July 23, 2026

Resvent Medical Technology Co., Ltd.
% Lisa Pritchard
VP, Regulatory, Quality, Clinical and Engineering
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Medical Arts Bldg.
Minneapolis, Minnesota 55402

Re: K253044
Trade/Device Name: RXiBreeze PAP System (RXiBreeze 20C)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 20, 2026
Received: July 20, 2026

Dear Lisa Pritchard:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.07.23 16:43:52 -04'00'

For

James J. Lee, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253044

Device Name
RXiBreeze PAP System (RXiBreeze 20C)

Indications for Use *(Describe)*
The RXiBreeze™ PAP system delivers positive airway pressure therapy for the treatment of obstructive sleep apnea in spontaneously breathing adult patients. It is for single patient use in the home, hospital, or institutional environment.

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

K253044

1. Submitter Information

Submitter	Resvent Medical Technology Co., Ltd. BC601,Gaoxinqi Factory, District 67, Xingdong Community,Xin'an Street, Bao'an District, 518100 Shenzhen, PEOPLE'S REPUBLIC OF CHINA Tel: +8675523027370
Contact Person (Title):	Mr. Harry Wang (Regulatory Affairs Director) harry.wang@resvent.com

2. Date Prepared: July 22, 2026

3. Subject Device Information

Device Trade Name:	RXiBreeze PAP System (RXiBreeze 20C)
Common Name:	Noncontinuous ventilator (IPPB)
Regulation Name	Ventilator, Non-Continuous (Respirator)
Regulation Number:	868.5905
Product Codes:	BZD
Regulatory Class:	II

4. Predicate Device Information

Predicate Device: K153387, Luna® CPAP System, Product Code BZD

Reference Device: K211155, M1 Mini Auto CPAP System, Product Code BZD

5. Device Description

The RXiBreeze PAP System (Model RXiBreeze 20C) is a prescription only,

microprocessor controlled, positive airway pressure ventilator device intended to treat individuals who are diagnosed with obstructive sleep apnea (OSA). The device provides continuous positive airway pressure (CPAP). Its design includes an integrated humidifier, uses an external AC power supply, and an integrated WIFI module for the transfer of therapy data.

The RXiBreeze PAP System is designed to release a continuous, slightly pressurized stream of air directly into a person's nose via connection tube and mask, which aids obstructed breathing during sleep, effectively treating the spontaneous pauses in breath that are associated with OSA.

This device is intended to be used with FDA-cleared masks and breathing tubes.

6. Indications for Use

The RXiBreeze PAP system delivers positive airway pressure therapy for the treatment of obstructive sleep apnea in spontaneously breathing adult patients. It is for single patient use in the home, hospital, or institutional environment.

7. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

Item	Subject Device: RXiBreeze PAP System	Predicate Device: K153387 Luna® CPAP System	Reference Device: K211155 M1 Mini Auto CPAP System	Comparison
Regulation number	868.5905	868.5905	868.5905	Identical
Classification	II	II	II	Identical
Product Code	BZD	BZD	BZD	Identical
Intended Use	Delivery of positive airway pressure for treatment of obstructive sleep apnea	Delivery of positive airway pressure for treatment of obstructive sleep apnea	Delivery of positive airway pressure for treatment of obstructive sleep apnea	Identical
Indications for use	The RXiBreeze PAP system delivers positive airway pressure therapy for the treatment of obstructive sleep apnea in spontaneously breathing adult patients. It is for single patient use in the home, hospital, or institutional environment.	The Luna® CPAP System is intended to delivery positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated heated humidifier is indicated for the humidification and warming of air from the flow generator. This device is intended for single patient use by prescription in the home / institutional environment on adult patients.	Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home. Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use. LightTrip App is a mobile application for patients to remotely operate BMC Mini serial devices, and transmit, store and display usage and treatment information. It can also receive	Similar to predicate device

Item	Subject Device: RXiBreeze PAP System	Predicate Device: K153387 Luna® CPAP System	Reference Device: K211155 M1 Mini Auto CPAP System	Comparison
			parameters and device firmware upgrade data from the cloud, and then transmit these data to the device. The LightTrip app also allows healthcare professionals to remotely configure compatible OSA therapy devices. LightTrip App is for prescription use only.	
Enviornment of Use	Home and healthcare facilities	Home and healthcare facilities	Home and healthcare facilities	Identical to predicate device
Therapy Delivered	CPAP	CPAP	CPAP, Auto CPAP	Identical to predicate device
Operating Temperature	5 to 35° C	5 to 35° C	Not available	Identical to predicate device
Storage/ Transport Temperature	-25 to 60° C	-25 to 70° C	Not available	Similar to predicate device
Storage/ Transport Humidity	5%-95% (non-condensing)	Up to 93% Non-condensing	Not available	Similar to predicate device

