December 5, 2025

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

Re: K251657
Trade/Device Name: Personalized Therapy Comfort Settings (PTCS)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: November 4, 2025
Received: November 5, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2025.12.05 13:56:33 -05'00'

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)*
K251657

Device Name
Personalized Therapy Comfort Settings (PTCS)

Indications for Use *(Describe)*
Personalized Therapy Comfort Settings ("PTCS") is an optional software accessory indicated for use by healthcare professionals and patients, providing recommended non-prescription comfort settings options to support patients when using their compatible Resmed PAP therapy device. The outputs provided by PTCS are optional recommendations and are not required to use the therapy device. It is intended for use in a home or clinical environment.

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: 5 November 2025

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
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San Diego, CA 92123 USA
Tel: 858-285-5670
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Name of Device: Personalized Therapy Comfort Settings (PTCS)

Device Common Name: Ventilator, Non-Continuous (Respirator)

Classification and Classification Name:
II
Noncontinuous ventilator (IPPB)

Product Code: BZD

Predicate Device:
myAir
K250624

Submission Reason: New device

Device Description

The subject device, Personalized Therapy Comfort Settings (PTCS), is an AI-enabled software accessory intended for use with compatible ResMed positive airway pressure (PAP) therapy devices. PTCS provides optional, non-prescription comfort setting (e.g., ramp, EPR and AutoSet Response) recommendations within the cleared configuration limits of the connected device. It is designed to support patients in personalizing comfort settings during onboarding and early therapy adaptation.

PTCS functions as a stand-alone, machine learning (ML)-based algorithm that generates individualized comfort setting recommendations based on patient-specific input data. The software outputs a limited set of predefined configuration options that can be reviewed by the patient or healthcare provider. PTCS does not automatically adjust device settings, modify prescribed therapy parameters, create new settings, or alter configuration limits. The recommendations are optional and may be accepted, disregarded, or further adjusted according to personal preference or clinical guidance. PTCS is integrated into compatible ResMed products through an application programming interface (API) and has no direct user interface or end-user access.

Indications for Use

Personalized Therapy Comfort Settings (“PTCS”) is an optional software accessory indicated for use by healthcare professionals and patients, providing recommended non-prescription comfort settings options to support patients when using their compatible Resmed PAP therapy device. The outputs provided by PTCS are optional recommendations and are not required to use the therapy device. It is intended for use in a home or clinical environment.

Non-clinical testing

ResMed conducted the necessary non-clinical testing on PTCS. Results determined that PTCS met all acceptance criteria and passed testing requirements, thus supporting determination of substantial equivalence. There are no hazards or critical tasks identified with PTCS 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 PTCS performance validation activities. Non-clinical testing conducted on PTCS included the following:

- Software verification and validation – PTCS 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).
- Model performance validation - Model performance validation was conducted to ensure the AI algorithm performs reliably, safely, and effectively for its intended use, in alignment with FDA’s draft guidance, “AI-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations” (issued January 2025) and ResMed’s product development processes for software and AIML.
- 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 testing was not required because model performance was comprehensively characterized using retrospective, de-identified clinical data representative of the intended population. This is consistent with FDA’s Guidance for the “Content of Premarket Submissions for Software Contained in Medical Devices” and “Good Machine Learning Practice for Medical Device Development: Guiding Principles”. Analytical validation demonstrated robust sensitivity, specificity, and generalizability, thereby establishing safety and effectiveness without prospective clinical study.

Retrospective analyses demonstrated that the PTCS model performs as safe and as effective as the predicate device by generating optional, non-prescription comfort setting recommendations that support patient usage with their PAP therapy device without altering prescribed therapeutic pressures. Analytical validation confirmed consistent and reliable model performance across large, representative datasets, with consistent treatment-effect results and no identified safety concerns. Retrospective comparisons of PTCS recommended settings to default configurations showed measurable improvements in patient therapy engagement, including increased nightly usage and additional usage days, while maintaining comparable residual AHI and mask leak. These data indicate that selecting from existing comfort settings, including those PTCS may recommend, is safe, effective, and consistent with real-world clinical practice. Usability evaluations with both clinical and non-clinical users confirmed clear comprehension of PTCS recommendations, appropriate application of judgment, and no critical tasks or use-related risks. Collectively, these findings demonstrate that PTCS provides reliable, user-comprehensible decision support that enhances comfort-setting selection without impacting therapy delivery or patient safety.

