May 26, 2020

Somnics, Inc.
% Sujith Shetty
Executive Vice President
Maxis LLC
75 E. Santa Clara St. 6th Floor
San Jose, California 95113

Re: K193460
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: April 16, 2020
Received: April 17, 2020

Dear Sujith Shetty:

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,

for Michael Ryan
Division Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193460

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.

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5.0 510(K) STATEMENT/SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CRF 807.92.

510 (k) number: K193460

I. Applicant Information

Somnics, Inc.
5F, No. 22, Sec. 2, Shengyi Rd.
Zhubei City, Hsinchu County, 30261 Taiwan

Contact Person
Chung Chu Chen
Chief Executive Officer
Somnics, Inc.
Email: chungchu1@somnics.com
Tel.: +886-3-550-9623
Date Prepared: May 25, 2020

II. Device Information

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

III. Predicate Device

Trade Name:	Winx™ Sleep Therapy System
Manufactuirer:	Somnics, Inc.
510(k)#:	K130538

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. Device Description

The iNAP One Sleep Therapy System consists of six (6) main components. The components are a console, a saliva container, a saliva absorbent (iNAP DryPad), a flexible polymer tubing (iNAP Tubing Set), a soft polymer oral interface (iNAP Oral Interface) and a software application for mobile devices (iNAP Care). One additional accessory is Oral Interface with Tubing, which is a combination of the Oral Interface and Tubing Set. The function of iNAP One Sleep Therapy

System is developing a negative pressure gradient in the user's oral cavity, which is set as -40 mmHg.

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

iNAP Saliva Container
The saliva container is attached directly to the console and retains up to 100 ml of saliva. An opening with 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 to be disposed after each use regardless full or not.

iNAP Tubing Set
The Tubing Set is the means of connecting between the console and oral interface with custom connectors.

iNAP Oral Interface
The Oral Interface is provided in three (3) sizes. Patients can choose one with optimum fitting and result.

iNAP Care (Mobile App)
The mobile app for patients was developed to keep usage records for personal reference and includes sealing-leakage time ratio.

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

V. 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 device.

VI. Comparison of Technological Characteristics with the Predicate Device:

A. Comparison elements

	Somnics' iNAP One Sleep Therapy System (Subject device)	Winx™ Sleep Therapy System (K130538)	Comment
Device Classification Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570, Product Code OZR, Intraoral Pressure Gradient Device)	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570, Product Code OZR, Intraoral Pressure Gradient Device)	Identical
Intended Use	Treatment of obstructive sleep apnea (OSA)	Treatment of obstructive sleep apnea (OSA)	Identical
Indication for Use	Indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults in whom positive airway pressure is not the preferred treatment device.	Indicated for home use in the treatment of obstructive sleep apnea (OSA) in adults	Similar – Updated based on new guidances
Target Population	Adults with mild, moderate, or severe obstructive sleep apnea	Adults with mild, moderate, or severe obstructive sleep apnea	Identical
Anatomical Sites	Oral cavity (tongue & soft palate)	Oral cavity (tongue & soft palate)	Identical
Mechanism of Action	Pressure gradient developed in oral cavity. Negative oral pressure supplied and maintained via the oral interface to the patient mouth.	Pressure gradient developed in oral cavity. Negative oral pressure supplied and maintained via the mouthpiece to the patient mouth.	Identical
OTC/Prescription Use	Prescription Use	Prescription Use	Identical
Single/Multiple Use	Single Person / Multiple Use	Single Person / Multiple Use	Identical
Treatment Time	Everyday Overnight	Everyday Overnight	Identical

