April 8, 2026

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

Re: K251889
Trade/Device Name: myAir
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS, BZD, MNR
Dated: December 2, 2025
Received: December 3, 2025

Dear Rose Malonzo:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory and Sleep Devices
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Office of Product Evaluation and Quality
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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)*
K251889

Device Name
myAir

Indications for Use *(Describe)*
The myAir app is indicated for patients:
• prescribed with a compatible ResMed Air11 PAP or NIV device to simulate therapy prior to using their device with their prescribed settings.
• prescribed with a compatible ResMed Air11 PAP device to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate and operate their therapy device.
• prescribed a NightOwl wearable device to provide the user interface to operate the connected device and aid in the home sleep testing process.

The device is intended for home and hospital use for:
• new and existing patients of ResMed Air10 and Air11 PAP and NIV therapy devices and
• new users who are prescribed a compatible NightOwl home sleep apnea test (HSAT).

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(c)]

Date of Submission:	13 March 2026
Company Name/Sponsor:	ResMed Corp 9001 Spectrum Center Blvd San Diego, CA 92123 USA
Official Contact:	Mrs. Rose Malonzo Senior Specialist, Global Product Regulatory Affairs ResMed Corp 9001 Spectrum Center Blvd San Diego, CA 92123 USA Tel: 858-285-5670 rose.malonzo@resmed.com
Name of Device:	myAir
Device Common Name and regulation:	Ventilator, continuous, non-life-supporting 21 CFR 868.5895
Classification and Classification Name:	II Continuous ventilator
Classification Product Code:	MNS
Subsequent Product Codes:	BZD MNR
Predicate Device:	EasyCare Online K132371
Reference Device:	myAir K250624
Submission Reason:	Device modification

Device Description

myAir is a companion mobile medical application ("app") that serves as a patient self-monitoring, therapy usage tracking, and engagement platform for patients prescribed with compatible ResMed therapy devices and the NightOwl home sleep apnea test (HSAT) sensors. The app allows the patient to connect via Bluetooth to a compatible hardware device for control of their prescribed device and to allow self-tracking of device usage data. myAir can also be used as a communication pathway using the Bluetooth connection with the compatible device in order to send or receive data. myAir includes device software functions related to controlling the device (i.e., starting and stopping HSAT test or therapy session), and control of comfort settings (collectively referred to as "device control"). Analysis of HSAT patient diagnostic data or display of diagnostic results are not in scope of myAir features.

myAir functions as a multiple function device software product, as it contains 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 functions subject to FDA oversight. Non-device "other" functions in myAir include educational content, coaching tools, general wellness features, and self-tracking usage data. These "other" functions are segregated from device software functions and do not perform medical device functions.

myAir is compatible with both iOS and Android mobile platforms. However, the device functions under review within this submission, including interoperability with Mariana devices (as cleared in K251661), is currently supported only on the iOS platform. Android users may download and use myAir for supported PAP and HST workflows; however, Mariana-specific features are not available on Android at this time.

The myAir subject device for this premarket submission is a device modification to the legally marketed myAir product by adding interoperability with ResMed non-invasive ventilator therapy devices (K251661 Mariana devices). The subject device also sustains the previously cleared medical device functions in myAir (K200565, K241216, and K250624).

Indications for Use

The myAir app is indicated for patients:

- prescribed with a compatible ResMed Air11 PAP or NIV device to simulate therapy prior to using their device with their prescribed settings.
- prescribed with a compatible ResMed Air11 PAP device to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate and operate their therapy device.
- prescribed a NightOwl wearable device to provide the user interface to operate the connected device and aid in the home sleep testing process.

The device is intended for home and hospital use for:

- new and existing patients of ResMed Air10 and Air11 PAP and NIV therapy devices and
- new users who are prescribed a compatible NightOwl home sleep apnea test (HSAT).

Non-clinical testing

ResMed conducted the necessary non-clinical testing on the subject device. Results determined that the subject device met all acceptance criteria and passed testing requirements, thus supporting determination of substantial equivalence. There are no hazards or critical tasks identified with myAir which are reasonably likely to cause injury, harm, or damage to the health of patients. Therefore, usability and human factors testing are not required for premarket review of the subject device. Non-clinical testing included:

- Software verification and validation – myAir was determined to require a Basic Documentation level, therefore V&V was conducted in accordance with ResMed's QMS processes for design

and development and aligns with FDA's guidance "Content of Premarket Submissions for Device Software Functions" (issued June 2023).

- Cybersecurity – ResMed's approach to cybersecurity aligns with the FDA guidance "Cybersecurity in Medical Devices" (issued March 2024) and Section 524B of the FD&C Act.

Clinical testing

Clinical tests were not required to demonstrate the safety and effectiveness of the device software functions under review within the myAir subject device.

Substantial Equivalence

The subject device myAir has the same intended use, and similar technological characteristics and operating principle as the predicate device. Specifically, both devices are software medical devices intended to support the management of sleep-disordered breathing and respiratory impairment through the transfer, display, and use of data from compatible ResMed therapy and diagnostic devices to supplement patient care. While there are technological differences between the subject and predicate devices, these differences relate to implementation and workflow, not intended use. Any identified differences in the technological characteristics have been reviewed and determined to not raise different questions of safety and effectiveness with the subject device. Therefore, the subject device myAir is substantially equivalent to the predicate device.

Characteristic	**Predicate Device:** EasyCare Online **Manufacturer:** ResMed Corp **510(k) Number:** K132371	**Subject device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K251889	**Comparison / Remarks**
Indications for Use	EasyCare Online 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 EasyCare Online compatible home sleep test device. • Transfer and display, usage and therapeutic information that has been transmitted remotely from the patient's therapy device located in the home. It is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed therapy device for the treatment of obstructive sleep apnea or respiratory insufficiency. EasyCare Online also provides remote settings capabilities.	The myAir app is indicated for patients: • prescribed with a compatible ResMed Air11 PAP or NIV device to simulate therapy prior to using their device with their prescribed settings • prescribed with a compatible ResMed Air11 PAP device to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate and operate their therapy device. • prescribed a NightOwl wearable device to provide the user interface to operate the connected device and aid in the home sleep testing process. The device is intended for home and hospital use for: • new and existing patients of ResMed Air10 and Air11 PAP and NIV therapy devices and • new users who are prescribed a compatible NightOwl home sleep apnea test (HSAT).	The devices share the same general intended use at the level required per FDA's substantial equivalence framework. Specifically, both devices are software medical devices intended to support the management of sleep-disordered breathing and respiratory impairment through the transfer, display, and use of data from compatible ResMed therapy and diagnostic devices to supplement patient care.
Intended End User Population	For use by healthcare specialists with patients prescribed a compatible ResMed therapy device.	For use by patients prescribed a compatible ResMed therapy device.	Although the primary end users differ, the underlying clinical purpose remains the same - supporting therapy and management of sleep-disordered breathing and respiratory impairment using compatible ResMed therapy devices. Additionally, D22212-004 myAir Risk Management File includes risks associated with the intended patient populations of the compatible hardware devices (i.e., NIV therapy devices), and therapy delivery and safety safeguards remain governed by the hardware device. The difference in the intended end user population does not raise new questions of safety or efficacy for the subject device.
Intended Environment of Use	Clinical and home	Clinical and home	Identical
Classification	Class II	Class II	Identical
Regulation Number	21 CFR §868.5895	21 CFR §868.5895	Identical
Classification Name	Ventilator, continuous, non-life supporting	Ventilator, continuous, non-life supporting	Identical