Substantial Equivalence

The primary predicate, myAir (K250624), is a software platform cleared under product code BZD that enables device connectivity with the compatible ResMed PAP devices via Bluetooth to configure non-therapeutic comfort settings, start and stop therapy, and provide supplemental therapy support.

The predicate and subject devices share a similar intended use and operate within equivalent ResMed PAP therapy device systems. The subject device differs from the predicate only in that it uses a machine-learning algorithm to recommend alternative default non-therapeutic comfort-setting options based on patient information. The recommended settings options and allowable ranges are unchanged from the predicate device, and no new operating modes are introduced. Differences are limited to software-based logic that provides optional, non-prescription recommendations for comfort settings, without altering delivered therapy or automatically changing device settings. Therefore, the AIML implementation does not raise different questions of safety or effectiveness relative to the predicate.

Table 1: Substantial Equivalence Table (Subject and Predicate Device Comparison)

Characteristic	**Primary Predicate Device** myAir **Manufacturer** ResMed Corp **510(k) Number** K250624	**Subject device** Personalized Therapy Comfort Settings (PTCS) **Manufacturer** ResMed Corp **510(k) Number** K251657	**Substantial Equivalence Justification**
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).	Personalized Therapy Comfort Settings (“PTCS”) is an optional software accessory indicated for use by healthcare professionals and patients, providing recommended non-prescription comfort settings options to support patients when using their compatible Resmed PAP therapy device. The outputs provided by PTCS are optional recommendations and are not required to use the therapy device. It is intended for use in a home or clinical environment.	The differences between the indications for use statements do not create a new intended use for the subject device when compared to the primary predicate device. Both devices serve as optional software accessories intended to support patients prescribed PAP therapy by facilitating comfort and engagement during device use. While the predicate (myAir) enables users to modify comfort settings directly, the subject device (PTCS) provides non-therapeutic comfort setting recommendations for the same therapy devices. The difference in the indications for use statements does not raise new questions of safety or efficacy for the subject device.
Intended Use	The myAir mobile application is a companion software accessory that connects via Bluetooth to compatible ResMed PAP and NightOwl HST devices, enabling patients to self-track therapy usage and control device functions such as starting/stopping therapy and adjusting comfort settings. It does not perform diagnostic analysis or display diagnostic results.	PTCS is an optional software accessory intended to support patients prescribed PAP therapy by providing non-therapeutic comfort setting recommendations (e.g., ramp, EPR, and AutoSet Response) for compatible ResMed PAP devices. PTCS does not deliver or control therapy and serves only to provide supplemental support for patients and clinicians during device use.	Similar. Both devices serve as optional software accessories intended to support patients prescribed PAP therapy by facilitating comfort and engagement during device use. While the predicate (myAir) enables users to modify comfort settings directly, the subject device (PTCS) provides non-therapeutic comfort setting recommendations for the same therapy devices. The functional difference (e.g., recommendation versus direct control) does not alter the intended use or raise new questions of safety or effectiveness.
Intended Population	Patients prescribed a compatible ResMed PAP therapy device or NightOwl HST.	Patients prescribed a compatible ResMed PAP therapy device.	Similar
Classification	Class II	Class II	Identical
Regulation Number	21 CFR §868.5905	21 CFR §868.5905	Identical

