RESMED

APR 2 0 2012

510(k) Summary – EasyCare Tx System K113780

[As required by 21 CFR 807.92 (c)]

Date Prepared	02 March 2012
Submitter	Nicole Gaddi Regulatory Affairs Manager ResMed Ltd, Australia
Official Contact	Mr. David D'Cruz V.P., Clinical & Regulatory Affairs ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 USA Tel: (858) 836 5984 Fax: (858) 836 5522
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Non-continuous ventilator (IPPB)
Proprietary Name	EasyCare Tx System
Predicate Device(s)	EasyCare Tx System (K092026)
Reason for submission	New Device

The EasyCare Tx System comprises of the titration software, *EasyCare Tx*, and the connection module accessory, *Tx Link*.

Indication for Use

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 therapy device setting changes remotely.

EasyCare Tx is intended to be used in a clinical environment.

The Tx Link is intended to provide connectivity between ResMed EasyCare Tx software and ResMed compatible therapy devices. The Tx Link relays real-time signals measured by the ResMed compatible therapy device to a polysomnograph (PSG).

The Tx Link is intended to be used in a clinical environment.

Device Description

ResMed's EasyCare Tx System enables clinicians to monitor real-time patient and flow generator information and adjust flow generator settings as required from the control room within the hospital and sleep lab clinical setting.

The EasyCare Tx System includes:

- EasyCare Tx, a software application that executes on the end-user's PC and interfaces with the accessory Tx Link to view and set various flow generator parameters and settings; and
- Tx Link, a hardware accessory that connects to a flow generator and interfaces to a remote PC via an Ethernet connection. The Tx Link also provides analog flow generator signals to third party Polysomnograph (PSG) systems, such as Embla (K971813).

Substantial Equivalence

The modified EasyCare Tx System has the following similarities to the previously cleared predicate device.

- Similar intended use
- Similar operating principle
- Same technologies
- Same manufacturing process

Design and Verification activities were performed on the EasyCare Tx System as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the modified device is Substantially Equivalent to the predicate device (K092026). The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)
- FDA Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 14, 2005)

Non-Clinical Testing:

Performance testing of EasyCare Tx has been conducted using End-to-End bench testing methodology to demonstrate that the modified EasyCare Tx performs to design input specifications.

EasyCare Tx met the predetermined pass/fail criteria as defined in the EasyCare Tx System Verification Report.

Clinical Testing:

Clinical testing was not deemed necessary as indentified in the Risk Analysis, as EasyCare Tx only obtains patient and machine information from therapeutic devices for which clinical trials have already been conducted, or compared with previous predicate comparison test results. Accordingly no clinical testing is required.

Conclusion

The modified EasyCare Tx System is Substantially Equivalent to the previously cleared predicate device, EasyCare Tx System (K092026).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

APR 20 2012

Re: K113780
Trade/Device Name: EasyCare Tx System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 7, 2012
Received: March 14, 2012

Dear Mr. D'Cruz:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: **EasyCare Tx System**

The EasyCare Tx System comprises of the Titration Software, *EasyCare Tx*, and the Connection Module accessory, *Tx Link*.

Indication for Use

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 therapy device setting changes remotely.

EasyCare Tx is intended to be used in a clinical environment.

The Tx Link is intended to provide connectivity between ResMed EasyCare Tx software and ResMed compatible therapy devices. The Tx Link relays real-time signals measured by the ResMed compatible therapy device to a polysomnograph (PSG).

The Tx Link is intended to be used in a clinical environment.

Prescription Use ___X___ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices