June 4, 2026

ResMed Corp
Prerana Gurubasavaraj
Manager, Regulatory Product Strategy & Delivery - San Diego
9001 Spectrum Center Blvd.
San Diego, California 92123

Re: K253553
Trade/Device Name: Orion
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 1, 2026
Received: May 1, 2026

Dear Prerana Gurubasavaraj:

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: 2026.06.04 11:08:50 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K253553

Device Name

Orion

Indications for Use *(Describe)*

Orion is a software platform intended to assist healthcare professionals in the management, and treatment of patients who have been diagnosed with sleep-disordered breathing by:

- Displaying and analyzing device and therapeutic information that has been transmitted remotely from the patient's compatible device to optimize patient care management and engagement.
- Providing remote settings capabilities for compatible Resmed devices.
- Communicating with digitally connected platforms.

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

[As required by 21 CFR 807.92]

Submission Number:	K253553
Date of Submission:	November 14, 2025
Company Name/Owner:	ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123, US
Official Contact:	Prerana Gurubasavaraj Manager, Regulatory Product Strategy & Delivery ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123, US prerana.gurubasavaraj@resmed.com
Device Trade Name:	Orion
Device Common Name:	Ventilator, Non-Continuous (Respirator)
Classification and Classification Name:	II Noncontinuous Ventilator (IPPB)
Regulation Number:	21 CFR 868.5905
Product Code:	BZD
Legally Marketed Predicate Device:	ResScan (K140054)

Device Description:

The Orion software is a web-based application that allows qualified healthcare professionals to view therapy information and adjust settings for compatible Resmed positive airway pressure (PAP) devices used in the management of sleep-disordered breathing. The system operates through secure, encrypted communication with compatible devices and is intended for use in clinical and homecare environments by trained personnel. The software version included in this submission is Orion Version 1.0.

Orion is a cloud-based software platform accessed through a secure web interface and supported by a secure cloud-hosted backend environment that manages data processing and device communication. Orion supports secure exchange of patient and therapy data with authorized external systems through authenticated interfaces. Compatible PAP devices transmit therapy data to the secure cloud environment using encrypted wireless communication. Authorized users access Orion through authenticated login with role-based access control. When a clinician initiates a therapy setting adjustment, the request is validated and securely transmitted to the compatible PAP device.

Orion is a multiple function device software product containing software functions that are considered medical device software functions as well as non-device software "other" functions. In accordance with FDA guidance "Multiple Function Device Products: Policy and Considerations," this submission focuses on the device software function subject to FDA oversight, which is the remote configuration of therapy settings for compatible Resmed positive airway pressure (PAP) devices. The remaining "other" functions consist of therapy data display, patient record management, reporting, user access controls, and system interoperability features that support system operation and do not independently perform medical device functionality. These "other" functions do not adversely impact the safety or effectiveness of the device software function under review.

Indication For Use:

Orion is a software platform intended to assist healthcare professionals in the management, and treatment of patients who have been diagnosed with sleep-disordered breathing by:

- Displaying and analyzing device and therapeutic information that has been transmitted remotely from the patient's compatible device to optimize patient care management and

engagement.
- Providing remote settings capabilities for compatible Resmed devices.
- Communicating with digitally connected platforms.

Non-clinical Testing:

Non-clinical testing completed for device software functions under review for Orion demonstrated that the device met all requirements and operates as intended in its defined use environment. Non-clinical testing included:

- System Verification & Validation Testing, Security Verification Testing, and Software Unit & Integration Testing conducted in accordance with Resmed's design control procedures consistent with FDA's guidance "Content of Premarket Submissions for Device Software Functions" (issued June 2023).
- Cybersecurity Testing in alignment with the FDA guidance "Cybersecurity in Medical Devices" (issued February 2026) and Section 524B of the FD&C Act.

Clinical Testing:

Clinical data was not required to support this submission. Orion's regulated functionality is substantially equivalent to predicate devices and does not introduce new clinical risks.

Substantial Equivalence:

The subject device, Orion, has the same intended use and similar technological characteristics as the predicate device, ResScan (K140054). The main differences between Resmed's ResScan software and Orion include:

- Orion is a cloud-based web application rather than a desktop application, allowing secure remote access through the Resmed Digital Health Platform.
- Orion uses secure, encrypted wireless communication instead of serial or removable-media connections used by ResScan.
- Orion supports BZD-classified positive airway pressure (PAP) devices and introduces modern interoperability and integration features for connected care workflows.
- Orion segregates regulated and non-regulated software functions, ensuring that only authorized clinical users can perform validated remote configuration of compatible therapy devices.

- Orion incorporates enhanced cybersecurity controls, including authenticated user access, encrypted data transmission, and digital certificate management.

Verification and validation testing confirmed that Orion performs as intended and that the identified technological differences do not raise new questions of safety or effectiveness. The indications for use, operating principles, and performance characteristics of Orion are therefore substantially equivalent to those of the predicate device.