Characteristic	**Predicate Device:** EasyCare Online **Manufacturer:** ResMed Corp **510(k) Number:** K132371	**Subject device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K251889	**Comparison / Remarks**
FDA Product Code	Primary product code: MNS Subsequent product codes: MNR	Classification product code: MNS Subsequent product codes: BZD MNR	Similar. The subject device is adding classification product code to support compatibility with NIV therapy devices. The differences in subsequent product codes does not change the general clinical purpose of the subject device, and therefore, does not raise new questions of safety or efficacy for the subject device.
Prescription Use	Yes	Yes	Identical
Patient Contacting	No, EasyCare Online is software.	No, myAir is software.	Identical
Device Compatibility	ResMed non-invasive ventilator devices (MNS) ResMed Air10 platform devices (BZD)	ResMed non-invasive ventilator devices (MNS) ResMed Air 10 and Air11 PAP devices (BZD) EctoSense NightOwl HST (MNR)	Similar. The underlying clinical purpose with the compatible devices remains the same - supporting therapy and management of sleep-disordered breathing and respiratory impairment using compatible ResMed therapy devices. The difference in the device compatibility does not raise new questions of safety or efficacy for the subject device.
Patient Population of Compatible Device	Patients diagnosed with obstructive sleep apnea or respiratory insufficiency	Patients diagnosed with obstructive sleep apnea or respiratory impairment	Similar. Patients with respiratory impairment represent a population with preserved or partially compensated gas exchange. This is in contrast to more advanced states of respiratory compromise, such as respiratory insufficiency or require life support ventilation. Thus, the difference in the patient population has no impact on patient risk (other than lowering it), and does not raise new questions of safety or efficacy with the subject device.
Device Software Functions	• Support standard follow-up care of patients for the treatment of obstructive sleep apnea or respiratory insufficiency • Remote settings capabilities • Assist in the diagnosis of sleep disordered breathing	• Test drive predetermined, scaled inspiratory pressures prior to using prescribed therapy. Patients prescribed a ResMed NIV platform device may also test drive predetermined, scaled expiratory pressures. • Device controls (start/stop therapy and modify comfort settings) • Start/stop NightOwl HST session	Similar. The differences in device software functions fall within the same general intended use and do not change the device's overall purpose or disease state addressed. The underlying clinical purpose remains the same - supporting therapy and management of sleep-disordered breathing and respiratory impairment using compatible ResMed therapy devices. Therefore, these differences do not raise new questions of safety or efficacy for the subject device.
Device Connection Requirement	EasyCare Online connects with the compatible hardware device via cloud infrastructure to perform interoperability functions as intended.	myAir connects with the compatible hardware device via Bluetooth to perform interoperability functions as intended.	Similar. The difference in the device connectivity relate to implementation and workflow. This does not raise new questions of safety or efficacy for the subject device.
Communication Pathways Available	Wireless communication module or with an SD card.	Bluetooth and HTTPS (cellular or wireless internet connection)	Similar. The differences in communication pathways relate to implementation and workflow. The underlying clinical purpose remains the same - supporting therapy and management of sleep-disordered breathing and respiratory impairment using compatible ResMed therapy devices. This does not raise new questions of safety or efficacy for the subject device. Furthermore, all non-clinical performance bench testing required for the subject device support the intended use of the product, and device safety and effectiveness.

Characteristic	**Predicate Device:** EasyCare Online **Manufacturer:** ResMed Corp **510(k) Number:** K132371	**Subject device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K251889	**Comparison / Remarks**
Display Type	Webpage display	Smartphone display	Similar. The difference in the display type relates to implementation and workflow as related to the intended end-user population. The underlying clinical purpose remains the same - supporting therapy and management of sleep-disordered breathing and respiratory impairment using compatible ResMed therapy devices. Therefore, this does not raise new questions of safety or efficacy for the subject device.

Conclusion

The subject device is substantially equivalent to the predicate because:

- They have the same intended use;
- They have similar technological characteristics;
- They have similar operating principles;
- The differences do not raise any new questions of safety or effectiveness; and
- Testing used to address the differences show that it is at least as safe and as effective as the predicate device.