of interchangeable rod has been conducted in the 510(k) Submission.