January 16, 2024

Oscimed SA
℅ Michael Chen
Quality Engineer
Rook Quality Systems
1155 Mount Vernon Hwy, Suite 800
Dunwoody, Georgia 30038

Re: K231138
Trade/Device Name: Anti-Snore Mouth Guard+
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: April 20, 2023
Received: April 21, 2023

Dear Michael Chen:

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.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K231138

Device Name

Anti-Snore Mouthguard+

Indications for Use *(Describe)*

The device is intended to aid in the reduction of snoring for adults at least 18 years old.

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) #: K231138

510(k) Summary

Prepared on: 2024-01-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Oscimed SA
Applicant Address	Allée du Quartz 3 2300 La Chaux-de-Fonds Suisse Switzerland
Applicant Contact Telephone	41 32 926 63 36
Applicant Contact	Mr. Jacques Magnin
Applicant Contact Email	jm@oscimedsa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Anti-Snore Mouthguard+
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	LRK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200657	SmartGuard Anti-Snore Device	LRK

Device Description Summary

21 CFR 807.92(a)(4)

The Anti-Snore Mouthguard+ is a thermoforming mandibular advancement device to reduce snoring. The device works by pulling the lower jaw forward. As such, the entirety of the device is tissue-contacting. The device combines an upper and lower molding with thermal impression material to conform to user's teeth morphology with an adjustable mechanism to position the user's lower jaw according to the user's need. The Anti-Snore Mouthguard+ is a "Boil and Bite" device where both the upper and lower moldings are constructed out of moldable material when heated in a water bath with rigid frames that allow for the straps to be attached to adjust the fitting. The device additionally comes with a ventilated storage box and Instructions for Use. This ventilated storage box is only provided for storage when the device is not in use and does not impact intended use of the device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is intended to aid in the reduction of snoring for adults at least 18 years old.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use of the subject device and predicate device are the same.

Technological Comparison

21 CFR 807.92(a)(6)

Equivalence to Predicate Device

The subject device has the same intended use, indications, principle of operation, similar technological and material characteristics as the predicate device, SmartGuard Anti-Snore Device (K200657). Comparisons of the devices can be found in the substantial equivalence comparison table.

Comparison of Indication for Use

Both the subject and predicate devices are indicated for Over-the-Counter (OTC) use in alleviating snoring for adults 18 and older by way of mandibular repositioning.

Comparison of Technological Features

Oscimed SA's Anti-Snore Mouthguard+ is designed similarly as the predicate device and the mechanisms of action.
The subject device is comprised of an upper and a lower tray, that are copolyester frames with a soft ethylene vinyl acetate (EVA) overmolding. The trays are connected via a flexible strap attached to the trays via hooks. The EVA overmolding is a thermal impression material that can be heat molded to the user's dentition in a home environment via common "Boil-and-Bite" method for retention. The predicate device is designed similarly as a "Boil-and-Bite" device with separate upper and lower thermoplastic trays overmolded with thermoforming resin. The trays in the predicate device are connected via advancement bars.
The subject and predicate devices position the lower mandible anteriorly to increase pharyngeal space. The subject device achieves this by supplying flexible bands of varying lengths that allow for the user to adjust the level of lower mandible/tray anterior positioning to their comfort level, up to +6mm. The predicate device likewise increases the pharyngeal space, providing advancement bars that position the lower jaw forward relative to the upper jaw, up to +6mm.
The subject device connects the upper and lower molding anteriorly on the maxilla and posteriorly on the mandible whereas the predicate connects the upper and lower molding posteriorly on the maxilla and anteriorly on the mandible. Although the connection points differ, the subject device distributes forces across the mouth resulting in force that is not greater than that applied by the predicate device at the front and rear connection points. This resulting force is proven through performance testing conducted comparing the forces applied to the front and at the anterior connection points by both the subject and predicate devices.
The technological features of the subject and predicate devices are similar and achieve the same principle of operation in increasing pharyngeal space by repositioning the lower mandible. Therefore, the technological features of the subject device does not raise any questions of safety or performance.

Comparison of Material Characteristics

The subject and predicate devices require biocompatibility testing for a surface device that contacts intraoral surfaces for prolonged contact (>24h to 30 days), per "Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry and FDA," ISO 10993 Part 5 and Part 10, Tests for in vitro Toxicity and Tests for irritation and skin irritation, respectively. A summary of the biocompatibility testing conducted for the subject device can be found in the Biocompatibility Section.

The subject device is comprised of a stiff copolymer frame overmolded with ethylene vinyl acetate thermal moldable resin, and a flexible strap. The flexible straps are thermoplastic elastomers which are rigid enough to position the lower tray and mandible forward to increase pharyngeal space. The predicate device is made from thermoplastic trays (polycarbonate) overmolded with thermoforming resin (EVA) and connected with advancement bars. Both the subject and predicate devices use materials with similar characteristics to achieve the same principle of operation and do not raise any questions of the safety or performance of the subject device.

Substantial Equivalence Conclusion

Based on the comparison of indication of use, material characteristics, technological features, and principle of operation, Oscimed SA's Anti-Snore Mouthguard+ is substantially equivalent to the predicate device.

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

Non-clinical validation testing was performed to demonstrate the safety and effectiveness of the device. The following tests were performed:
• Strap Tensile Testing - ensures that the straps do not stretch under expected load to keep the device in the appropriate position while in use
• Validation of Temperature Indicator - ensures that the temperature indicator is accurate for when water bath is at the correct temperature to permit molding of the upper and lower moldings to the user's teeth
• Force Measurement and Mandibular Advancement Testing - evaluates the amount of advancement achieved for each strap up to +6mm and ensure that forces applied by the device are clinically tolerable through comparison of forces applied by the predicate

Oscimed SA believes that the aforementioned non-clinical testing demonstrates that the subject device is designed in such a way that, when used under the conditions and for the purposes intended, the safety and effectiveness, as well as the performance characteristic of the subject device is substantially equivalent to the predicate device and meet the testing requirements contained within the Intraoral Devices for Snoring and/or Obstructive Sleep Apnea - Class II Special Controls Guidance Document for Industry and FDA.