Where Used	At home	At home	Identical

B. Technological Characteristics

	Somnics' iNAP One Sleep Therapy System (Subject device)	**Winx™ Sleep Therapy System (K130538)**	**Comment**
Energy Source	Operation mode: Rechargeable Lithium ion battery Charge mode: 5 VDC, 2A	6.2 V DC, 1100 mA	Similar Technology
Human Factors	Use during sleep period. User operates console, saliva container and oral interface before use	Use during sleep period. User operates console and mouthpiece before use.	Similar Technology
Design – Components	1 Console 1 Saliva reservoir Saliva Absorbents	1 Console with saliva reservoir	Similar Technology
	1 Tubing Set	1 Tubing	
	1 Oral interface	1 Mouthpiece	
	Additional accessory: Oral Interface with Tubing		
	App (iNAP Care)		
Design – Energy Used and Delivered	The setting of negative pressure is -40 mmHg in oral cavity, the accuracy is ±10%	The setting of negative pressure is -20 inches of water (~-37.5 mmHg) in oral cavity, the accuracy is ±10%	Similar Technology
Design – LED display	Battery Power Vacuum Status Clean Saliva Container	1. Power icon (OFF, warming up, ready, need attention) 2. Reservoir icon (Empty/partially full, clean soon, clean now) 3. Vacuum level icon (OFF, reaching target vacuum, at target vacuum, extended vacuum break)	Similar Technology

Design – Console size	5.98" x 3.14" x 1.41" (152mm x 80mm x 36mm)	5.6" x 3.7" x 3.8" (143mm x 94mm x 97mm)	Similar Technology
Design – Weight	Weight: 0.47 lbs (0.21kg) with batteries	Weight (Console): 1.4 lbs. (0.65 kg)	Similar Technology
Design – Data storage	Flash memory in MCU (64K bytes, storage data: operation time/ duration, pumping duration/leaking)	SD card (standard capacity SD card 2GB or less, storage data: operation time/ duration, pumping duration/leaking)	Similar Technology
Design – Saliva container volume	100 ml	100ml	Identical Technology
Design – Liquid to console protection	With filter – water-repellent and ventilate film between saliva container to console	With filter – water-repellent and ventilate film between Reservoir to console	Identical Technology
Design – Oral Interface Structure	Oral interface Structure: Oral interface connector Lip shield Flexible tube with vacuum port Tongue shield	Mouthpiece Structure: Mouthpiece connector Lip seal Arched pad with vacuum port	Similar Technology
Design – Oral interface size	Oral Interface: 3 sizes Oral Interface with Tubing: Adjustable Flexible Tube Length (3 size)	10 sizes	Similar Technology
Design – Vacuum Delivering Location in Oral Cavity	One vacuum port between upper palate and tongue	One vacuum port between upper palate and tongue	Identical Technology
Design – Patient Contacting Materials	Oral Interface: Polymers (polycarbonate, thermoplastic elastomer) Oral Interface with Tubing: Silicone & Polypropylene	Polymers (polycarbonate, thermoplastic elastomer, Tygon tubing), adhesive	Similar Technology
Clean Median	Oral interface: Warm water	Mouthpiece: Warm water	Identical Technology
Sterility	Non-sterile	Non-sterile	Identical Technology

C. Principle of Operation and Non-Clinical Performance Data

Design verification & validation testing were performed on the iNAP Sleep Therapy System and compared to the testing and features of the predicate device.

	Somnics' iNAP Sleep Therapy System (Subject device)	**Winx™ Sleep Therapy System (K130538)**	**Comment**
Biocompatibility	Biocompatibility testing based on ISO 10993-1	Biocompatibility testing based on ISO 10993-1	Identical
Operating conditions	Operating Temperature & Humidity: 5 to 40°C and 15 to 93% humidity(noncondensing) based on IEC 60601-1	Operating Temperature & Humidity: 5 to 40°C and 15 to 95% humidity	Similar
Storage conditions	Storage Temperature & Humidity: -20 to 50°C and 15 to 93% humidity (noncondensing) based on IEC 60601-1	Storage Temperature & Humidity: -20 to 60°C and 15 to 95% humidity	Similar
Acoustics	Acoustic power < 30 dB per ISO 7779	Acoustic power < 30 dB per ISO 7779	Identical
Electromagnetic Compatibility (EMC)	Compliance: IEC 60601-1-2	Compliance: IEC 60601-1-2	Identical
Electrical Safety	Electrical safety (Follow IEC 60601-1): Class II Equipment, Type BF, IP22, Continuous Operation	Electrical safety (Follow IEC 60601-1): Class II Equipment, Type BF, IPX0, Continuous Operation.	Identical except for IP code, but no additional risks induced.
Safety for home environment	Compliance: IEC 60601-1-11	Un-known	N/A
Performance – Negative pressure setting and accuracy	40 mmHg (±10%)	40 mmHg (±10%)	Identical
iNAP app	Mobile app for patients to keep usage records for personal reference and includes sealing-leakage time ratio.	Personal reference and sealing-leakage time ratio is kept on SD card for review on computer	Similar Technology

