December 15, 2025

SleepRes, Inc
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K251770
Trade/Device Name: SleepRes PAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD, BZE
Dated: November 16, 2025
Received: November 17, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2025.12.15 17:08:05 -05'00'

For

Rachana Visaria
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)*
K251770

Device Name
SleepRes PAP system

Indications for Use *(Describe)*
The SleepRes PAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lbs. (30 kg.). The SleepRes PAP system is intended for home, hospital / institutional and sleep center settings.

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:	December 15, 2025
Sponsor:	SleepRes, Inc. 1508 Carl Adams Dr Ste 200 Murfreesboro, TN 37129 Tel: (615) 921-2406
Sponsor Contact:	Craig Salazar - Chief Financial Officer
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	SleepRes PAP system
Common/Usual Name:	CPAP
Classification Name:	BZD – 868.5905 - Noncontinuous Ventilator (IPPB) Secondary BZE – 868.5270 - Breathing System Heater
Predicate Device:	Philips DreamStation 2 - K200480
Common/Usual Name:	CPAP
Classification Name:	BZD – 868.5905 - Noncontinuous Ventilator (IPPB)
Reference Device:	Exceleron Thermalite CPAP Heated Tubing - K241268
Common/Usual Name:	Heated CPAP Hose
Classification Name:	BZE – 868.5270 - Breathing System Heater

Device Description

The SleepRes PAP system consists of a firmware-controlled console, power cable and power adapter, air filter, water tank, and heated breathing tube. The PAP console is composed of a control system, motor system, and heating system. The control system includes the main board, buttons, screen, and sensor. The motor system includes the motor, fan blade, motor outer shell, and silence box. The heating system includes a heating plate and temperature sensor. The PAP console of the subject device does not include foam.

The SleepRes PAP system also includes the following components of PAP therapy systems:

- Water tank
- Air filter
- Breathing Tube

The SleepRes PAP system offers several modes:

- CPAP
  - Provides continuous positive airway pressure at the prescribed pressure
- APAP
  - Functions to titrate the pressure up (and down as well) to balance reducing or eliminating sleep events while using the lowest effective pressure. Pressure limits are pre-set by the prescribing clinician.
- Kairos Positive Airway Pressure (KPAP)
  - This algorithm reduces airway pressure during both inspiration and during most of expiration, only returning pressure to the prescribed treatment level towards the end of expiration.

Connectivity to a Cloud platform via Wi-Fi connection.

Principle of Operation
A PAP therapy system works by creating and delivering pressurized air into the airway through a patient interface, mask or nasal pillows, to keep the airway open while sleeping. The pressure is set to a therapy level, or it can change based on the patient's breathing needs. Typical therapy pressure averages 11-12 cmH_2O but can range from between 4 and 20 cmH_2O during APAP use.

Indications for Use:
The SleepRes PAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lbs. (30 kg.). The SleepRes PAP system is intended for home, hospital / institutional and sleep center settings.

Table 1 - Comparison of Subject vs. Predicate

	Subject device **SleepRes PAP System** **K251770**	**Predicate** **Philips DreamStation 2** **K200480**	**Comparison**
Product Code	BZD – 868.5905 Noncontinuous Ventilator (IPPB) BZE – 868.5270 Breathing System Heater	BZD – 868.5905 Noncontinuous Ventilator (IPPB)	Similar
Indications for Use	The SleepRes PAP system is intended to deliver positive airway pressure therapy for the treatment of obstructive sleep apnea (OSA) in patients weighing over 30 kg. (66 lbs.). The SleepRes PAP system is intended for home, hospital / institutional and sleep center settings.	The DreamStation 2 CPAP / DreamStation 2 Auto CPAP system delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30 kg (66 lbs). It is for use in the home or hospital/institutional environment.	Similar to Predicate
Patient Population	Patients weighing over 30 kg (66 lbs).	Patients weighing over 30 kg (66 lbs).	Similar to Predicate
Environment of Use	Home, hospital/institutional and sleep center settings	Home, hospital/institutional environment	Similar to Predicate
Fundamental scientific technology	Microprocessor Software controlled Blower Heater	Microprocessor Software controlled Blower Heater	Similar to Predicate
Modes of Operation	CPAP Auto CPAP (APAP) KPAP	CPAP Auto CPAP - Auto-Trial - CPAP-check C-Flex	Both devices adjust pressure during inspiration and then increase pressure during expiration. Sleep comparison of algorithms demonstrated any difference does not raise different risks compared to predicate
Energy delivered	Continuous Positive Airway Pressure (CPAP)	Continuous Positive Airway Pressure (CPAP)	Similar to Predicate
Pressure Range	4 to 20 cmH_2O	4 to 20 cmH_2O	Similar to Predicate
Pressure Accuracy **Static** **Dynamic**	+/- 0.5 cmH_2O +/- 1.0 -1.5 cmH_2O from 10-20 BPM	+/- 0.5 cmH_2O for 15 and 22mm tubing +/- 1.0 cmH_2O for 12 mm tubing +/- 1.0 cmH_2O for 15 and 22mm tubing +/- 2.0 cmH_2O for 12 mm tubing	Similar to Predicate
Flow Range	10-60 lpm	10-60 lpm	Similar to Predicate

