May 28, 2025

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

Re: K250624
Trade/Device Name: myAir
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: February 28, 2025
Received: March 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 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
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)*
K250624

Device Name
myAir

Indications for Use *(Describe)*
The myAir app is indicated for patients:
• prescribed with a compatible ResMed Air11 platform device to simulate therapy prior to using their device with their prescribed settings, and to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate to 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 therapy devices and
• new users who are prescribed a compatible NightOwl home sleep test (HST).

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.

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date of Submission:	28 February 2025
Company Name/Owner:	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
Device Trade Name:	myAir
Device Common Name:	Ventilator, Non-Continuous (Respirator)
Classification and Classification Name:	II Noncontinuous ventilator (IPPB)
Product Code:	BZD MNR (secondary)
Predicate Device:	myAir K241216
Submission Reason:	Modified device

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 PAP therapy devices and the NightOwl home sleep test (HST) sensors. The app allows the patient to connect via Bluetooth to a compatible hardware device for control of their prescribed PAP or HST 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. Analysis of patient diagnostic data or display of diagnostic results are not in scope of myAir features.

The myAir subject device for this premarket submission adds device software functions related to starting and stopping therapy, and control of comfort settings (collectively referred to as "device control"). The addition of these device software functions within the myAir subject device is a modification to the K241216 myAir predicate device, in addition to sustaining previously cleared medical device functions.

Indications for Use

The myAir app is indicated for patients:

- prescribed with a compatible ResMed Air11 platform device to simulate therapy prior to using their device with their prescribed settings, and to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate to 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 therapy devices and
- new users who are prescribed a compatible NightOwl home sleep test (HST).

Non-clinical testing

Non-clinical verification and validation testing completed for device software functions under review introduced with the modifications to the myAir app demonstrated that the device met all intended performance requirements. Testing included:

- Software verification and validation, including non-functional requirements and end-to-end functional testing.

The following FDA guidance were conformed to:

- Content of Premarket Submissions for Device Software Functions: June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: September 2023

Substantial Equivalence

The subject device and predicate device have a similar intended use, and similar technological characteristics and operating principle.

The predicate for this premarket submission is myAir (K241216) as this predicate has a similar intended use and technological characteristics to the subject device myAir. Similar technological characteristics include:

- Bluetooth connectivity and communication
- Executing Test Drive workflow (device function cleared under K200656)
- Executing HST workflow (device function cleared under K241216)

The technological difference between the predicate and subject device is:

- The subject device adds device control functions (device functions under review)

Characteristic	**Predicate Device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Subject Device:** myAir with device control functions **Manufacturer:** ResMed Corp **510(k) Number:** K250624	**Substantial Equivalence**
Indications for Use	The myAir app is indicated for patients: • prescribed with a compatible ResMed Air11 platform device to simulate therapy prior to using their device with their prescribed settings. It is an optional software accessory to allow patients to acclimate to 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 therapy devices and • new users who are prescribed a compatible NightOwl home sleep test (HST).	The myAir app is indicated for patients: • prescribed with a compatible ResMed Air11 platform device to simulate therapy prior to using their device with their prescribed settings and to configure their settings to support therapy. It is an optional software accessory to allow patients to acclimate to 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 therapy devices and • new users who are prescribed a compatible NightOwl home sleep test (HST).	The proposed myAir indications for use adds language to support device control functions. This device modification uses the same technological characteristics to execute the added device software functions. The difference in the indications for use does not raise new questions of safety or efficacy for the subject device.
Regulation Number	21 CFR §868.5905	21 CFR §868.5905	Identical

Characteristic	**Predicate Device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Subject Device:** myAir with device control functions **Manufacturer:** ResMed Corp **510(k) Number:** K250624	**Substantial Equivalence**
Classification Name	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	Identical
FDA Product Code	BZD	BZD	Identical
Prescription Use	Yes	Yes	Identical
Patient Population	Patients weighing more than 66 lb (30kg)	Patients weighing more than 66 lb (30kg)	Identical
Intended Environment of Use	Home	Home	Identical
Patient Contacting	No, myAir is software.	No, myAir is software.	Identical
Display Type	Smartphone display	Smartphone display	Identical
Device Interoperability and V&V	ResMed Air11 platform devices and NightOwl HST	ResMed Air11 platform devices and NightOwl HST	Identical, however device software functions related to NightOwl HST are not impacted by this modification and are therefore not in scope for this premarket notification.
Device Connection Requirement	Yes. myAir app must be connected to a compatible AS11 or HST device to operate device functions as intended.	Yes. myAir app must be connected to a compatible AS11 or HST device to operate device functions as intended.	Identical, however device software functions related to NightOwl HST are not impacted by this modification and are therefore not in scope for this premarket notification.

Characteristic	**Predicate Device:** myAir **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Subject Device:** myAir with device control functions **Manufacturer:** ResMed Corp **510(k) Number:** K250624	**Substantial Equivalence**
Device Control	Yes. myAir can control the connected therapy or HST device.	Yes. myAir can control the connected therapy or HST device.	Identical
Communication Pathways Available	Bluetooth and HTTPS (cellular or wireless internet connection)	Bluetooth and HTTPS (cellular or wireless internet connection)	Identical
Device data to app communication pathway	Pathways: 1) Device data transfers to Machine Cloud Service (MCS) then to Galapagos. 2) Therapy device data transferred from device to app to MCS. 3) HST device data transfers from sensor through the myAir app to EctoSense backend server for analysis.	Pathways: 1) Device data transfers to Machine Cloud Service (MCS) then to Galapagos. 2) Therapy device data transferred from device to app to MCS. 3) HST device data transfers from sensor through the myAir app to EctoSense backend server for analysis.	Identical
App Store Availability	Google Play Store	Apple App Store	Difference in mobile app store availability does not raise new questions of safety or efficacy for the subject device.
Therapy Settings Changes	None	None	Identical
Adjust Comfort Settings	None	Yes. The subject device myAir can adjust comfort settings on the connected AS11 therapy device.	Difference in functionality does not raise new questions of safety or efficacy for the subject device.
Software Level of Documentation	Basic	Basic	Identical

Substantial Equivalence Conclusion

The subject device is substantially equivalent to the predicate K241216 because:

- They have similar intended use;
- They have similar technological characteristics;
- They have similar performance characteristics;
- The differences do not raise any new questions of safety or effectiveness; and
- It is as safe and effective as the predicate device.