



June 29, 2020

Somnera Inc.  
Mary Lou Mooney  
Vice President of RA/QA/CA  
1291 Puerta Del Sol Suite #200  
San Clemente, California 92673

Re: K200698  
Trade/Device Name: Somnera™ System  
Regulation Number: 21 CFR 868.5273  
Regulation Name: Positive Airway Pressure Delivery System  
Regulatory Class: Class II  
Product Code: QBY  
Dated: May 26, 2020  
Received: May 28, 2020

Dear Mary Mooney:

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](mailto: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)

Device Name  
Somnera System

### Indications for Use (Describe)

The Somnera System is intended to treat Obstructive Sleep Apnea by delivering a therapeutic breathing pressure to a patient. It provides positive airway pressure during expiration and during an incipient apnea. The system includes a dedicated flow generator and a patient interface; and is intended for use in the home environment. The system is to be used by adult patients weighing more than 66 lbs. (30 kg.).

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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## 6. 510(k) Summary

### 510(k) Summary (as required by 21 CFR 807.92)

#### I. SUBMITTER

Somnera Inc.  
 1291 Puerta Del Sol, Suite 200  
 San Clemente, CA 92673  
 Phone: 949-542-3535  
 Fax: 949-542-8312

**Contact Person:** Mary Lou Mooney, Vice President of RA/QA/CA  
**Date Prepared:** March 16, 2020

#### II. DEVICE

**Name of Device:** Somnera™ System  
**Common or Usual Name:** Positive Airway Pressure System  
**Classification Name:** Positive Airway Pressure System (21 CFR 868.5273)  
**Regulatory Class:** II  
**Product Code:** QBY

#### III. PREDICATE DEVICE

**Predicate Device:** FRESCA Medical CURVE™ Positive Airway Pressure System (DEN170089)

**Reference Device:** Respiroics, Inc. Dream Station Go Auto CPAP (K131982)

#### IV. DEVICE DESCRIPTION

The Somnera System is a positive airway pressure system comprised of an airflow generator and a patient interface. The patient interface has a SmartValve™ seated in either a nasal mask or nasal pillow mask. A hose connects the valve to the generator. The mask is held in place with adjustable headgear straps. The patient interface is supplied non-sterile and intended for single patient reuse in the home environment.

The Somnera System is a prescription device.

#### V. INDICATIONS FOR USE

The Somnera System is intended to treat Obstructive Sleep Apnea by delivering a therapeutic breathing pressure to a patient. It provides positive airway pressure during expiration and during an incipient apnea. The system includes a dedicated flow generator and a patient interface; and is intended for use in the home environment. The system is to be used by adult patients weighing more than 66 lbs. (30 kg.).

The Indications for Use for the Somnera System is identical to the predicate device.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Use of positive airway pressure (PAP) to deliver therapeutic breathing pressure to the patient is the technological principle for both the subject and predicate devices. Both devices incorporate a valve (SmartValve™) that is seated in the patient mask. The valve controls airflow to provide PAP during inspiration and expiration, by utilizing the patient's own breathing effort along with airflow from the generator.

The subject and predicate device are based on the following same technological elements:

- Use of a dedicated flow generator and patient interface
- Use of airflow controlled by a SmartValve™
- Use of the same range of therapeutic pressure settings

The following technological differences exist between the subject device and the predicate device:

- Use of event detection for input to an auto-adjusting pressure algorithm
- Use (optional) of an auto-adjusting pressure mode (“APAP”)
- Use (optional) of several patient comfort settings to ramp pressure at the start of therapy and/or reduce pressure during exhalation

<b>Characteristic</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Reference Device</b>	<b>Comparison</b>
	<b>Somnera System</b>	<b>Curve Positive Airway Pressure System (DEN170089)</b>	<b>Dream Station Go Auto CPAP (K131982)</b>	
Patient Population	Adult patients weighing more than 66 lbs (30 kg).	Adult patients weighing more than 66 lbs (30 kg).	Patients weighing more than 66 lbs (30 kg).	Identical to predicate device.
Intended Use Environment	Home use.	Home use.	Home or hospital use.	Identical to predicate device.
System components	-Blower. -Mask, hose, valve, headgear.	-Blower. -Mask, hose, valve, headgear.	-Blower and hose (Mask and headgear sold separately.)	Blower technology is identical to predicate device.  Nasal pillow mask, hose valve and headgear design are identical to predicate device.
Accessory humidifier	No	No	No	Identical to predicate device.

