September 26, 2024

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

Re: K241216
Trade/Device Name: myAir
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 28, 2024
Received: August 28, 2024

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)*
K241216

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. 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).

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.

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date of Submission:	25 September 2024
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) [primary]
Classification and Classification Name:	II Noncontinuous ventilator (IPPB) [primary]
Product Code:	BZD
Primary Predicate Device:	Galapagos K200565
Reference Device:	NightOwl Companion App (patient mobile application in the NightOwl System) K220028
Submission Reason:	Modified device

Device Description

myAir is a companion mobile medical application ("app") for self-monitoring use of the compatible devices that serve as a patient Home Sleep Test (HST), pre-therapy, and engagement platform for positive airway pressure (PAP) therapy. The app allows the patient to connect via Bluetooth to a compatible hardware device for temporary control of their prescribed HST or PAP 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 subject device modifies the predicate device by adding interoperability with the NightOwl HST (Stella functions) in addition to sustaining previously cleared medical device function of connecting to the Air11 platform.

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).

Non-clinical testing

Non-clinical verification and validation testing completed for NightOwl HST interoperable (Stella) functions 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 the same intended use, and similar technological characteristics and operating principle.

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

- The subject device adds interoperability with the NightOwl HST, allowing myAir to control the hardware HST (on/off) and facilitate data transfer during the home sleep testing process (i.e., non-device MDDS function) to the EctoSense NightOwl backend server for analysis.
- The subject device sustains the previously cleared medical device function of connecting to the Air11 platform device to allow the subject device app to control (on/off the hardware and to facilitate transfer of data (i.e., non-device MDDS function) between the hardware and cloud backend server.

Characteristic	**Primary Predicate Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Reference Device:** NightOwl Companion App (patient mobile application in the NightOwl System) **Manufacturer**: EctoSense **510(k) Number:** K220028	**Subject Device:** myAir with Stella functions **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Substantial Equivalence**
Indications for Use	The Galapagos app is intended for patients who are prescribed a compatible ResMed S10 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.	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).	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	The proposed myAir indications for use adding Stella functions (i.e., compatibility with NightOwl HST sensor) with this premarket submission is similar to the predicate device in that the subject device mobile app has software device functions which are considered medical functions associated with Bluetooth connection intended for limited device control and non-device-MDDS data transfer. The difference in the indications for use does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use.

Characteristic	**Primary Predicate Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Reference Device:** NightOwl Companion App (patient mobile application in the NightOwl System) **Manufacturer**: EctoSense **510(k) Number:** K220028	**Subject Device:** myAir with Stella functions **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Substantial Equivalence**
			• new users who are prescribed a compatible NightOwl home sleep test (HST).	
Regulation Number	21 CFR §868.5905	21 CFR §868.2375	Primary: 21 CFR §868.5905	Similar. The modification to add device compatibility does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use.
Classification Name	Noncontinuous ventilator (IPPB)	Ventilatory effort recorder	Primary: Noncontinuous ventilator (IPPB)	Similar. The subject device adds device compatibility with the cleared NightOwl device (K220028). Data analysis, processing, and results are out of scope from the subject device functions.
FDA Product Code	BZD	MNR	BZD	Similar. The subject device adds compatibility with cleared NightOwl device (K220028).
Prescription Use	Yes	Yes	Yes	Identical

Characteristic	**Primary Predicate Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Reference Device:** NightOwl Companion App (patient mobile application in the NightOwl System) **Manufacturer**: EctoSense **510(k) Number:** K220028	**Subject Device:** myAir with Stella functions **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Substantial Equivalence**
Patient Population	Patients weighing more than 66 lb (30kg)	22 years old and older	Patients weighing more than 66 lb (30kg)	Identical. The difference in patient population for the reference device does not raise new questions of safety or effectiveness for the subject device. Patients are unable to use myAir as intended without connecting to the intended compatible device. Due to the intended compatibility of myAir with the Air11 or NightOwl devices, the same patient population and user environment for the respective compatible hardware devices inherently applies to the subject myAir device.
Intended Environment of Use	Home	Clinical and home	Home	Identical
Patient Contacting	No, Galapagos is software.	No, NightOwl Companion App is software.	No, myAir is software.	Identical
Display Type	Smartphone display	Smartphone display	Smartphone display	Identical
Device Interoperability and V&V	ResMed Air11 platform devices	NightOwl HST	ResMed Air11 platform devices and EctoSense NightOwl HST	The modification for additional compatibility with the cleared NightOwl Companion App (patient mobile app within the NightOwl System, K220028) does not raise new questions of safety or effectiveness. Furthermore, all non-clinical performance bench testing required for the subject device myAir with Stella functions support the intended design of the product, and device safety and effectiveness.

Characteristic	**Primary Predicate Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Reference Device:** NightOwl Companion App (patient mobile application in the NightOwl System) **Manufacturer**: EctoSense **510(k) Number:** K220028	**Subject Device:** myAir with Stella functions **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Substantial Equivalence**
Device Connection Requirement	Yes. Galapagos app must be connected to a compatible therapy device for usage.	Yes. NightOwl Companion App must be connected to a compatible HST device for usage.	Yes. myAir app must be connected to a compatible HST to operate Stella functions as intended.	Difference in functionality does not raise new questions of safety or effectiveness.
Device Control	Yes. Galapagos can control the connected therapy device.	No. NightOwl Companion App does not allow control of the connected therapy device.	Yes. myAir can control the connected therapy or HST device.	Difference in functionality from the NightOwl companion app does not raise new questions of safety or effectiveness.
Communication Pathways Available	Bluetooth and HTTPS (cellular or wireless internet connection)	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. Therapy device data transferred from device to app to MCS.	Pathways: HST device data transfers from sensor through the NightOwl Companion App to the EctoSense backend server for analysis.	Pathways: 1) Device data transfers to Machine Cloud Service (MCS) then to Galapagos. Therapy device data transferred from device to app to MCS.	Differences in types of data transferred and communication pathways available does not raise new questions of safety or effectiveness. Software functions related to data analysis and display of diagnostic results are out of scope of the subject device myAir app as these medical device software functions are within the NightOwl Backend Server and

Characteristic	**Primary Predicate Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Reference Device:** NightOwl Companion App (patient mobile application in the NightOwl System) **Manufacturer**: EctoSense **510(k) Number:** K220028	**Subject Device:** myAir with Stella functions **Manufacturer:** ResMed Corp **510(k) Number:** K241216	**Substantial Equivalence**
			3) HST device data transfers from sensor through the myAir app to EctoSense backend server for analysis.	HCP Dashboard components of the NightOwl System (K220028).
App Store Availability	Google Play Store	Google Play Store and Apple App 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. The Galapagos app does not have capabilities of altering therapy settings.	Not applicable	None	Identical
Adjust Comfort Settings	None. The Galapagos app does not have capabilities of adjusting comfort settings.	Not applicable	None	Identical
Software Level of Documentation	Moderate	Moderate	Basic	Similar. The differences in level of software documentation are determined in accordance with the FDA guidance “Content of Premarket Submissions for Device Software Functions”. The subject device follows FDA’s risk-based approach for basic vs. enhanced (2023), while the predicate devices followed FDA’s Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005.

Substantial Equivalence Conclusion

The subject device is substantially equivalent to the predicate K200656 because:

- They have the same 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 devices.