February 12, 2021

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

Re: K202651
Trade/Device Name: NOA Sleep Apnea and Snoring Device
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: January 15, 2021
Received: January 19, 2021

Dear Jose Repolles 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)*
K202651

Device Name

NOA SLEEP APNEA AND SNORING DEVICE

Indications for Use *(Describe)*

NOA SLEEP APNEA AND SNORING DEVICE is a mandibular advance 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.

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

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K202651

510(k) SUMMARY

DATE OF SUBMISSION: 2021-02-12
SUBMITTER NAME: Orthoapnea S.L
SUBMITTER ADDRESS: Calle Flauta Mágica 22
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SPAIN

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DEVICE TRADE NAME: NOA SLEEP APNEA AND SNORING DEVICE
COMMON NAME: MANDIBULAR ADVANCEMENT DEVICE
CLASSIFICATION NAME: INTRAORAL DEVICES FOR SNORING
PRODUCT CODE: LRK (Anti-snoring device)
REGULATION DESCRIPTION: Device, Anti-snoring (21 CFR 872.5570)

PREDICATE DEVICE(S): K133683 (Microdental) – Primary predicate
K143244 (Panthera Dental)

A. Description of the Device

The NOA Sleep Apnea and Snoring Device is a customized prescription intraoral mandibular advancement device for snoring and obstructive sleep apnea intended for single-patient use by those who are 18 years or older.

The device consists of CAD/CAM fabricated maxillary and mandibular splints connected by symmetrical, twin-mated posts that are customizable to allow lateral jaw movement as well as jaw opening. The series of splints consist of one or more mandibular splints, and one or more maxillary splints to be exchanged with other splints in the series according to the prescriber, to titrate protrusive jaw movement according to patient comfort and needs. The described mandibular advancement is intended to reduce snoring and mild to moderate obstructive sleep apnea by holding the mandible and base of tongue forward during sleep, to provide increased pharyngeal space to improve the patient's ability to exchange air and decrease air turbulence.

The NOA Sleep Apnea and Snoring Device does not have any additional adjustment mechanisms to modify or maintain the mandibular position such as pistons, straps, repositioning elastics or screws, eliminating the need for utilizing external controlling components such as keys, screwdrivers or ligature ties.

The NOA device is designed with lateral fins called cam and follower. Contact between the cam and the follower prevents any mandibular retrusion even with the opening of the mouth.

The device design is configured according to the patient's specific dental arch, to maximize tongue space and to allow

open, close and laterality movements during wear. These movements can be personalized by the doctor. Furthermore, the doctor can change the height of the cam in the prescription to limit the maximum mouth opening during wear.

Orthoapnea NOA device designs can be **Standard or Customized**.
A Standard device is designed with standard height in the lateral cams among all lower splints. If the practitioner provides a measurement of the antero-posterior mobility (Maximum retrusion and protrusion), a Customized device is designed decreasing the height of the cam according to the degree of advancement. As the advancement increases, the ability to open the mouth without mandibular retrusion decreases, making the cam shorter.

The following additional device design features can be customized when ordering the prescription device:

- Advance regulation/titration sequence
- Lateral movement
- Device opening limit
- Frontal opening of the device

B. Intended Use

NOA Sleep Apnea and Snoring Device is a device that consists of 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. Comparison of Technology

Technological characteristics of the NOA Sleep Apnea and Snoring Device are compared to those of the primary predicate – K133683 MicrO2 – and reference device - K143244 Panthera – as listed in Table 1 below.

In all cases, the intended use / indications for use are to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea. In additional, in all cases, the devices are removable, non-sterile and for mandibular adjustment to be performed by the physician or dentist.

The material used for the subject device is different to that of the primary predicate device. However, this same material is used in the reference device.

Also, the mandibular adjustment range for the subject device is wider than that of the primary predicate device but with the range stated for the reference device.

These differences in technology, therefore, do not raise additional concerns of safety and effectiveness.

Characteristic	Subject Device	Primary predicate	Reference device	Substantially Equivalent / Comments
Model Name	NOA Sleep Apnea and Snoring Device	MicrO2 Obstructive Sleep Apnea Device	Panthera Anti-snoring Device	-
510K number	NA	K133683	K143244	-
Intended use	Intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults	Intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults	intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Yes
Material	Polymers (Polyamide 12)	Hard PMMA material – Acrylic (polymethyl methacrylate)	Polymers (Polyamide 12)	The material used in the subject device is NOT same as the material used in the primary predicate. However, the material used in the subject device is the same as the material used in the reference device.
Fixed /removable	Removable	Removable	Removable	Yes
Sterile	Non- sterile	Non-sterile	Non-sterile	Yes
Mandibular adjustment	Performed by physician or dentist	Performed by dentist or physician	Performed by dentist or physician	Yes
Mandibular adjustment range	Up to 10.0 mm	Up to 6 mm	Up to 15.0 mm	The mandibular adjustment range for the subject device is higher than for the primary predicate device. However, the mandibular adjustment range for the subject device is within that of the reference device.

Table 1: Comparison of Technology

D. Non-clinical Performance Testing

The following guidance documents have been taken into consideration:

- Intraoral Devices for Snoring and/or Obstructive Sleep Apnea–Guidance for Industry and FDA 2002
- Technical Considerations for Additive Manufactured Medical Devices–Guidance for Industry and FDA 2017.

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.

Specific performance testing on the NOA Sleep and Snoring device include:

- Determination of flexural properties with ISO 178:2010.
- Determinations of the Tensile properties with ASTM D638-02

- Biocompatibility evaluation in accordance with ISO 10993-1 and specifically
  - Cytotoxicity testing in accordance with ISO 10993-5:2009;
  - Irritation and sensitization testing in accordance with ISO 10993-10:2009.

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 for the NOA Sleep Apnea and Snoring device.

E. Clinical Performance Testing

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

F. Conclusion

Based on the indications for use and comparison of technology together with the results of non-clinical performance testing, we conclude that our device OrthoApnea NOA Sleep Apnea and Snoring device is substantially equivalent to the predicate device MicrO2 Obstructive Sleep Apnea (K133683).