August 27, 2026

Resmed Corp
% Lawrence Kwan
Specialist, Regulatory Product Strategy & Delivery - San Diego
Resmed Pty , Ltd.
1 Elizabeth Macarthur Dr.
Bella Vista, NSW 2153
Australia

Re: K261360
Trade/Device Name: EasyCare Tx 2
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: MOD, MNS, BZD
Dated: April 24, 2026
Received: April 24, 2026

Dear Lawrence Kwan:

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
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K261360

Device Name
EasyCare Tx 2

Indications for Use *(Describe)*
The EasyCare Tx 2 software is indicated for use by healthcare professionals in a clinical environment with compatible Resmed therapy devices via TxLink 2 to display real-time therapy data and treatment settings, and to provide therapy device setting changes.

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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1 510(k) Summary

[As required by 21 CFR 807.921(c)]

Date of Revision:	August 27, 2026
Company Name/Owner:	ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123, US
Official Contact:	Lawrence Kwan Specialist, Regulatory Product Strategy & Delivery ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW, 2153, Australia lawrence.kwan@resmed.com.au +61 2 8884 1000
Device Trade Name:	EasyCare Tx 2
Device Common Name:	Therapy titration software
Regulation	21 CFR 868.5895
Classification and Classification Name:	II Continuous Ventilator

Legally Marketed Predicate Device:	EasyCare Online (K132371)
Legally Marketed Reference Device:	EasyCare Tx 2 (K241939)
Device Description:	EasyCare Tx 2 is a personal computer application designed to allow clinicians to monitor real-time data from the ResMed compatible therapy device and adjust the therapy device settings from the control room of the sleep lab.
Indication For Use:	The EasyCare Tx 2 software is indicated for use by healthcare professionals in a clinical environment with compatible Resmed therapy devices via TxLink 2 to display real-time therapy data and treatment settings, and to provide therapy device setting changes.

Indication For Use Comparison	**EasyCare Online (K132371)** 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	**EasyCare Tx 2 (subject device)** The EasyCare Tx 2 software is indicated for use by healthcare professionals in a clinical environment with compatible Resmed therapy devices via TxLink 2 to display real-time therapy data and treatment settings, and to provide therapy device setting changes.
Indication for Use Discussion	Same intended use as primary predicate. Both devices are clinician-facing software used to review therapy/device information and support therapy device configuration/setting changes for non-life-supporting ventilation therapy. The subject device indications represent a subset of the predicate's indications related to therapy device data display and clinician-controlled settings management; the subject device does not include the predicate's diagnostic/home sleep test functionality	

Technological Characteristics Comparison

	EasyCare Online (K132371)	EasyCare Tx 2	Discussion
Prescription Use	Yes	Yes	Same
Intended Environment of Use	Clinical	Clinical	Same
Intended User	Trained clinician	Trained clinician	Same
Display Type	PC	PC	Same
Hardware Requirements (User PC)	• PC – Pentium 1.6 GHz or greater with an active internet connection • Memory – 500MB RAM or greater • Screen resolution – 1024 x 768 (or higher) • SD card reader (if downloading data from a data card)	Standard PC platform with microprocessor and ancillary controllers	Similar *Hardware of predicate is indicative of requirements at the time of clearance. Updated requirements for subject device reflect the current state of the art for hardware and do not raise questions of safety or efficacy.*
Operating System (User PC)	• Microsoft® XP SP3 32 bit • Microsoft® Windows Vista - 32 bit • Microsoft® Windows 7 32 and 64 bit	Microsoft Windows	Similar *Hardware of predicate is indicative of requirements at the time of clearance. Updated requirements for subject device reflect the current state of the art for hardware and do not raise questions of safety or efficacy.*
Compatible Therapy Devices	• ResMed S8 & S9 series PAP devices (BZD) • ResMed VPAP series non-invasive ventilators (MNS) • ApneaLink Plus (MNR)	• ResMed Air11 series PAP devices (BZD) • ResMed Mariana non-invasive ventilation devices (MNS)	Similar *The compatible therapy devices for the subject device represent a subset of the equivalent devices supported by the predicate device. Differences between names of specific supported devices reflect the updates to the manufacturer's portfolio over time.*

