January 29, 2021

Sunset Healthcare Solutions, Inc.
% Thomas Kroenke
Application Correspondent
Speed To Market, Inc.
2235 East Flamingo Road, Suite 201G,
Las Vegas, NV 89119 USA

Re: K201418
Trade/Device Name: Sunset Heated CPAP Tube
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: December 22, 2020
Received: December 28, 2020

Dear Thomas Kroenke:

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, Ph.D.
Assistant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K201418

Device Name
Sunset Heated CPAP Tube

Indications for Use *(Describe)*
The Sunset Heated CPAP Tube is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for adult patients. It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics Dreamstation Heated Humidifier.

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) Summary

**I SUBMITTER**

| | |
|---|---|
| **Submitter Name:** | Sunset Healthcare Solutions. |
| **Submitter Address:** | 180 N. Michigan Ave, Suite 2000<br>Chicago, IL 60601, US |
| **Phone Number:** | +1 312-533-2449 |
| **Contact Person:** | Greg Marler |
| **Date Prepared:** | January 28, 2021 |

**II. DEVICE**

| | |
|---|---|
| **Device Trade Name:** | Sunset Heated CPAP Tube |
| **Common Name** | Breathing system, heater |
| **Classification** | 21 CFR 868.5270 |
| **Product Code:** | BZE |
| **Review Panel:** | Anesthesiology |

**III. PREDICATE DEVICE** K140424, Philips Respironics Reusable Heated Tubing, Respironics, Inc.

**IV. DEVICE DESCRIPTION**

**Description** The Sunset Heated CPAP Tube warms air, or breathable gas, as it travels to and from the respiratory patient along the breathing circuit of a respiratory system. It reduces condensation that can form in breathing circuit.

The Sunset Heated CPAP Tube has a proprietary connector with two locking tabs that makes it compatible with the Respironics System One and with the Respironics Dreamstation series.

**Physical Description:** Sunset Heated CPAP Tube: length: 1.83 m, internal diameter 15mm
Operating voltage: 3.3 VDC
Power consumption: max 5A

**V. INTENDED USE / INDICATION FOR USE STATEMENT** The Sunset Heated CPAP Tube is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for adult patients. It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics Dreamstation Heated Humidifier.

## VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICES

### Technological Characteristics:

| Characteristics | Philips Respironics Reusable Heated Tubing (K140424) | Sunset Healthcare Solutions Heated CPAP Tube (proposed device) | Discussion of Differences |
|---|---|---|---|
| *Intended Use* | The Philips Respironics Reusable Heated Tubing is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and multi-patient use in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for patients weighing over 10 kg (22lbs).<br>It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics A-Series System One Heated Humidifier. | The Sunset Heated CPAP Tube is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for adult patients.<br>It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics Dreamstation Heated Humidifier. | Similar.<br>Proposed device is restricted to:<br>• Single patient reuse.<br>• Adult patients. |
| *Compatibility with Humidifiers, Standard Connectors and Humidification Chambers* | The tubing has a proprietary connector with two locking tabs that makes it compatible with the Philips Respironics System One Humidifier (K113068) and Philips Respironics A-Series System One Heated Humidifier (K121623). | The tubing has a proprietary connector with two locking tabs that makes it compatible with the Respironics System one (K113068) and with the Respironics Dreamstation series. | Similar.<br>Compatibility with a subset of the devices with which the predicate is compatible. |
| *Anatomical Site* | Non-invasive | Non-invasive | Same. |
| *Patient Population* | Patients weighing over 10 kg (22lbs). | Adult patients | Similar.<br>Device is used with a subset of the predicate device's population. |
| *Environment of Use* | Home and hospital | Home and hospital | Same. |
| *Operating Principle* | During use a voltage is applied and a current flows through the heating wires, encapsulated in the tubing. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed reducing or eliminating water condensation and/or pooling of water in the breathing circuit. | During use a voltage is applied and a current flows through the heating wires, encapsulated in the tubing. Due to the wire resistance, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. As a result, the air passing through the tubing is warmed reducing or eliminating water condensation and/or pooling of water in the breathing circuit. | Same. |

