September 27, 2024

ResMed Corp
Prerana Gurubasavaraj
Senior Regulatory Affairs Specialist
9001 Spectrum Center Blvd
San Diego, California 92123

Re: K241939
Trade/Device Name: EasyCare Tx 2
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 1, 2024
Received: July 2, 2024

Dear Prerana Gurubasavaraj:

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,
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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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K241939

Device Name
EasyCare Tx 2

Indications for Use *(Describe)*
The EasyCare Tx 2 software is intended to be used with ResMed compatible therapy devices in a clinical environment. EasyCare Tx 2 provides therapy device setting changes and displays real-time data and treatment settings from compatible ResMed therapy devices when used together with the TxLink 2 module.

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.**

# 1 510(k) Summary

*[As required by 21 CFR 807.921(c)]*

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|---|---|
| **Date of Submission:** | July 1, 2024 |
| **Company Name/Owner:** | ResMed Corp<br>9001 Spectrum Center Boulevard<br>San Diego, CA 92123, US |
| **Official Contact:** | Prerana Gurubasavaraj<br>Senior Regulatory Affairs Specialist<br>ResMed Corp<br>9001 Spectrum Center Boulevard<br>San Diego, CA 92123, US<br>prerana.gurubasavaraj@resmed.com |
| **Device Trade Name:** | EasyCare Tx 2 |
| **Device Common Name:** | Therapy titration software |
| **Classification and Classification Name:** | II<br>Noncontinuous Ventilator (IPPB) |
| **Product Code:** | BZD |

**Legally Marketed Predicate Device:** EasyCare Tx System (K113780)

**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 intended to be used with ResMed compatible therapy devices in a clinical environment. EasyCare Tx 2 provides therapy device setting changes and displays real-time data and treatment settings from compatible ResMed therapy devices when used together with the TxLink 2 module.

**Intended Use Comparison**

| EasyCare Tx<br><br>(K113780) | EasyCare Tx 2 |
|---|---|
| EasyCare Tx is intended to be used with ResMed compatible therapy devices via the Tx Link. EasyCare Tx provides real-time data and treatment settings display, and can also provide | The EasyCare Tx 2 software is intended to be used with ResMed compatible therapy devices in a clinical environment. EasyCare Tx 2 provides therapy device setting changes and displays real-time data and treatment settings |

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| therapy device setting changes remotely.<br><br>EasyCare Tx is intended to be used in a clinical environment. | from compatible ResMed therapy devices when used together with the TxLink 2 module. |

**Technological Characteristics Comparison**

| | EasyCare Tx (K113780) | EasyCare Tx 2 | Discussion |
|---|---|---|---|
| Prescription Use | Yes | Yes | Same |
| Intended Environment of Use | Hospital or Sleep Lab | Hospital or Sleep Lab | Same |
| Display Type | PC | PC | Same |
| Hardware Requirements (User PC) | Standard PC platform with microprocessor and ancillary controllers | Standard PC platform with microprocessor and ancillary controllers | Same |
| Operating System (User PC) | Microsoft Windows | Microsoft Windows | Same |
| Accessories | CD for downloading to PC<br><br>Tx Link | CD for downloading to PC<br><br>Tx Link 2 | Same |

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| Compatible Therapy Devices | BZD<br>MNS<br>MNT | BZD | Same<br>EasyCare Tx 2 does not support product codes MNS and MNT |
| Therapy Device Adjustments (Settings) | | | |
| Adjust Device Therapy Mode | Yes | Yes | Same |
| Adjust Device Therapy Settings | Yes | Yes | Same |
| Available Therapy Modes | CPAP<br>AutoSet<br>AutoSet for Her<br>S<br>ST<br>TVAuto<br>ASV<br>ASVAuto<br>PAC<br>iVAPS | CPAP<br>AutoSet<br>AutoSet for Her<br>S<br>ST<br>TVAuto<br>ASV<br>ASVAuto<br>PAC | Same<br>The PAC and iVAPS modes are no longer used and supported as they are for devices under the MNS and MNT product codes, and not in scope for EasyCare Tx 2 with BZD devices. |