Item	Subject Device: RXiBreeze PAP System	Predicate Device: K153387 Luna® CPAP System	Reference Device: K211155 M1 Mini Auto CPAP System	Comparison
Atmospheric Pressure	70 to 106 kPa	76 to 106 kPa	Not available	Similar to predicate device
AC Power Consumption	100-240V~, 50/60 Hz, 2A Max	100-240VAC, 50/60Hz, 2.0A max	100-240VAC, 50/60Hz, 1.0A max	Identical to predicate device
Software	Microprocessor controlled	Microprocessor controlled	Microprocessor controlled	Identical
IEC 60601-1 Classification for Protection Against Electric Shock	Class II	Class II	Class II	Identical
IEC 60601-1 Degree of Protection Against Electric Shock	Type BF	Type BF	Type BF	Identical
Degree of Protection Against Ingress of Water	IP22	IP22	IP22	Identical
Pressure Range	4-20 cmH_2O	4-20 cmH_20	4-20 cmH_20	Identical

Item	Subject Device: RXiBreeze PAP System	Predicate Device: K153387 Luna® CPAP System	Reference Device: K211155 M1 Mini Auto CPAP System	Comparison
Expiratory Pressure Relief	Yes iPR function Range: Off, 1 ~ 3	Yes Reslex function Range: Off, 1 ~ 3	Yes Reslex function Range: Off, 1 ~ 3	Similar to predicate and reference devices
Sound Pressure Level	30 dB(A) with uncertainty of 2dB(A)	<30 dB, when the device is working at the pressure of 10 cmH_20	<30 dB, when the device is working at the pressure of 10 cmH_20	Similar
Air filter	Yes	Yes	Yes	Identical
Ramp	0-60 minutes	0-60 minutes	0-60 minutes	Identical to predicate and reference devices
Integrated Humidifier	Yes	Yes	No	Identical
Static pressure accuracy	±0.5 cmH_2O with a measurement uncertainty of 1.87%	±1 cmH_20	±(0.5 hPa + 4%)	Similar to predicate and reference devices
Dynamic pressure accuracy	±1 cmH_2O with a measurement uncertainty of 2.55%	±1 cmH_20	±(0.5 hPa + 4%)	Identical to predicate device
Humidifier water capacity	290 ml (MAX Water Level)	350 ml at recommended water level	None	Similar to predicate device and reference

Item	Subject Device: RXiBreeze PAP System	Predicate Device: K153387 Luna® CPAP System	Reference Device: K211155 M1 Mini Auto CPAP System	Comparison
				device
Wireless function	WiFi	N/A	Bluetooth	Different from predicate device, similar to reference device
Remote programing	No	No	Yes	Identical to predicate device

As shown in the table above, the proposed RXiBreeze PAP System and the selected predicate device and reference device do not have identical indications for use statements; however, their intended uses are the same (delivery of positive airway pressure for treatment of obstructive sleep apnea). The RXiBreeze PAP System also has the same therapy delivered, operating temperature, atmospheric pressure, AC power consumption, software type, IEC 60601 classification, ingress protection, pressure range, air filter, ramp, integrated humidifier, and humidity range as the primary predicate device.

The differences between the RXiBreeze PAP System and the primary predicate device include storage/transportation temperature range, storage/transportation humidity range, expiratory pressure relief, sound pressure level, static pressure accuracy, humidifier capacity, and wireless function. All have been determined not to raise different questions of safety and effectiveness in comparison to the primary predicate device or reference devices.

8. Summary of Non-clinical Testing

The proposed device has been tested to all applicable guidance and standards that include:

- Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff
- Radio Frequency Wireless Technology in Medical Devices Guidance for Industry and Food and Drug Administration Staff
- IEC 60601-1: 2020 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 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ANSI C63.18-2014 American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters

- 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
- 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

The following Biocompatibility testing and assessment were performed according to applicable guidances and standards:

- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests

for 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
- ISO 10993-18: 2020/Amd 1: 2022 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 10993-17: 2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
- 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
- ISO 18562-4: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

The following testing was also performed according to applicable guidances and standards:

- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- ANSI/AAMI ST98:2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- AAMI TIR12:2020/(R)2023; Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- Storage and Transportation
- Service Life

9. Conclusion

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

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