Characteristic	**Primary Predicate Device** myAir **Manufacturer** ResMed Corp **510(k) Number** K250624	**Subject device** Personalized Therapy Comfort Settings (PTCS) **Manufacturer** ResMed Corp **510(k) Number** K251657	**Substantial Equivalence Justification**
Classification Name	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	Identical
FDA Product Code	BZD	BZD	Identical
Prescription Use	Yes	Yes	Identical
Intended Environment of Use	Clinical and home	Clinical and home	Identical
Patient Contacting	No, myAir is software.	No, PTCS is software.	Identical
Interface Display Type	Smartphone display	No user interface	Difference in display type does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use. Furthermore, the lack of display type for the subject device does not impact the intended use of the subject device because the subject device is a standalone algorithm which may be integrated with a ResMed software product which may have a web or mobile application interface.
Device Compatibility	ResMed Air 10 and Air11 platform devices and EctoSense NightOwl HST	ResMed Air 10 and Air11 platform devices. PTCS does not have capabilities of interoperability with the NightOwl HST.	Similar. Difference in interoperability does not raise new questions of safety or efficacy for the subject device as the compatible ResMed therapy devices are substantially equivalent in and of themselves. PTCS provides comfort-setting recommendations for the same compatible devices without altering therapy delivery. This difference does not raise new questions of safety or effectiveness.
Device Connection Requirement	Yes. myAir app must be connected to a compatible HST to operate Stella functions as intended.	No, PTCS does not require direct connection to a compatible Resmed device to operate as intended.	Difference in functionality does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use.
Device Control	Yes. myAir can control the connected therapy or HST device.	No. PTCS does not have capabilities of controlling a compatible therapy device.	Difference in functionality does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use.
Comfort Settings Supported	• AutoSet Response • Ramp • Pressure relief (expiratory pressure relief or “EPR”) • EPR level • Start pressure • Climate control • Tube temperature • Humidity level • Smart start/stop	• AutoSet Response • Ramp • EPR (expiratory pressure relief) and level	PTCS recommends a subset of established comfort parameters (ramp, EPR, AutoSet Response) already available in the predicate device. The difference is limited to providing recommendations rather than direct control and does not introduce new comfort features or safety concerns.
Communication Pathways Available	Bluetooth and HTTPS (cellular or wireless internet connection)	HTTPS and API	Similar. Difference in communication pathways does not raise new questions of safety or efficacy for the subject device. Furthermore,

Characteristic	**Primary Predicate Device** myAir **Manufacturer** ResMed Corp **510(k) Number** K250624	**Subject device** Personalized Therapy Comfort Settings (PTCS) **Manufacturer** ResMed Corp **510(k) Number** K251657	**Substantial Equivalence Justification**
			performance testing required for the subject device support the intended design of the product, and device safety and effectiveness.
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.	None. PTCS does not have capabilities of transferring device data between a therapy device and app.	Difference in functionality does not raise new questions of safety or efficacy for the subject device as the devices have the same intended use.
App Store Availability	Apple App Store	None	Difference in mobile app store availability does not raise new questions of safety or efficacy for the subject device.

Predetermined Change Control Plan

This premarket submission contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, enacted on December 29, 2022. The PCCP does not include provision for implementation of adaptive algorithms that continuously learn a production environment. All algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. A procedure has also been established for updating the electronic user guide(s) to inform users about modifications to the algorithm changes enabled under this FDA-authorized PCCP, including a summary of changes, characterization of algorithm performance, and availability and compatibility of the function. ResMed will publish updated electronic user guide documentation on its company website and make them accessible within the product for end users.

The PCCP specifies possible device modifications to the subject device as well as design control activities to implement the changes in a controlled manner such that the device remains safe and effective with the changes as the authorized subject device and predicate device. The PCCP includes a list of planned scope of modifications. The PCCP includes impact assessment considerations, specific requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data processing practices. Specific test methods are specified in the PCCP to establish substantial equivalence relative to the PTCS subject device and include analysis methods and acceptance criteria. Details of the proposed changes are summarized in Table 2 below.

Table 2: Proposed Modifications to PTCS under the PCCP

Modification Description	Testing Methods	PCCP Rationale
Performance or data drift updates	Comparison against baseline performance. Performance for the modification will be evaluated against predefined metrics, which must pass verification and validation.	Data attributes remain unchanged. Maintain and improve the model performance and device effectiveness in production.
Infrastructure updates		Data attributes remain unchanged. To maintain or improve the operational performance of the ML service.

Conclusion

The subject device is substantially equivalent to the predicate K250624 because:

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