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| Humidifier Control | Humidifier on/off | Humidifier on/off, level control, auto | Similar<br><br>Auto mode in the attached ResMed therapy device optimizes the humidifier temperature to ensure rainout does not occur as ambient temperature varies during the night. EasyCare Tx 2 controls the humidifier settings on the ResMed compatible therapy device. |
| Tubing Control | Tube Temperature on/off, auto | Tube Temperature on/off, auto | Same<br><br>ResMed therapy device optimizes the tube temperature to ensure rainout does not occur as ambient |

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| | | | temperature varies during the night. |
| Ramp | 0 to 45 min | 5 to 45 min, off, auto | Similar<br><br>Ramp is in the attached ResMed therapy device. In auto mode, the ramp stops as soon as sleep is detected to ensure the patient obtains the best therapy outcome.<br><br>Off mode was added for usability purposes instead of ramping to 0 in the predicate. |
| Output Parameters[1] | | | |
| Pressure | -3 to 35 cm $H_2O$ | 0 to 30 cm $H_2O$ | Similar<br><br>Therapy range has not changed. |

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| | | | -3cm $H_2O$ was previously used to cover an extremely niche case, which presented little clinical benefit in AirSense 10 and was subsequently removed in AirSense 11. The reduction in pressure is based on the fact that that EasyCare Tx 2 only supports OSA devices which require a lower therapy pressure. |
| Flow | -120 to 120 L/min | -240 to 240 L/min | Similar<br><br>Risks associated |

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| | | | with the increase in flow as an output parameter are ultimately considered by the parent therapy device. EasyCare Tx 2 uses a larger data model with scalable architecture to achieve the greater range. |
| Leak | -30 to 120 L/min | 0 to 2 L/s | Similar<br><br>Leak parameters are sent from the attached ResMed therapy device in L/s. EasyCare Tx 2 allows the option to toggle between L/s and L/min. |
| Respiratory Rate | 6 to 35 BPM | 0 to 90 BPM | Similar |

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| | | | The subject device's higher range supports pediatric patients using the AirSense 11. |
| Tidal Volume | 0.01 to 3 L | 0 to 4 L | Similar |
| Target Ventilation | 0 to 30 L/min | 0 to 30 L/min | Same |
| Minute Ventilation | 0 to 30 L/min | 0 to 30 L/min | Same |
| Ti (Inspiration Time) | 0 to 9 seconds | 0.3 to 4 seconds | Similar |
| Pulse Rate | 18 to 300 BPM | 0 to 300 BPM | Similar |

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| $SpO_2$ | 40 to 100% | 0 to 100% | Similar<br><br>Expansion of range on pulse rate and $SpO_2$ – the new sensor that is utilised for EasyCare Tx 2 now supports an increased range of data monitoring. |

[1]Easycare Tx 2 does not contain any PAP device information and receives data packets from AirSense 11 flow generators that contain the range for each parameter.

**Submission Reason:** New 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

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

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| | The verification testing performed with EasyCare Tx 2 was software verification and validation against the non-functional requirements and end-to-end functional testing. The predicate testing conducted with EasyCare Tx 2 to the predicate EasyCare Tx System device (K113780) demonstrate substantial equivalence to the technology andoperating 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 similar features and interfaces as the device cleared in K113780. The main differences between ResMed's EasyCare Tx System and the EasyCare Tx 2 include:<br>1. Compatible therapy devices are not hardcoded into the EasyCare Tx 2 software, and EasyCare Tx 2 can receive data packets from the compatible flow generators (e.g., AirSense 11, K203126).<br>2. EasyCare Tx 2 contains all the same therapy settings and output parameters as the predicate, but has updated features for auto modes, up-to-date therapy settings, and extended ranges.<br>3. The EasyCare Tx 2 is only for use with compatible ResMed devices, including the updated TxLink™ 2. EasyCare Tx 2 is not reverse compatible with EasyCare Tx or TxLink™.<br>4. The EasyCare Tx 2 introduces secure communication initialization via CSR, implements code-signing for the installer, and enhances the certificate generation and use process.<br><br>The subject device has the same intended use and similar technological characteristics as the predicate device (K113780). 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 the subject device does 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. |

**Substantial Equivalence Conclusion:**

The EasyCare Tx 2 is substantially equivalent to the predicate EasyCare Tx System (K113780):

- It has similar 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