<b>Characteristic</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Reference Device</b>	<b>Comparison</b>
	<b>Somnera System</b>	<b>Curve Positive Airway Pressure System (DEN170089)</b>	<b>Dream Station Go Auto CPAP (K131982)</b>	
Therapy Mode	PAP APAP	PAP	CPAP APAP	PAP mode is identical to predicate device.  APAP mode is a similar feature to the reference device.
Therapeutic Pressure range	4-20 cmH <sub>2</sub> O (physician selectable only).	4-20 cmH <sub>2</sub> O (physician selectable only).	4-20 cmH <sub>2</sub> O (physician selectable only).	Identical to predicate device.
Patient Comfort Features:  Go To Sleep	User-selectable as “Off” up to 45 minutes.	NA	NA	Similar comfort feature to ramp in predicate device.
Pressure Ramp Duration	User-selectable as “Off” up to 45 minutes.	User-selectable as “Off” up 45 minutes.	User-selectable as “Off” up to 45 minutes.	Identical to predicate device.

<b>Characteristic</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Reference Device</b>	<b>Comparison</b>
	<b>Somnera System</b>	<b>Curve Positive Airway Pressure System (DEN170089)</b>	<b>Dream Station Go Auto CPAP (K131982)</b>	
Expiratory Pressure Comfort Setting	Selectable as Off, 1, 2 or 3.	NA	Selectable as Off, 1, 2 or 3.	Similar feature to reference device.
Data Storage	Micro SD Card.	Standard-sized SD Card.	Micro SD Card.	SD card is identical feature to predicate device.
Graphical User Interface	Touchscreen display.	LCD display.	Touchscreen display.	Touchscreen display similar feature to reference device.
Power Supply	Power adaptor.	Power adaptor.	Power cord or battery pack.	Identical to predicate device.
Patient contact materials	Comply with ISO 10993-1.	Comply with ISO 10993-1.	Comply with ISO 10993-1.	Testing and risk assessment confirm the biocompatibility of the new system. Changes do not impact safety or effectiveness.



## VII. PERFORMANCE DATA

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

### **Biocompatibility Testing**

The biocompatibility evaluation of the subject device was conducted in accordance with FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Tests were selected based on ISO 10993-1, ISO 18562 – 1 and use of well-characterized patient contact materials known to be widely used in medical devices. The skin contact components are categorized as skin surface devices with permanent (> 30 days) duration. The gas pathway components are categorized as external communicating devices, tissue/bone/dentin with permanent (> 30 days) duration. The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization
- Volatile Organic Compound (VOC) Analysis of Gas Pathway
- Emitted Particulate Gas Analysis
- Ozone Gas Analysis
- Carbon Monoxide (CO) and Carbon Dioxide (CO<sub>2</sub>) Gas Analysis
- Extractables

### **Electrical Safety and Electromagnetic Compatibility (EMC)**

Electrical safety and EMC testing were conducted on the flow generator and power adaptor in accordance with the following standards:

IEC 60601-1:2005 + A1:2012 +C1:2009 +A2:2010/(R)2012: Medical electrical equipment – Part1: General requirements for safety of Medical electrical equipment – General requirements for basic safety and essential performance

IEC 60601-1-2:2014 and EN 60601-2:2015: Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC60601-1-11:2015: Medical electrical equipment – Part1-11: 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

### **Software Verification and Validation Testing**

Software verification and validation testing was conducted and documented 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 designated as a "moderate" level of concern, since a failure or latent flaw in the software could result in minor harm to the patient.

### **Performance Testing**

Testing included sound power level, CO<sub>2</sub> rebreathing, component cycling, pressure regulation, waveform testing, maximal output temperature testing and device integrity testing.

### **Clinical Testing**

The clinical study was a non-inferiority, prospective, open-label, randomized crossover assignment, multi-center study at six U.S. sites. The study enrolled 52 subjects, of which 42 were available for primary endpoint analysis. Subjects completed two in-lab sleep nights, in a randomized sequence, with the predicate device programmed to PAP mode and the subject device programmed to APAP mode and an Exhale Pressure Comfort setting of 3. The in-lab sleep nights were scored by an independent, central scorer blinded to the sequence assignment.

#### Primary effectiveness endpoint:

The difference in mean Apnea-Hypopnea Index (AHI) between the predicate and subject device were tested after treatment intervention.

#### Primary safety endpoint:

Device and procedure-related adverse events were summarized after treatment intervention.

#### Effectiveness

The difference in mean AHI between treatment groups in this cross-over design was 1.7/h., with a 95% confidence interval of (-0.2-3.6) and non-inferiority  $p = 0.002$ . This demonstrates that the subject device is non-inferior to the predicate device in the treatment of OSA

### Safety

The study reported 8 subjects with a total of 20 adverse events occurring during one or both randomization nights. One adverse event was reported as related to the predicate device, one adverse event was reported as related to the subject device and the remaining device-related events were associated with the patient interface. All events resolved by the end of the sleep night. Adverse event types were similar on both sleep nights and included primarily skin and nose irritation and difficulty breathing.

### Summary

Based on the results from this clinical study, the subject device was found to have a safety and effectiveness profile that is equivalent to the predicate device.

## VIII. CONCLUSIONS

Based on the results of non-clinical and clinical studies, the subject device is shown to be substantially equivalent to the predicate device (DEN170089).