VII. Performance Data:

The Following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation of the patient contact portion of the iNAP One Sleep Therapy System. This testing was performed on both oral interfaces intended to be used with the system. A summary of the biocompatibility results is shown in the table below.

#	Test Description	Test Lab	Test report #	Result
1	Cytotoxicity for iNAP Oral Interface (I07/IO7M/IO7S) and Tubing Set (T01)	SGS	UB/2016/20122	Pass
2	Skin Sensitization for iNAP Oral Interface (I07/IO7M/IO7S) and Tubing Set (T01)	SGS	UB/2016/20122A-02	Pass
3	Oral Mucosa Irritation Test for iNAP Oral Interface (I07/IO7M/IO7S) and Tubing Set (T01)	SGS	UB/2016/20122A-01	Pass
4	MTT Cytotoxicity for iNAP Oral Interface with Tubing Set (I02C)	NAMSA	15T_32873_04	Pass
5	ISO Guinea Pig Maximization Test for iNAP Oral Interface with Tubing Set (I02C)	NAMSA	15T_32873_05 15T_32873_06	Pass
6	Oral Mucosa Irritation Study in Hamsters for iNAP Oral Interface with Tubing Set (I02C)	NAMSA	15T_32873_07	Pass
7	Pyrogenicity for for iNAP Oral Interface (I07/IO7M/IO7S) and Tubing Set (T01)	SGS	UB/2019/80040	Pass
8	Pyrogenicity for iNAP Oral Interface with Tubing Set (I02C)	SGS	UB/2019/80039	Pass
9	Leechable and Extractables test for	SGS	UB/2019/A0257	Independent Toxoloigical

	iNAP Oral Interface (I07/IO7M/IO7S) and Tubing Set (T01)			Risk Assement Provided
10	Leechable and Extractables test for iNAP Oral Interface with Tubing Set (I02C)	SGS	UB/2019/A0258	Independent Toxoloigical Risk Assement Provided

Summary of the Bench Testing:

Based on the test results, the subject device iNAP One Sleep Therapy System is substantially equivalent to the Winx device in the application and maintenance of negative pressure. In addition, the sound power level of iNAP One Sleep Therapy System during normal operation is substantially equivalent to Winx based on testing according to ISO 7779:2010.

Software

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 "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical Summary:

Clinical testing of the iNAP One Sleep Therapy System included two randomized studies: one performed in Taiwan, and the other a multicenter international study with sites in Germany, Taiwan and the United States.

The clinical performance of the iNAP One Sleep Therapy System is non-inferior to the clinical performance of the Winxmouthpiece used with the Winx Sleep Therapy System. Moreover, the incidence of adverse events and serious adverse events was lower using the iNAP device as compared to the Winx or Winx+ mouthpieces used with the Winx Sleep Therapy System. Finally, the beneficial effect of iNAP and the sleep apnea therapy devices generating negative oral pressure to pull or hold the tongue out of the oropharyngeal airway is durable over the 28-30 days that the devices have been tested. For all these reasons, the iNAP One Sleep Therapy meets the requirements of substantial equivalence compared to the FDA-cleared predicate device, and the risks of using the iNAP One Sleep Therapy System are outweighed by the substantial benefits of using the iNAP device in appropriately selected patients.

VIII. 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.