October 3, 2024

Somnomed, Inc.
Timothy Cowart
Regulatory Affairs Contractor
6513 Windcrest Drive, Suite 100
Plano, Texas 75024

Re: K233497
Trade/Device Name: Rest Assure System
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: PLC, LRK, LQZ
Dated: October 29, 2023
Received: January 10, 2024

Dear Timothy Cowart:

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K233497

Device Name
Rest Assure System

Indications for Use *(Describe)*

Rest Assure is an intraoral device intended to be used in the treatment of snoring and mild to moderate obstructive sleep apnea in patients over 18. Rest Assure has the capability to record and monitor patient compliance to oral device/ appliance therapy.

Type of Use *(Select one or both, as applicable)*

[x] 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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K233497

510(k) Summary

Rest Assure System

1.0 Submitter

SomnoMed, Inc.
6513 Windcrest Drive, Suite 100
Plano, TX 75024
Telephone: 888-447-6673

Official Contact
Timothy Cowart
Regulatory Contractor
Telephone: 678-481-9246
Email: tcowart@somnomed.com

2.0 Date Prepared

October 3, 2024

3.0 Device Identification

Proprietary Names: Rest Assure System
Common Name: Device, Anti-Snoring
Classification Name: Intraoral device for snoring and Intraoral devices for snoring and obstructive sleep apnea
Device Classification: Class II Product Code: LRK, LQZ, PLC
Regulation Number: 21 CFR 872.5570

4.0 Legally Marketed Predicate Device

Candidate(s)	Primary Predicates	Manufacturer	Document Number
Rest Assure System SomnoDent® with Micro-Recorder	SomnoDent® Herbst Advance Appliance with Micro-Recorder	SomnoMed, Inc.	K150369
	SomnoDent® Avant		K183443

The Rest Assure System is substantially equivalent to the SomnoDent® Herbst Advance Appliance with the Micro-Recorder (K140278) and the SomnoDent® Avant (K183443).

5.0 Device Description

The SomnoDent intraoral devices functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep. The increase in the patient's pharyngeal space improves their ability to breather during sleep. The devices are patient specific (they are customized for each patient) and have an adjustable coupling mechanism enabling the amount of mandibular advancement to be set by the sleep dentist at the time of fitting the device. The devices can then be adjusted by the sleep dentist to control the treatment to find the best possible adjustment.

This Rest Assure System consists of two appliances, namely the Rest Assure Elite Appliance with (formerly the SomnoDent Herbst commercially distributed under K150369) and the Rest Assure Avant. Both hold current 510(k) clearances from FDA, K150369 for the SomnoDent Herbst Advanced with embedded micro-recorder and K183443 for the SomnoDent Avant.

6.0 Intended Use

Rest Assure is an intraoral device intended to be used in the treatment of snoring and mild to moderate obstructive sleep apnea in patients over 18. Rest Assure has the capability to record and monitor patient compliance to oral device/appliance therapy.

7.0 Comparison to the Predicate Devives

Technological Characteristics	**Predicate Devices**		**Proposed Device**
	SomnoDent ® Avant (K183443)	**Herbst Advance with Micro-Recorder ((150369)**	**Rest Assure**
Intended Use			
Intended as an intraoral device	Yes	Yes	Yes
Intended to reduce snoring or help alleviate snoring	Yes	Yes	Yes
Treatment of mild to moderate obstructive sleep apnea	Yes	Yes	Yes
Intended for nighttime use	Yes	Yes	Yes
Indicated for single patient multiuse	Yes	Yes	Yes
Indicated for use at home or sleep laboratories	Yes	Yes	Yes
Target population: adults	Yes	Yes	Yes
Prescription device	Yes	Yes	Yes
Design			
Customized fit for each patient	Yes	Yes	Yes
Separate upper and lower tray pieces	Yes	Yes	Yes

Works by mandibular advancement	Yes	Yes	Yes
Can be adjusted or refit	Yes	Yes	Yes
Lower jaw adjustment using supplied components	Yes	Yes	Yes
Permits patient to breathe through mouth	Yes	Yes	Yes
Cleaned and inspected daily by patient	Yes	Yes	Yes
Material			
Trays constructed from a soft lining material adhered to a hard surface acrylic	Yes (Flex retention Avant and Herbst) No (Classic retention – with Herbst only)		Yes (Flex retention)
Advancement mechanism constructed of surgical grade stainless steel	Yes		Yes

Like the Micro-Recorder embedded within the Somnomed Herbst appliance, the sensors and embedded pcba within the Rest Assure Appliances do not change the intended use of the SomnoDent device for the treatment of night-time snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. Also, the Micro-Recorder embedded within the Somnomed Herbst appliance are self-contained, and the sensors and embedded pcba within the Rest Assure appliances are encapsulated, so there is isolation resulting in no physical or electrical exposure to the sensor or embedded pcba. Furthermore, the size, position, and location of the embedded Micro-Recorder in the SomnoDent appliances does not increase any risk to patient safety as there is ample space in the patient's oral cavity to accommodate the appliances.

8.0 Performance Testing

To demonstrate the performance of the Rest Assure System, the following performance testing was completed:

A. Software Testing per IEC 62304
B. Safety Testing by UL per 60601-1 series
C. EMC Testing per 60601-1-2
D. Risk Analysis per ISO 14971
E. Cybersecurity Evaluation and Assessment
F. Co-existence Testing and Assessment
G. Biocompatibility Assessment per the specific guidance "Intraoral Devices for Snoring and/or Obstructive Sleep Apnea – Class II Special Controls Guidance Document for Industry" and "FDA Biocompatibility Guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"
H. Usability Testing per IEC 62366

Further, functional and systems testing was performed to demonstrate requirements were successfully completed to demonstrate compliance with the device requirements and specifications. Since the device characteristics and features,

intended use, instructions for use, and materials of the Rest Assure System were consistent with the identified predicate, clinical testing was not required or performed.

9.0 Conclusion

Based on the similarities in the intended use, principles of operation, functional design, established materials used, and testing performed combined with the test results, the Rest Assure System is safe and effective for its intended purpose and the submitted supports a substantial equivalence decision.