June 16, 2023

Somnics Inc.
℅ Feng-Yu Lee
Principal Regulatory Consultant
IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212
San Juan Capistrano, California 92675

Re: K220907
Trade/Device Name: The iNAP One Sleep Therapy 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: OZR
Dated: May 17, 2023
Received: May 18, 2023

Dear Feng-Yu Lee:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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)*
K220907

Device Name
The iNAP One Sleep Therapy System

Indications for Use *(Describe)*
The iNAP One Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment choice.

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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510 (k) Summary

Date Prepared: June 16, 2023

510(k) number: K220907

1. Applicant Information

Somnics, Inc.
5F, No. 22, Sec. 2, Shengyi Rd.
Zhubei City, Hsinchu County, 30261 Taiwan
Contact Person: Chung Chu Chen
Chief of Executive Officer
Somnics, Inc.
Email: chungchu1@somnics.com
Tel.: +886-3-550-9623

c/o IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212, San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
TEL: 1-949-218-0929
FAX: 1-949-218-0928

2. Device Information

Trade Name:	The iNAP One Sleep Therapy System
Common Name:	Intraoral Pressure Gradient Device
Classification:	Class II
Classification name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570)
Product Code:	OZR

3. Predicate Device

Trade Name:	The iNAP One Sleep Therapy
System Manufacturer:	Somnics, Inc.
510(k)#:	K193460

4. Indications for Use:

The iNAP One Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment choice.

5. Device Description:

The iNAP One Sleep Therapy System consists of six (6) main components. The components include a console (Model R07-A), a saliva container, a saliva absorbent (iNAP DryPad), a flexible polymer tubing (iNAP Tubing Set), soft polymer oral interfaces (iNAP Oral Interface), a Muffler (Optional) and a software application for mobile devices (iNAP Lab+). One additional accessory set (I02C) is included, which is a combination of the iNAP Oral Interface and iNAP Tubing Set. The function of iNAP One Sleep Therapy System (Console Model: R07-A) is to develop a negative pressure gradient in user's oral cavity which can be adjusted between -20 to -90 mmHg (-27 to -122 cmH_2O) via the App (iNAP Lab+) to achieve or maintain proper vacuum pressure for users.

iNAP One Console

The console generates a gentle negative pressure, collects excess saliva and is driven by a built-in rechargeable Li-ion battery.

iNAP Saliva Container

The saliva container is attached directly to the console and retains up to 100 ml of saliva. An opening with the membrane is at the bottom of the container to connect the console.

iNAP DryPad (Saliva Absorbent)

The saliva absorbent is inserted into the saliva container to minimize foaming formed from saliva. The saliva absorbent retains over 30ml of saliva and is to be disposed off after each use regardless full or not.

iNAP Tubing Set

The Tubing Set (T01) is the means of connecting between the console and oral interface with custom connectors. Different styles of Oral Interface are used with this Tubing Set.

iNAP Oral Interface

The Oral Interface is provided in four (4) styles. Patients can choose one with optimum fitting and result.

Muffler (Optional)

The Muffler is to reduce the noise of the device by stabilizing the air flow from the iNAP outlet. It is an optional accessory for users to decrease the noise of iNAP device during use. To use the Muffler, the user attaches the Muffler to the bottom of the iNAP device.

iNAP Lab+ (Mobile App)

The mobile app for patients is intended to keep usage records for personal reference, including pressure setting, intensity setting and usage time (compliance records). It also allows the patients to set intensity and authorized users (physician) to set pressure.

iNAP Oral Interface with Tubing

The Oral Interface with Tubing (I02C) is a combination of the Oral Interface and Tubing Set with an adjustable function. The material of the oral interface is silicone rubber.

6. Comparison of Technological Characteristics with the Predicate Device

Product Name	The iNAP One Sleep Therapy System (Subject Device/K220907)	The iNAP One Sleep Therapy System (Predicate Device/K193460)
Intended Use	The iNAP One Sleep Therapy System is indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment choice.	Same
Console Model	R07-A	R07-B
Compatible App	iNAP Lab+ App (for R07-A and R07-B)	iNAP Care App
Functions on App	Compliance record Pressure Setting Intensity Setting	Compliance record
Pressure	Adjustable pressure range -20 to -90 mmHg (-27 to -122 cmH_2O)	Set as -40 mmHg. (-54 cmH_2O)
Compatible Oral Interface	I07/ I07S/ I07M/ I02C /I07H	I07/ I07S/ I07M/ I02C
Muffler	Optional	N/A
Mechanism of Action	Pressure gradient developed in oral cavity supplied and maintained via the oral interface to the patient mouth.	Same
Single/Multiple Use	Single Person / Multiple Use	Same

A. Comparison of Technological Characteristics

Product Name	The iNAP One Sleep Therapy System (Subject Device/K220907)	The iNAP One Sleep Therapy System (Predicate Device/K193460)	Comment
Energy Source	Operation mode: Rechargeable Lithium ion battery Charge mode: 5 VDC, 2A	Same	Identical
Human Factors	Use during the sleep period. A user operates the console, saliva container, and oral interface during use	Same	Identical
Design – Components	Console Saliva Container Saliva Absorbents	Same	Identical
	Tubing Set	Same	