	EasyCare Online (K132371)	EasyCare Tx 2	Discussion
Adjust Device Therapy Settings	Yes	Yes	Same
Available Therapy Modes	CPAP AutoSet S ST T ASV ASVAuto PAC iVAPS VAuto APAP	CPAP AutoSet AutoSet for Her S ST T VAuto ASV ASVAuto PAC iVAPS	Similar *Modes are controlled solely by the connected flow generator device and are not influenced by EasyCare Tx 2 beyond selection of and transition between modes for therapy.*
Output Parameters *(NB EasyCare Tx 2 does not contain any PAP device information and receives data packets from compatible therapy devices that contain the range for each parameter.)*			
Pressure	0 to 30 cmH2O	0 to 30 cmH2O	Same
Flow	1 to 30 L/min	-240 to 240 L/min	Similar *Risks associated with the increase in flow as an output parameter are ultimately considered by the compatible therapy device. The subject device uses a larger data model with scalable architecture to achieve the greater range. These parameters are identical to the reference device and are verified with its testing methodologies.*
Respiratory Rate	5.0 to 50.0 BPM	0.0 to 90.0 BPM	Similar *The subject device's higher range supports pediatric patients using the AirSense 11 device. These parameters are identical to the reference device and are verified with its testing methodologies.*

	EasyCare Online (K132371)	EasyCare Tx 2	Discussion
Tidal Volume	-	0.0 to 4.0 Liters	Similar *The subject device's data model supports an additional parameter of tidal volume; the risk of the output parameter is ultimately considered by the compatible therapy device. These parameters are identical to the reference device and are verified with its testing methodologies.*
Target Ventilation	1 to 30 L/min	0 to 30 L/min	Similar *Risks associated with the decreased minimum of target ventilation as an output parameter are ultimately considered by the compatible therapy device. The subject device uses a larger data model with scalable architecture to achieve the greater range. These parameters are identical to the reference device and are verified with its testing methodologies.*
Minute Ventilation	-	0 to 30 L/min	Similar *The subject device's data model supports an additional parameter of minute ventilation; the risk of the output parameter is ultimately considered by the compatible therapy device. These parameters are identical to the reference device and are verified with its testing methodologies.*
Ti (Inspiration Time)	0.3 to 4.0 seconds	0.3 to 4.0 seconds	Same

	EasyCare Online (K132371)	EasyCare Tx 2	Discussion
Pulse Rate	-	0 to 300 bpm	Similar *The subject device's data model supports an additional parameter of pulse rate; the risk of the output parameter is ultimately considered by the compatible therapy device. These parameters are identical to the reference device and are verified with its testing methodologies.*
SpO_2	-	0 to 100%	Similar *The subject device's data model supports an additional parameter of SpO_2; the risk of the output parameter is ultimately considered by the compatible therapy device. These parameters are identical to the reference device and are verified with its testing methodologies.*

Submission Reason:	Modification to device
Non-clinical testing:	Non-clinical verification and validation testing completed for EasyCare Tx 2 demonstrated that the device met all intended performance requirements. Testing included: • Software verification and validation • Cybersecurity The verification testing performed with EasyCare Tx 2 was software verification and validation against the non-functional requirements and end-to-end functional testing. Methodology used for testing was based on the reference device K241939, which represents an earlier version of the subject device. The testing conducted with EasyCare Tx 2 to the predicate device demonstrates substantial equivalence to the technology and operating principle of the devices.
Clinical Testing	Clinical tests were not required to demonstrate the safety and effectiveness of EasyCare Tx 2.
Substantial Equivalence	The subject device has the same intended use and similar technological characteristics to the predicate device (K132371). Both devices are software medical devices intended to support the management of sleep-disordered breathing and respiratory impairment through the management and monitoring of compatible therapy devices and the display and use of data to supplement patient care. EasyCare Tx 2 has undergone performance testing to ensure the device is as safe and effective as the predicate, and it can be concluded that any differences in technological characteristics do not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed EasyCare Tx 2 are assessed to be substantially equivalent to the predicate device.

Standards

EasyCare Tx 2 was assessed and/or tested in accordance with the applicable requirements in relevant FDA consensus standards including:

- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- IEC 62366-1:2015/AMD1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 15223:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements [Including Amendment 1 (2025)]
- ANSI AAMI IEC 80001-1:2010 Application of risk management for IT Networks incorporating medical devices - Part 1: Roles responsibilities and activities
- IEC 62304:2015 Medical device software - Software life cycle processes

The EasyCare Tx 2 is substantially equivalent to the predicate EasyCare Online (K132371):

- It has the same 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