August 2, 2024

Exceleron Medical
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr. NE
Saint Petersburg, Florida 33704

Re: K241268
Trade/Device Name: THERMALITE CPAP Heated Tubing
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE
Dated: May 4, 2024
Received: May 6, 2024

Dear Paul Dryden:

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.

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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)*
K241268

Device Name
THERMALITE CPAP Heated Tubing

Indications for Use *(Describe)*
The THERMALITE® CPAP 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 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 DreamStation 1 and DreamStation 2 heated humidifiers.

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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510(k) Summary
(in accordance with 21 CFR 807.92)

Date:	30 July 2024
Sponsor:	Exceleron Medical, LLC 5000 Township Parkway Saint Paul, MN 55110 USA Keith Roberts - CEO Phone: +1 (877) 834-9279
Submission Correspondent:	Paul Dryden ProMedic, LLC Phone: +1 (239) 307-6061
Trade Name:	THERMALITE® CPAP Heated Tubing
Common and Classification Name:	Breathing System, Heater
Classification Regulation:	21 CFR §868.5270
Product Code:	BZE
Predicate:	K140424 Philips Heated CPAP Tube
Device Description:	The Exceleron Medical, LLC (Exceleron) THERMALITE® CPAP Heated Tubing (THERMALITE) is a heated tube that connects between a continuous positive airway pressure (CPAP) machine and the patient's interface, typically a CPAP mask. The THERMALITE is compatible with the Philips Respironics DreamStation 1 and DreamStation 2 heated humidifiers. The THERMALITE has a unique design that helps prevent condensate from forming within the heated air stream during CPAP therapy by controlling the airflow temperature, creating an environment to maintain water in its vapor form. This condition of condensation is commonly known as "rainout," and is usually the result of temperature and humidity differentials between the device versus the surrounding air. The THERMALITE is available in a three (3) or two (2) wire configuration.
Indications for Use:	The THERMALITE® CPAP 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 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 DreamStation 1 and DreamStation 2 heated humidifiers.

510(k) Summary
(in accordance with 21 CFR 807.92)

Manufacturer / Device	*Cleared*	*Reason for Inclusion*	*Regulation (Product Code)*
Primary Predicate Philips Respironics Reusable Heated Tubing	K140424	Same indications for use and same or similar technology.	21 CFR §868.5270 (BZE)
Reference Philips Respironics Dream Station 2 System which includes heated tubing	K200480	Same indications for use and same or similar technology.	21 CFR 868.5905 (BZD) But contains heated tubing as an accessory

Table - Primary Predicate and Reference Devices

510(k) Summary
(in accordance with 21 CFR 807.92)

Characteristics	**Primary Predicate Philips Respironics Reusable Heated Tubing (K140424)**	**Reference Philips Respironics Reusable Heated Tubing (K200480)**	**Exceleron Medical Heated CPAP Tube (3 wire design) – Subject Device**	**Exceleron Medical Heated CPAP Tube (2 wire design) – Subject Device**	**Discussion of Differences**
Indications for 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). It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics A-Series System One Heated Humidifier.	The heated tube is used, along with the heated humidifier, to control the provided humidification. This is accomplished by controlling the temperature of the air in order to ensure that it does not cool down prior to reaching the mask.	The Exceleron 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 Dreamstation 1 (**K140424)** and Dreamstation 2 (**K200480)** Heated Humidifiers	The Exceleron 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 Dreamstation 1 and Dreamstation 2 Heated Humidifiers.	Similar. Subject devices restricted to: • Single patient reuse. 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 Dreamstation 2 machine.	The tubing has a proprietary connector with two locking tabs that make it compatible with the Respironics Dreamstation Series (Dreamstation 1 and Dreamstation 2 CPAP machine (K200480))	The tubing has a proprietary connector with two locking tabs that make it compatible with the Respironics Dreamstation Series (Dreamstation 1 and Dreamstation 2 CPAP machine (K200480))	Similar. Compatibility with a subset of the devices with which the predicate is compatible.
Anatomical Site	Non-invasive	Non-invasive	Non-invasive	Non-invasive	Same.

510(k) Summary
(in accordance with 21 CFR 807.92)

Characteristics	**Primary Predicate Philips Respironics Reusable Heated Tubing (K140424)**	**Reference Philips Respironics Reusable Heated Tubing (K200480)**	**Exceleron Medical Heated CPAP Tube (3 wire design) – Subject Device**	**Exceleron Medical Heated CPAP Tube (2 wire design) – Subject Device**	**Discussion of Differences**
Patient Population	Patients weighing over 10 kg (22lbs).	Patients weighing more than 66 lb (30 kg)	Adult patients	Adult patients	Similar. Device is used with a subset of the predicate device's
Environment of Use	Home and hospital	Home and hospital	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.	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 to or above the dew point (of the air existing the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit 41 ºC. The raising of the gas temperature does not exceed	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.

