June 12, 2026

Somnomed, Inc.
Hai Tei Tan
Senior Global Regulatory Affairs and Quality Specialist
6513 Windcrest Dr., Suite 100
Plano, Texas 75024

Re: K261366
Trade/Device Name: Virtus
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 24, 2026
Received: April 28, 2026

Dear Hai Tei Tan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261366

Device Name
Virtus

Indications for Use *(Describe)*
Virtus is a patient-matched mandibular advancement device (MAD), available under medical prescription and intended for the treatment in patients 18 years of age or older with:
» Mild to moderate obstructive sleep apnea (OSA)
» Snoring

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.

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510(k) #: K261366

510(k) Summary

Prepared on: 2026-06-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	SomnoMed Inc.
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Correspondent Contact	Ms. Hai Tei Tan
Correspondent Contact Email	htan@somnomed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Virtus
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
K183443	SomnoDent Avant	LRK

Device Description Summary

21 CFR 807.92(a)(4)

The Virtus device is an intraoral device used for treating snoring and obstructive sleep apnea. It consists of two splints, an upper (maxillary) splint and a lower (mandibular) splint, that are mechanically connected by a strap to reposition the mandible in a forward (protrusive) position during sleep. By repositioning the mandible forward, the device increases the patient's pharyngeal airway space, thereby improving airflow and reducing airway obstruction during sleep. The Virtus device is customized for each patient and has an adjustable coupling mechanism that allows a dentist or qualified healthcare professional to set the amount of mandibular advancement at the time of fitting. The Virtus device is identical to the predicate device, SomnoDent Avant, except for differences in the splints color, an updated connecting strap design, and corresponding modifications to the fixing elements.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Virtus is a patient-matched mandibular advancement device (MAD), available under medical prescription and intended for the treatment in patients 18 years of age or older with:
» Mild to moderate obstructive sleep apnea (OSA)
» Snoring

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

The intended use of the Virtus device is the same as that of the predicate device, SomnoDent Avant. The Virtus device is indicated for the treatment of snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older, consistent with the SomnoDent Avant. Minor wording modifications have been made to improve clarity and include additional descriptive information (e.g., identification as a patient-matched mandibular advancement device and prescription use). These changes do not alter the intended use, patient population, or clinical conditions of use. No new indications for use are introduced. Therefore, the Virtus device has the same intended use as the SomnoDent Avant device.

Technological Comparison 21 CFR 807.92(a)(6)

The Virtus device has the same intended use, fundamental scientific technology, and principle of operation as the predicate device, SomnoDent Avant. Both are custom manufactured, removable intraoral mandibular advancement devices consisting of upper and lower splint bodies mechanically connected by a strap to maintain the mandible in a forward position during sleep to improve upper airway patency, operating solely through passive mechanical means without an energy source. Virtus differs only in the use of clear PMMA instead of pigmented PMMA (base polymer unchanged), an updated polyamide strap incorporating an internal metal core, and corresponding fixing element modifications to accommodate the strap geometry. These differences do not alter the technological function or raise new or different questions of safety or effectiveness.

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

Clinical testing was not required for this Special 510(k) because the design modifications to the Virtus device (clear PMMA material, metal core strap, and refined fixing element geometry) do not change the intended use, indications for use, or fundamental scientific technology relative to the predicate device, SomnoDent Avant. The changes were addressed through design controls and risk management and were shown not to introduce new or increased risks. Comprehensive non-clinical verification and validation testing, including mechanical performance, durability, environmental conditioning, biocompatibility per ISO 10993-1, and human factors, demonstrated that all acceptance criteria were met and that device safety and effectiveness are maintained, supporting substantial equivalence without clinical testing.