	Oral interface	Same	
	Additional accessory: Oral Interface with Tubing	Same	
	App (iNAP Lab+) with adjustable settings	App (iNAP Care) without adjustable settings	Similar, with adjustable settings
Design – Energy Used and Delivered	The adjustable pressure is -20 to -90 mmHg (-27 to -122 cmH_2O), and the accuracy is ±5 mmHg (±6.8 cmH_2O)	The setting of negative pressure is -40 mmHg, and the accuracy is ±10%	Similar
Design – Console size	5.98" x 3.14" x 1.41" (152mm x 80mm x 36mm)	Same	Identical
Design – Weight	Weight: 0.47 lbs. (0.21kg) with batteries	Same	Identical
Design – Data storage	Flash memory in MCU (64K bytes, storage data: operation time/ duration, pumping duration/leaking)	Same	Identical
Design – Saliva container volume	100 ml	Same	Identical
Design – Oral Interface Structure (Materials)	Oral Interface Structure: 1. Oral Interface connector 2. Flexible tube with vacuum port 3. Lip shield 4. Tongue shield	Same	Identical
Design – Vacuum Delivering Location in Oral Cavity	One vacuum port between upper palate and tongue	Same	Identical
Design –Oral Interface - Patient Contacting Materials	I07 series Oral Interface: Polymers (thermoplastic elastomer, polycarbonate) I02C Oral Interface with Tubing: Silicone & polypropylene	I07 series Oral Interface: Polymers (thermoplastic elastomer, polycarbonate) I02C Oral Interface with Tubing: Silicone & polypropylene	Same materials and same production processes. I07H has similar structure.
Sterility	Non-sterile	Same	Identical

B. Principle of Operation and Non-Clinical Performance Data

Product Name	The iNAP One Sleep Therapy System (Subject Device/K220907)	The iNAP One Sleep Therapy System (Predicate Device/K193460)	Comment
Principle of Operation	The iNAP One Sleep Therapy System provides a negative pressure gradient within the oral cavity and the pressure gradient pulls the tongue toward the upper palate and also pulls the soft palate forward as well to reduce or eliminate the obstruction of the upper airway, allowing a patient to breathe from nose naturally during sleep.	Same	Identical
Biocompatibility	Biocompatibility evaluation based on ISO 10993-1	Same	Identical
Operating conditions	Operating Temperature & Humidity: 5 to 40°C and 15 to 93% humidity (noncondensing) based on IEC 60601-1	Same	Identical
Storage conditions	Storage Temperature & Humidity: -20 to 50°C and 15 to 93% humidity (noncondensing) based on IEC 60601-1	Same	Identical
Acoustics	Acoustic power < 30 dB per ISO 7779	Same	Identical
Electromagnetic Compatibility (EMC)	Compliance: IEC 60601-1-2 AIM 7351731	Same	Identical
Electrical Safety	Electrical safety (Follow IEC 60601-1): Class II Equipment, Type BF, IP22, Continuous Operation	Same	Identical
Safety for home environment	Compliance: IEC 60601-1-11	Same	Identical
Performance – Negative pressure Setting and accuracy	-20 to -90 mmHg ± 5mmHg (-27 to -122 ± 6.8 cmH_2O)	40 mmHg (±10%)	Similar, with user adjustable settings. Safety and performance validated using clinical testing.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Electrical Safety and Battery Safety: Testing was conducted per:

- IEC 60601-1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11:2015: Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62133 Edition 2.0 2012-12: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

Electromagnetic compatibility (EMC): Testing was conducted per:

- IEC 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- AIM Standard 7351731 Rev. 2.00 2017-02-23 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard.

Software and Cybersecurity:

- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since a failure or latent flaw in the software could lead to delay in delivery of appropriate medical care that would likely lead to minor injury.
- Cybersecurity concerns for monitoring system were addressed in accordance with FDA's "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff" document issued October 2, 2014.

Biocompatibility:

- The patient contacting components for the subject device come under the category of surface contact (mucosal membrane) with permanent contact duration (> 30 days). No new biocompatibility testing was deemed necessary due to the lack of significant changes in patient contacting components compared to the predicate (Testing was conducted based on the FDA guidance on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process").

Functional Testing:

- Functional and mechanical testing of oral interfaces after shelf life and repeated cleaning. This includes pressure stability testing.
- Device noise evaluation with and without optional muffler.

8. Discussion of Clinical Tests Performed

A clinical study with 30 OSA patients was conducted to evaluate the outcomes of iNAP treatment following the pressure configuration process. Polysomnogram (PSG) was used to evaluate the inclusion criteria (AHI > 5), baseline AHI, and post-treatment AHI after 28 days of therapy. In this study, a subgroup analysis revealed that 18 subjects received iNAP treatment within the intended pressure range of -20mmHg to - 90mmHg. The rest received higher negative pressure in order to assess device safety and therapy tolerance at high negative pressures. Of these 18 subjects, 72.2% (13 subjects) experienced successful response (defined as treated AHI < 5) and 22.2% (4 subjects) experienced partial response (defined as AHI reduction > 50% from baseline and treated AHI < 15) with iNAP at pressures below -90mmHg. An improvement in mean treated AHI was observed for patients who receive therapy pressures below -90mmHg: Baseline AHI = 36.01 ±15.87; Treated AHI: 5.53 ± 9.53 (P value < 0.001 based on paired-t test). No adverse events were reported during this study. The performance of the subject device was determined to be non-inferior to the FDA-cleared predicate device (K193460).

9. Conclusions

Based on the indications for use, product performance, and clinical information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.