5/27/2026

Resmed Corp
Marzia Signoroni
Senior Specialist Regulatory Affairs
9001 Spectrum Center Blvd.
San Diego, California 92123

Re: K254104
Trade/Device Name: ResScan Essentials
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD, MNS, MNT, CBK
Dated: April 27, 2026
Received: April 28, 2026

Dear Marzia Signoroni:

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: 2026.05.27 14:47:10 -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)*
K254104

Device Name
ResScan Essentials

Indications for Use *(Describe)*
ResScan Essentials is intended to augment the standard follow-up care of patients by transferring and analyzing machine and therapeutic information from ResMed compatible therapy devices to the ResScan Essentials application. ResScan Essentials is intended to be used by clinicians.

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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1 510(k) Summary

[As required by 21 CFR 807.921(c)]

Date of Submission:	5th Dec 2025
Company Name/Owner:	ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123, US
Official Contact:	Marzia Signoroni Senior Regulatory Affairs Specialit ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123, US marzia.signoroni@resmed.com.au
Device Trade Name:	ResScan Essentials
Device Common Name:	Ventilator, Non-Continuous (Respirator) (BZD)
Classification, Classification Name	21 CFR 868.5905 (Class II) Non continuous ventilator (IPPB)
Product codes:	BZD, MNS, MNT, CBK

Legally Marketed Predicate Device: ResScan (K140054)

Device Description: ResScan Essentials is an offline desktop application specifically developed to function as a patient data viewer for therapy information collected by compatible ResMed therapy devices. Its primary purpose is to assist clinicians in the analysis of patient therapy data, which can be transferred from supported ResMed devices using SD cards or USB drives. By importing this data into ResScan Essentials, clinicians are able to analyze and manage patient information effectively, supporting the processes of diagnosis and ongoing patient management.

Indication For Use: ResScan Essentials is intended to augment the standard follow-up care of patients by transferring and analyzing machine and therapeutic information from ResMed compatible therapy devices to the ResScan Essentials application. ResScan Essentials is intended to be used by clinicians.

Intended Use Comparison

ResScan Essentials (K254104)	**ResScan (K140054)**	**Substantial Equivalence**
ResScan Essentials is intended to augment the standard follow-up care of patients by transferring and analyzing machine and therapeutic information from ResMed compatible therapy devices to the ResScan Essentials application. ResScan Essentials is intended to be used by clinicians.	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.	Same. Devices are intended to support the standard follow-up care of patients by transferring machines and therapeutic information. Unlike the predicate device, ResScan Essentials is not intended to modify therapeutic settings. This modification eliminates the risks associated with changing the compatible therapy device settings while ensuring that no new concerns regarding safety or effectiveness are introduced.

Technological Characteristics Comparison

Characteristic	**Subject Device:** ResScan Essentials **Manufacturer:** Resmed Corp **510(k) Number:** **K254104**	**Predicate Device:** ResScan **Manufacturer:** Resmed Corp **510(k) Number:** **K140054**	**Substantial Equivalence**
Regulation Number	21 CFR §868.5905	21 CFR §868.5905	Same
Classification Name	Ventilator, Non-Continuous (Respirator) (BZD)	Ventilator, Non-Continuous (Respirator) (BZD)	Same
Compatible flow generators	• BZD • MNS • MNT • CBK	• BZD • MNS • MNT • CBK	Same
Prescription Use	• Yes	• Yes	Same
Functionality	• PC Application • Reports (Compliance and Therapy) • Patient management • Display of therapy and usage data	• PC Application • Display of therapy and usage data • Reports (Compliance and Therapy) • Settings management (non- life support devices only) • Patient management	Similar: Settings management is not available on ResScan Essentials. This modification eliminates the risks associated with changing the compatible therapy device settings while ensuring that no new concerns regarding safety or effectiveness are introduced.
Operating System	Windows 10, 11 Pro, Home, Enterprise	Microsoft Windows XP Service Pack 2 (or later); Microsoft Windows Vista. Microsoft Windows 7, Windows 10	Same: obsoleted Operating Systems (OS) removed, Windows API remains identical in latest OS.

Characteristic	**Subject Device:** ResScan Essentials **Manufacturer:** Resmed Corp **510(k) Number:** **K254104**	**Predicate Device:** ResScan **Manufacturer:** Resmed Corp **510(k) Number:** **K140054**	**Substantial Equivalence**
Data transfer technology	• SD Card • USB Memory Stick	• Serial connection (RS232) • SD Card • USB Stick • Smart Media Card • Smart Card	Similar. Data transfer technology reduced to align with user needs.
Cybersecurity Features	• Authenticated user access • Encrypted data storage	• Authenticated user access	Similar. Subject adds encrypted data storage
Patient information	• Usage: daily hours, sessions, no-use days • Event & Sleep Quality Indices: AHI, AI, RERA, CSR, Flow Limitation Index, Snore Index • Pressure Metrics: Set/Delivered Pressure, IPAP/EPAP, Min/Max, PS, Ramp Start / End Pressure, Pressure Graphs •Mask Leak •Oximetry: SpO_2, Pulse, ODI Therapy & Comfort Settings: Mode, Pressure, Ramp, EPR, Climate Control, Tube Temp, Humidifier, SmartStart/Stop, RR, Vt, MV, I:E Ratio	• Usage: daily hours, sessions, no-use days • Event & Sleep Quality Indices: AHI, AI, RERA, CSR, Flow Limitation Index, Snore Index • Pressure Metrics: Set/Delivered Pressure, IPAP/EPAP, Min/Max, PS, Ramp Start / End Pressure, Pressure Graphs •Mask Leak •Oximetry: SpO_2, Pulse, ODI Therapy & Comfort Settings: Mode, Pressure, Ramp, EPR, Climate Control, Tube Temp, Humidifier, SmartStart/Stop, RR, Vt, MV, I:E Ratio	Same

Non-clinical testing:

Non-clinical verification and validation testing for ResScan Essentials demonstrated that the device met all intended performance requirements. This testing was conducted in accordance with applicable FDA guidance documents, including General Principles of Software Validation; Final Guidance for Industry and FDA Staff (11 January 2002), Content of Premarket Submissions for Device Software Functions (14 June 2023), and Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (27 September 2023).

The verification testing performed with ResScan Essentials was software verification and validation against the non-functional requirements and end-to-end functional testing.

Clinical Testing

Clinical tests were not required to demonstrate safety and effectiveness of ResScan Essentials.

Substantial Equivalence

The subject device and predicate devices have similar intended use, technological characteristics, and operating principles.

Similar technological characteristics include:

- Both the subject and predicate devices are software that are intended to provide transfer of machine and therapeutic information from compatible ResMed PAP therapy devices.

The technological differences between the predicate device and subject device are:

- The subject device is unable to modify therapy settings on a compatible ResMed PAP therapy device.

Substantial Equivalence Conclusion:

ResScan Essentials is substantially equivalent to the predicate ResScan K140054 because:

- It has similar intended use
- It has similar technological characteristics
- It has similar operating principles
- The differences do not raise any new questions of safety or effectiveness
- It is at least as safe and as effective as the predicate device