February 25, 2021

Orthoapnea S.L.
Jose Llecha
Managing Director
C / Flauta Magica 22
Malaga, Malaga 29006
SPAIN

Re: K203477
Trade/Device Name: Classic
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: November 15, 2020
Received: November 27, 2020

Dear Jose Llecha:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K203477

Device Name

Classic

Indications for Use *(Describe)*

Classic is a Mandibular Advancement Device (MAD) indicated for mild to moderate obstructive sleep apnea (OSA) and to alleviate or reduce snoring 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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SECTION 5 - 510(k) SUMMARY

K203477

DATE OF SUBMISSION: 2020-11-15
SUBMITTER NAME: Orthoapnea S.L
SUBMITTER ADDRESS: Calle Flauta Mágica 22
29006 Málaga
SPAIN

CONTACT: Jose Repollés Llecha
TELEPHONE: +34 952 122 174 ext. 154
e-mail: jrepolles@orthoapnea.com

DEVICE TRADE NAME: Classic
COMMON NAME: MANDIBULAR ADVANCEMENT DEVICE
CLASSIFICATION NAME: INTRAORAL DEVICES FOR SNORING
PRODUCT CODE: LRK
REGULATION DESCRIPTION: Intraoral devices for snoring and intraoral device for snoring and obstructive sleep apnea (21 CFR 872.5570)

PREDICATE DEVICE(S): K060388 (Airway Management Inc.) – Primary predicate
K062951 (Airway Management Inc.) Reference device

A. Description of the Device

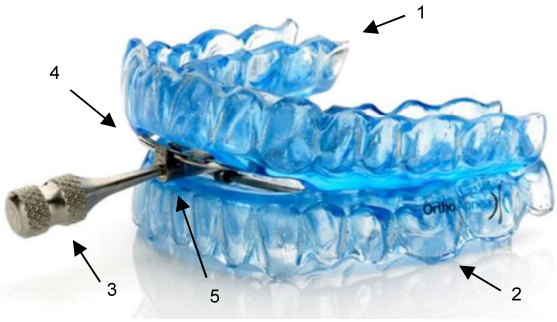
Classic device is an intraoral device specially indicated for the treatment of snoring and obstructive sleep apnea syndrome. Its design makes it simple to use and comfortable to wear. It is intended for single-patient use by adults who are 18 years or older.

Classic device consists of two splints united to each other by a screw that allows controlled advancement of the mandible by the increase of the muscular tone at the airway level. Consequently, the flow of air through the upper airway is increased, and reducing snoring and apnea events.

patient's

The maximum protrusion of Classic arch form is 10 mm, measuring from plate to plate. This device needs an external controlling component such as screwdriver included in the kit. The design of the device is according arches, maximizes tongue space and allow open, close and laterality movements during wear. These movements can be personalized by the doctor.

Each Classic device has the following components:



Component #	Component Name
1	Upper splint
2	Lower splint
3	Activation key
4	Guide (Bar)
5	OrthoApnea screw

B. Intended Use

Classic is a device that consist in maxillary and mandibular devices connected with a personalized mechanism to reduce snoring and mild to moderate sleep apnea by holding the mandible forward during sleep.

C. Summary of Testing and Comparison to the Predicate Device

The devices are designed and manufactured in accordance with the following standards:

- ISO 20795-2 Second edition 2013-03-01 Dentistry - Base polymers - Part 2: Orthodontic base polymers
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2009 Biological evaluation of medical devices – Part 10: Test for irritation and delayed-type hypersensitivity
- ISO 5832-3 2016 Implants for surgery - Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- ISO 5832-1 2016 Implants for surgery - Metallic materials - Part 1: Wrought stainless steel

And according the following guidance:

- Intraoral Devices for Snoring and/or Obstructive Sleep Apnea–Guidance for Industry and FDA 2002

Comparison of Technological Characteristics

Table 1: Device Comparison

Characteristic	Subject Device	Primary predicate	Reference predicate	SE / Comments
Model Name	Classic	TAP II	TAP III	-
510K	K203477	K060388	K062951	-
Intended use	To reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea (OSA).	The TAP II is intended to reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea, OSA.	The TAP III is intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea, OSA.	Yes
Material	Polymer PET G and TPU Polymethylmethacrylate Stainless steel and Titanium alloy	Polycarbonate Stainless steel	Polycarbonate Stainless steel	Yes
Fixed /removable	Removable	Removable	Removable	Yes
Sterile	Non- sterile	Non-sterile	Non-sterile	Yes
Mandibular adjustment	Customized by physician or dentist.	Customized by physician or dentist.	Customized by physician or dentist.	Yes
Mandibular adjustment range	Up to 10.0 mm	Up to 7.0 mm	Up to 7.0 mm	Yes

Classic device is substantially equivalent intended use as the identified predicates. Classic device is similar in fundamental scientific technology to the predicate devices in that they all have been designed, manufactured and tested in compliance with FDA'S Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea.

Classic device is substantially equivalent in materials, indications and intended use, packaging, labeling and performance to the predicate devices currently marketed in the U.S.

The only differences the subject device and the predicate are slight differences in adjustment and mandibular advancement range.

Non-Clinical performance tests

The proposed devices have been subject to bench testing to determine fulfillment of design and performance requirements. Bench testing followed the recommendations provided in FDA Guidance Document – Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea.

Performance testing on the Classic device included:

- Determination of flexural properties (ISO 178:2010)
- Determinations of the Tensile properties (ASTM D638-02)
- Biocompatibility evaluation in accordance (ISO 10993-1:2009)

but as we use widely used standard components in the market there are considered not necessary to perform additional tests.

Test data from the device was leveraged for the previous performance tests based on the use of identical device and packaging materials as well as identical manufacturing, packaging and cleaning processes.

D. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the determination of substantial equivalence.

E. Conclusion of Substantial Equivalence

Based on the similarities observed and results of non-clinical testing performed, we conclude that the proposed devices are substantially equivalent to the predicate devices.