	Subject device SleepRes PAP System K251770	Predicate Philips DreamStation 2 K200480	Comparison
Accuracy	+/- 2 lpm or 10% of reading		
Humidifier	Integrated	Integrated	Similar to Predicate
Water tank capacity	250 ml	325 ml	Similar to Predicate
Patient Interface **User supplied**	Mask Nasal pillows	Mask Nasal pillows	Similar to Predicate
Cleaning	Main unit – exterior only Water tank – soap and water Heated Tube – soap and water	Main unit – exterior only Water tank – soap and water Heated Tube – soap and water	Similar to Predicate
Specifications			
Dimensions **Weight**	243mm x 181mm x 110mm 1370 grams	274mm x 158mm x 85mm 1040 grams	Similar to Predicate
Operating temperature range	5℃ to 32℃ (41˚F to 95˚F)	5° to 35°C (41° to 95°F)	Similar to Predicate
Storage Temperature range	-20℃ to 55℃ (-13˚F to 158˚F)	-20° to 60°C (-4° to 140°F)	Similar to Predicate
Service Life	Water Tank – 6 months Heated Tubing – 3 months	Water Tank – 12 months Heated Tubing – 6 months	Similar to Predicate
Atmospheric Pressure	700 to 1060 hPa (0-3000m / 0-9880ft)	101 to 77 kPa (0 - 2286m / 0 - 7500ft)	Similar to Predicate
Electrical Safety and EMC	Input: AC100-240V, 50/60Hz 1.8Amax Output: DC24V, 3.33A	Input: AC100–240 VAC, 50/60 Hz 2.0-1.0 A Output: DC 12V	Similar to Predicate
Noise / Sound	<35 dB(A)	27 dB(A)	higher than the predicate; Labeling mitigation added to address difference*
Therapy algorithm comparison	Comparative Sleep studies were substantially equivalent	Comparative Sleep studies were substantially equivalent	Similar to Predicate
Communications	Wi-Fi	Wi-Fi BLE Cellular	Similar to Predicate

*Warnings have been included on the user manual to inform the users about the device sound pressure level as compared to the recommended level by the World Health Organization.

Table 2 - Comparison of Heated Tubing Subject vs. Reference

	Subject device SleepRes PAP System K251770	Reference Exceleron Thermalite CPAP Heated Tubing K241268	Comparison
Product Code	BZD – 868.5905 Noncontinuous Ventilator (IPPB) BZE – 868.5270 Breathing System Heater	BZE – 868.5270 Breathing System Heater	Similar
Indications for Use	The SleepRes PAP system is intended to deliver positive airway pressure therapy for the treatment of obstructive sleep apnea (OSA) in patients weighing over 30 kg. (66 lbs.). The SleepRes PAP system is intended for home, hospital / institutional and sleep center settings.	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 noninvasive ventilation for adult patients. It is compatible with the Philips Respironics DreamStation 1 and DreamStation 2 heated humidifiers	Similar
Patient Population	Patients weighing over 30 kg (66 lbs.).	Adult patients	Similar
Environment of Use	Home, hospital/institutional and sleep center settings	Home, hospital/institutional environment	Similar
Operating Principle	During use a voltage is applied and a current flows through the heating wires.	During use a voltage is applied and a current flows through the heating wires, encapsulated in the tubing.	Similar
Technology	The power is generated by the humidifier and due to the wire resistance in the device. Main unit controller monitors 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.	Similar
Dimensions	ID – 22 mm Length – 1.83 m	ID – 22 mm Length – 1.83 m	Similar