| **Characteristics (continued)** | **Philips Respironics Reusable Heated Tubing (K140424)** | **Sunset Healthcare Solutions Heated CPAP Tube (proposed device)** | **Discussion of Differences** |
|---|---|---|---|
| *Technology* | The power is generated by the humidifier and due to the wire resistance in the device, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. An in-circuit integrated Negative Temperature Coefficient thermistor (NTC) at the mask-end senses the temperature of the passing air flow. The resistance characteristics of the NTC changes with temperature and regulates the current through the heated wires and thereby regulates the temperature of the breathed air. | The power is generated by the humidifier and due to the wire resistance in the device, heat is dissipated through the wall of the tube construction into the air flow in the lumen of the tubing. An in-circuit integrated Negative Temperature Coefficient thermistor (NTC) at the mask-end senses the temperature of the passing air flow. The resistance characteristics of the NTC changes with temperature and regulates the current through the heated wires and thereby regulates the temperature of the breathed air. | Same. |
| *Materials* | Standard breathing circuit Polymeric materials | Standard breathing circuit Polymeric materials | Similar. |
| *Device Design and Physical Properties* | Use of heated tubing on respiratory systems is a proven technology and is well accepted by the medical community | Use of heated tubing on respiratory systems is a proven technology and is well accepted by the medical community | Similar. |
| *Dimensions* | Length: 1.83 mm<br>Inner Diameter: 15 mm version and 22 mm version | Length: 1.83 meter<br>Inner Diameter: 15 mm | Proposed device is the similar to the 15 mm predicate version. |
| *Reusable* | Single-patient reuse in the home and multi-patient use in clinical setting | Single patient reuse. | Similar. Proposed device is labeled the same for home use and for single use only in a clinical setting. |
| *Sterility* | Non-sterile. | Non-sterile. | Same. |
| *Breathing Gases Specified* | Not specified | Not Specified | Same. |
| *Power Source* | Humidifier controlled | Humidifier controlled | Same. |
| *Heating Wire* | Encased | Encased | Similar. |
| *Active Controller* | No, humidifier controlled | No, humidifier controlled | Same. |
| *Standards of Conformity / Performance* | ISO 5367<br>IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 8185 | ISO 5367<br>IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-11<br>ISO 80601-2-70<br>ISO 80601-2-74 | Similar. Proposed device has applied relevant standards. |
| *Compliance (mlpa)*<br>*Resistance to Flow (mb)$^2$ Tube Volume* | ISO 5367 compliant | ISO 5367 compliant | Same. |

| Characteristics (continued) | Philips Respironics Reusable Heated Tubing (K140424) | Sunset Healthcare Solutions Heated CPAP Tube (proposed device) | Discussion of Differences |
|---|---|---|---|
| *Biocompatibility* | ISO 10993,<br>tests for: Cytotoxicity, sensitization, irritation, genotoxicity, implantation, extractables and leachables. | ISO 10993-1<br>ISO 18562-1<br>ISO 18562-2<br>ISO 18562-3<br>ISO 18562-4<br>tests for: emissions of particulate matter, emissions of volatile organic compounds (VOCs) and leachables in condensate. | Similar.<br>Proposed device has applied relevant standards. |

**Summary of Performance Data And Design Controls:**

**Bench testing** was carried out on the following characteristics:

- Performance of sleep apnea breathing therapy equipment
- Performance with interaction of respiratory humidifying equipment
- Requirements for breathing sets and connectors
- Electromagnetic compatibility (EMC)
- Electrical safety testing
- Mechanical safety testing

**Usability Testing:**

In addition to the above, usability evaluation was also conducted as per the Guidance for Industry and Food and Drug Administration Staff, Applying Human Factors and Usability Engineering to Medical Devices February 3, 2016.

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**Referenced Standards and Performance Testing:**

The Sunset Heated CPAP Tube was tested and meets the requirements of following performance standards.

- ISO 5367, edition 5.0, Anaesthetic and respiratory equipment -- Breathing sets and connectors
- ISO 80601-2-70, edition 1.0 Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnea Breathing Therapy Equipment
- ISO 80601-2-74, edition 1.0 Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of respiratory humidifying equipment

**Summary of Performance Data And Design Controls (continued):**

**Biocompatibility testing:**
The Sunset Heated CPAP Tube was tested on biological safety and meets the requirements of following biocompatibility standards:

- ISO 10993-1:2018: Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process
- ISO 18562-1 First edition, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2 First edition, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3 First edition, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-4 First edition, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

**Electrical & Mechanical safety and electromagnetic compatibility (EMC)**
Electrical & Mechanical safety and EMC testing were conducted on the Sunset Heated CPAP Tube. The device complies with the following safety standards:

- ANSI/AAMI/ES 60601-1:2005/(R)2012, A1:2012 edition 3.1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, edition 4.0 2014, Medical electrical equipment – Part 1-2 General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-11, edition 2.0 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

**VIII. CONCLUSION OF SUBSTANTIAL EQUIVALENCE**

Comparison with the predicate device demonstrates that the Sunset Heated CPAP Tube is substantially equivalent to the predicate device. The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the Sunset Heated CPAP Tube should perform as intended in the specified use conditions.