September 4, 2025

Oniris
Maria Markarova
Export and Regulatory Affairs Manager
147 avenue Paul Doumer
RUEIL MALMAISON, 92500
FRANCE

Re: K250353
Trade/Device Name: Oniris; Oniris Plus
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: July 22, 2025
Received: July 22, 2025

Dear Maria Markarova:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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)*
K250353

Device Name
Oniris;
Oniris Plus

Indications for Use *(Describe)*
Oniris and Oniris Plus devices are indicated for use on adult patients 18 years of age or older as an aid for the reduction of snoring (OTC).

Oniris Plus device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults. (Rx)

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K250353

510(k) Summary

Prepared on: 2025-07-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Oniris
Applicant Address	147 avenue Paul Doumer RUEIL MALMAISON 92500 France
Applicant Contact Telephone	0033147161717
Applicant Contact	Mrs. Maria MARKAROVA
Applicant Contact Email	export@oniris-ronflement.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Oniris; Oniris Plus
Common Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification Name	Device, Anti-Snoring
Regulation Number	872.5570
Product Code(s)	LRK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200657	SmartGuard	LRK
K150566	Oniris	LRK

Device Description Summary

21 CFR 807.92(a)(4)

The Oniris and Oniris Plus devices are intraoral mandibular advancement appliances. Each device consists of two independent splints, over-molded with a thermoforming material, ensuring a customized fit for the user. One splint is designed for the maxillary arch (labeled "Up") and the other for the mandibular arch (labeled "Down"). The splints are custom-fitted by the end user at home using a simple "Boil-and-Bite" process, eliminating the need for professional dental impressions.

The two splints are connected via advancement hooks, which allow for mandibular protrusion adjustments. Oniris and Oniris Plus OTC devices offer 5 sizes of advancement hooks, while Oniris Plus Rx device provides 10 sizes, enabling precise customization of the mandibular advancement. These hooks maintain the mandible in a forward position, optimizing airflow and reducing air turbulence, a key factor in snoring and airway obstruction. Users can adjust the device for up to 6 mm (OTC) and 11 mm (Rx) of mandibular advancement by interchanging the hooks to achieve the most effective and comfortable setting.

As predicate devices, Oniris and Oniris Plus feature an independent bi-bloc design, allowing for vertical articulation. This enhances patient comfort and ensures a more natural fit.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Oniris and Oniris Plus devices are indicated for use on adult patients 18 years of age or older as an aid for the reduction of snoring (OTC).

Oniris Plus device is indicated in the treatment of snoring and/or mild to moderate obstructive sleep apnea in adults. (Rx)

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject devices and predicates have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The Oniris and Oniris Plus devices share the same or similar technological characteristics as the predicate devices, functioning as mandibular advancement devices. These devices are substantially equivalent in terms of design, materials, labeling, and functionality. Like the predicate devices, Oniris and Oniris Plus consist of an upper and lower tray made from a rigid outer shell with moldable material inside, which is customized to the user's dentition through a "boil and bite" process at home.
Both the subject and predicate devices follow the same mandibular advancement principle and allow adjustability through interchangeable advancement hooks of varying lengths. The upper and lower trays are exclusively connected by these hooks, which facilitate vertical articulation and enhance comfort. The primary predicate SmartGuard device allows up to 6mm of mandibular advancement as well as the subject Oniris and Oniris Plus devices for OTC use. The reference Oniris and the subject Oniris Plus devices allow up to 11mm for Rx use.
The connecting mechanism of the interchangeable hooks differs slightly from that of the SmartGuard predicate device. The lower tray of Oniris devices features an enlarged stopper to minimize the risk of hook detachment, along with an integrated slot that facilitates secure attachment through applied pressure. The hooks are designed to be adjusted via angular rotation along their axis, a mechanism that is only possible when handling the device outside the mouth. This feature ensures that hook detachment does not occur during use, enhancing safety. On the upper tray, hooks attach using a key-like system, rotating around an axis until they lock into their functional position. In contrast, the predicate device secures hooks solely through applied pressure on both trays. These design modifications improve the stability and usability of the device while maintaining equivalent safety and effectiveness.

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

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical testing submitted within this 510(k) includes bench testing focused on verifying the dimensional conformity and packaging compliance of the ONIRIS and ONIRIS PLUS anti-snoring devices. The testing was performed using calibrated precision instruments (caliper and scale) with traceability to international standards (Calibration Certificates: FACOM CK311539, RS PRO JS-10). Testing covered representative production lots, specifically lot numbers 048668 and 2406963.Dimensional measurements were conducted to ensure compliance with internal specifications concerning product weight, length, width, thickness, and marking. The results confirmed all measured units met the established tolerances (+/- 0.5g for weight, +/- 0.05mm for dimensions).In addition, comparative testing was conducted between ONIRIS / ONIRIS PLUS and the predicate device, Smartguard (Part# SGASDFC Rev.2). Measurements demonstrated comparable features in tray geometry, hook attachments, transparency, and packaging. While ONIRIS devices were slightly larger in dimensions, the comparative testing confirmed the differences did not affect the intended use or target patient population. All testing adhered to internal specifications relevant to OTC and Rx markets. No FDA-recognized consensus standards or guidance documents were specifically cited; testing was based on internal product specifications and predicate device comparison

The results of the nonclinical bench testing demonstrate that the ONIRIS and ONIRIS PLUS devices conform to all internal dimensional and packaging specifications. The devices have been verified through calibrated measurement tools to meet design requirements related to weight, dimensions, and functional components such as hook attachments. Comparative testing against the legally marketed predicate device, Smartguard, confirmed that ONIRIS and ONIRIS PLUS offer equivalent performance in terms of design characteristics, geometry, packaging, and intended use. Minor dimensional differences were noted but do not affect the safety or effectiveness of the device. Based on the nonclinical evidence provided, the ONIRIS and ONIRIS PLUS devices are concluded to be as safe, as effective, and to perform as well as the legally marketed predicate device identified in this submission