510(k) Summary
(in accordance with 21 CFR 807.92)

Characteristics (continued)	**Philips Respironics Reusable Heated Tubing (K140424)**	**Philips Respironics Reusable Heated Tubing (K200480)**	**Exceleron Heated CPAP Tube (3 wire design) – Proposed Device**	**Exceleron Medical Heated CPAP Tube (2 awire design) – 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.	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 machine end. The machine will sense the resistance of the thermistor and will determine the amount of voltage to apply to the heaters to achieve the tubing temperature.	Same with the only difference on the 2 wire design is the NTC is at the machine end and provides the same voltage regulation through the heated wires as both predicate 3 wire designs.
Dimensions/specs	Length: 1.83 mm Tubing Inner Diameter: 15 mm version and 22 mm version Patient Fitting – 22 mm Machine Fitting – Proprietary to the humidifier	Length: 1.83 mm Tubing Inner Diameter: 15 mm version and 22 mm version Patient Fitting – 22 mm Machine Fitting – Proprietary to the humidifier	Length: 1.83 meter Inner Tubing Inner Diameter: 15 mm Patient Fitting – 22 mm Machine Fitting – Proprietary to the humidifier	Length: 1.83 meter Inner Tubing Inner Diameter: 15 mm Patient Fitting – 22 mm Machine Fitting – Proprietary to the humidifier	Proposed device is the similar to the 15 mm predicate versions.

510(k) Summary
(in accordance with 21 CFR 807.92)

Characteristics	**Primary Predicate Philips Respironics Reusable Heated Tubing (K140424)**	**Reference Philips Respironics Reusable Heated Tubing (K200480)**	**Exceleron Medical Heated CPAP Tube (3 wire design) – Subject Device**	**Exceleron Medical Heated CPAP Tube (2 wire design) – Subject Device**	**Discussion of Differences**
Reusable	Single-patient reuse in the home and multi-patient use in clinical setting	Single patient reuse.	Single patient reuse.	Single patient reuse.	Similar. Proposed device is labeled the same for home use and for single use only in a clinical
Power Source	Humidifier controlled	Humidifier controlled	Humidifier controlled	Humidifier controlled	Same.
Standards of Conformity / Performance	ISO 5367 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 8185	ISO 5367 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-70 ISO 80601-2-74	ISO 5367 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-70 ISO 80601-2-74	ISO 5367 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-70 ISO 80601-2-74	Similar. Proposed device has applied relevant standards.
Biocompatibility	ISO 10993, tests for: Cytotoxicity, sensitization, irritation, genotoxicity, implantation, extractables and leachables.	ISO 10993-1 ISO 18562-1 ISO 18562-2 ISO 18562-3 ISO 18562-4 tests for: emissions of particulate matter, emissions of volatile organic compounds (VOCs)	ISO 10993-1 ISO 18562-1 ISO 18562-2 ISO 18562-3 ISO 10993-18 tests for: Cytotoxicity, sensitization, irritation, emissions of particulate matter, emissions of volatile organic compounds (VOCs), extractables and leachables.	ISO 10993-1 ISO 18562-1 ISO 18562-2 ISO 18562-3 ISO 10993-18 tests for: Cytotoxicity, sensitization, irritation, emissions of particulate matter, emissions of volatile organic compounds (VOCs), extractables and leachables.	Similar

510(k) Summary
(in accordance with 21 CFR 807.92)

Summary of Performance Testing:

Biocompatibility

The indirect patient-contact materials in the Exceleron THERMALITE were tested for biocompatibility compliance in accordance with the following Standards and guidance documents:

- *ISO 10993-1: 2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.*
- *ISO 10993-18: 2020, Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process.*
- *ISO 18562-1: 2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process.*
- *ISO 18562-2: 2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter.*
- *ISO 18562-3: 2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds.*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," 04 Sep 20.*

Test results indicated that the indirect patient-contact materials in the Exceleron THERMALITE complies with the applicable Standards and guidance documents.

Electrical Safety

The Exceleron THERMALITE was tested for patient safety in accordance with the following Standards:

- *IEC 60601-1: 2005, Am1: 2012, Am2: 2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*
- *IEC 60601-1-11: 2020, 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.*

Test results indicated that the Exceleron THERMALITE complies with the applicable Standards.

510(k) Summary
(in accordance with 21 CFR 807.92)

Electromagnetic Compatibility

The Exceleron THERMALITE was tested for EMC in accordance with the following Standards and guidance documents:

- *IEC 60601-1-2: 2020, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*
- *Electromagnetic Compatibility (EMC) of Medical Devices, 06 Jun 22.*

Test results indicated that the Exceleron THERMALITE complies with the applicable Standards and guidance documents.

Performance Testing – Bench

The Exceleron THERMALITE was tested for performance in accordance with internal requirements, applicable Standards, and guidance documents.

- *IEC 60601-1-6: 2020, Medical electrical equipment: General requirements for basic safety and essential performance – collateral standard: Usability.*
- *IEC 62366-1: 2020, Medical devices – Application of usability engineering to medical devices.*
- *ISO 5356-1: 2015, Anaesthetic and respiratory equipment — Conical connectors – Part 1: Cones and sockets.*
- *ISO 5367: 2014, Anaesthetic and respiratory equipment -- Breathing sets and connectors.*

Performance Testing – Bench

The Exceleron THERMALITE was tested for performance in accordance with internal requirements, applicable Standards, and guidance documents.

- *ISO 80601-2-70: 2020, Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment.*
- *ISO 80601-2-74: 2017, Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.*
- *ISTA Procedure 3A – 2018, Parcel Delivery System Shipments 150 lb (70 kg) or Less.*

Test results indicated that the Exceleron THERMALITE complies with internal requirements, applicable Standards, and the guidance documents.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the Exceleron THERMALITE. The results of these activities demonstrate that the Exceleron THERMALITE is as safe and as effective as the predicate device when used in accordance with its intended use and labeling.

Therefore, the Exceleron THERMALITE is considered substantially equivalent to the predicate device.