	Subject device SleepRes PAP System	Reference Exceleron Thermalite CPAP Heated Tubing K241268	Comparison
Reusable	Single-patient, multi-use Clean – soap and water	Single-patient, multi-use Clean – soap and water	Similar
Power Source	Humidifier controller	Humidifier controller	Similar

Discussion of Differences Between Subject and Predicates
We presented in the tables above a comparison of the proposed device and then the accessory. We have provided the rationale for the use of a predicate for the proposed PAP system. Separately, we compared the accessory heated wire hose to a reference device.

Technological Characteristics –
The subject device and the predicate, Philips DreamStation 2 utilize a blower to generate pressure and therefore flow to the patient which is software controlled. Each device has a series of algorithms which include APAP, CPAP and a feature referred to as KPAP and C-Flex for the subject device and predicate, respectively. The subject device and the predicate both include an integrated humidifier which provides heat and humidification to the patient via a heated wire hose. We compared the technology of the heated wire hose to a reference device, Exceleron Thermalite, which was found to be similar in all features and functions and is considered substantially equivalent. Both the subject device and the predicate include types of wireless connectivity which permits data transfer for review by the provider who may also provide changes to the PAP device.

Non-clinical Testing –
The proposed device has been tested to all applicable standards that include:

- ISO 5367:2023 Anaesthetic and respiratory equipment — Breathing sets and connectors
- IEC 60601-1: 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
- 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
- ISO 80601-2-70:2020 Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
- ISO 80601-2-74:2021 Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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"
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

Human factors validation was conducted according to FDA's Guidance for Industry and FDA Staff:

- "Applying Human Factors and Usability Engineering to Medical Devices"

Additional non-clinical performance testing included:

- Storage
- Transportation
- Service-life
- Altitude
- Cleaning
- Wireless coexistence
- Comparative waveform Testing

Biocompatibility Assessment

The subject device is categorized as permanent contact duration (>30 days) including dry and humidified gas pathways. The following Biocompatibility testing was performed.

- ISO 10993-1: 2025 Biological evaluation of medical devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:201 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-23, 2021, Biological Evaluation of Medical Devices - Part 23: Tests for Irritation
- ISO 10993−11, 2017, Biological Evaluation of Medical Devices − Part 11: Tests for Systemic Toxicity -Acute Systemic Toxicity and Material Mediated Pyrogenicity
- ISO/TR 10993-33, 2015, Biological Evaluation of Medical Devices - Part 33: Guidance on Tests to Evaluate Genotoxicity - Supplement to ISO 10993-3.
- ISO 10993-18:2020 – Biological evaluation of medical devices – part 18: Chemical characterization of medical device materials within a risk management process and TRA
- ISO 18562-1: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs) and Inorganic gases – CO, CO2 and Ozone
  ISO 18562-4: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 4: Tests for leachables in condensate

Additionally, to verify the biocompatibility of the subject device at end of service-life following testing was conducted post accelerated aging.

- ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)

The proposed device demonstrated that it met the performance and safety requirements to be found safe and effective compared to the predicates.

Clinical Testing

A clinical validation study was conducted to support the substantial equivalence of the SleepRes APAP device, a Philips APAP device and the SleepRes APAP + KPAP algorithms. The proposed device was compared in PSG sleep studies to the primary predicate for the treatment of OSA.

This study consisted of 50 OSA patients all of whom were on standard APAP in the home. Each patient underwent a full night polysomnogram. Half of the night was spent on CPAP and the other half of the night on APAP, and APAP + KPAP.

The results demonstrated no significant difference in disordered breathing events (AHI3a), sleep quality and metrics of sleep architecture between treatments.

Substantial Equivalence Conclusion

The comparison of features and specifications, non-clinical performance testing and the comparative clinical studies demonstrate that the proposed device is substantially equivalent to the predicates.

Any differences do not raise different concerns of safety or effectiveness when compared to the predicates.