Characteristic	Subject Device Orion **Manufacturer**: ResMed Corp **510(k) Number: K253553**	Predicate Device ResScan **Manufacturer:** ResMed Ltd **510(k) Number:** K140054	Reference Device AirView **Manufacturer:** ResMed Ltd **510(k) Number:** K151901	Substantial Equivalence
Indications for Use	Orion is a software platform intended to assist healthcare professionals in the management, and treatment of patients who have been diagnosed with sleep-disordered breathing by: • Displaying and analyzing device and therapeutic information that has been transmitted remotely from the patient's compatible device to optimize patient care management and engagement. • Providing remote settings capabilities for compatible Resmed devices • Communicating with digitally connected platforms.	ResScan is intended to augment the standard follow-up care of patients by providing transfer of machine and therapeutic information. This includes the ability to remotely change settings in non-life support devices only. It is intended to be used by Clinicians in conjunction with ResMed compatible therapy devices, using ResMed's proprietary communications protocol.	AirView is a web-based solution for healthcare specialists intended to: • assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded by an AirView compatible home sleep device. • transfer and display machine and therapeutic information that has been transmitted remotely from the patient's therapy device. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device. AirView also provides remote settings capabilities for non-life support devices only.	Same - Both devices display and manage therapy data and allow remote setting changes for compatible PAP devices.

Characteristic	Subject Device Orion **Manufacturer**: ResMed Corp **510(k) Number: K253553**	Predicate Device ResScan **Manufacturer:** ResMed Ltd **510(k) Number:** K140054	Reference Device AirView **Manufacturer:** ResMed Ltd **510(k) Number:** K151901	Substantial Equivalence
Regulation Number	21 CFR §868.5905	21 CFR §868.5905	21 CFR §868.5895	Same
Classification Name	Ventilator, Non-Continuous (Respirator)	Ventilator, Non-Continuous (Respirator)	Ventilator, Continuous, Facility Use	Same
FDA Product Code	Classification: BZD	Classification: BZD Subsequent: CBK, MNS, MNT	Classification: CBK Subsequent: BZD, MNS, MNR	Same - Orion supports the same classification code.
Prescription Use	Yes	Yes	Yes	Same
Intended Environment of Use	Clinical or homecare environment.	Clinical or homecare environment.	Clinical or homecare environment.	Same
Intended User	Clinicians and qualified technical personnel	Clinicians and qualified technical personnel	Clinicians and qualified technical personnel	Same
Functionality	Web Application for therapy data display, reporting, settings management, patient management, patient engagement, and external integration.	PC application for therapy data display, reporting, settings management, and patient management.	Web Application with therapy display, reporting, settings management, patient management, external Integration, diagnostic, and home sleep test reporting.	Similar – Additional patient engagement and integration features do not affect therapy configuration or performance.

Characteristic	**Subject Device** Orion **Manufacturer**: ResMed Corp **510(k) Number: K253553**	**Predicate Device** ResScan **Manufacturer:** ResMed Ltd **510(k) Number:** K140054	**Reference Device** AirView **Manufacturer:** ResMed Ltd **510(k) Number:** K151901	**Substantial Equivalence**
Data Transfer/ Communication Technology and Pathways	Wireless	• Serial Connection • Removable Medium (SD Card) • USB Sticks	• Wireless • SD Card/Internet • File upload/Internet • USB Stick/Internet	Similar – Wireless Data Transfer/Communication is a cleared feature of the reference device.
Therapy Settings Changes	• Pressure • Mode Comfort	• Pressure • Mode • Comfort	• Pressure • Mode • Comfort	Same
Patient Information	• Usage • Event & Sleep Quality Indices • Pressure Metrics • Mask Leak • Oximetry • Therapy & Comfort Settings	• Usage • Event & Sleep Quality Indices • Pressure Metrics • Mask Leak • Oximetry • Therapy & Comfort Settings	• Usage • Event & Sleep Quality Indices • Pressure Metrics • Mask Leak • Oximetry • Therapy & Comfort Settings	Same –.

Characteristic	**Subject Device** Orion **Manufacturer**: ResMed Corp **510(k) Number: K253553**	**Predicate Device** ResScan **Manufacturer:** ResMed Ltd **510(k) Number:** K140054	**Reference Device** AirView **Manufacturer:** ResMed Ltd **510(k) Number:** K151901	**Substantial Equivalence**
Cybersecurity Features	• Authenticated user access • Role-based authorization • Encrypted data transmission • Encrypted data storage	• Authenticated user access • Encrypted data storage	• Authenticated user access • Role-based authorization • Encrypted data transmission • Encrypted data storage	Similar – Cybersecurity features are equivalent to the reference device.

Conclusion:

The subject device, Orion, has the same intended use and similar technological characteristics as the predicate ResScan (K140054). The differences in technological characteristics do not raise new questions of safety or effectiveness. Accordingly, the subject device is substantially equivalent to the predicate device.