K093684

510(k) Summary – EasyCare Online

Date Prepared	1st Feb, 2010	FEB 2 6 2010

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Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	EasyCare Online
Predicate Device(s)	ResTraxx Online (K083816) ResScan Pro (K082983)
Reason for submission	New Device

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

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

EasyCare Online remains largely the same as the predicate devices ResTraxx Online (K083816) for web based browser and patient data management and ResScan Pro (K082983) for Graphics User Interface (GUI) functionality, including the use of ResMed's proprietary communications protocol. Areas of difference relate to new operating platform and software operating system (Windows 2000 NT to Windows 2008) which provides improved performance in the connectivity and transfer of data from the flow generator to the clinician along with improved (GUI) which provides better usability.

Design and Verification activities such as software development life cycle according to FDA guidance documents were followed as a result of the risk analysis and design requirements. Demonstrating Substantial Equivalence between the predicate device ResTraxx Online (K083816) and the new device (EasyCare Online) involved End-to-End testing that shows patient and treatment data can be successfully transferred from the flow generator to the EasyCare Online system.

System testing includes a PC (GUI) with a Web Browser which is used to access the EasyCare Online server. Based upon the user's instructions, the PC sends a request via the internet to the server (EasyCare Online) to retrieve patient and machine data from the flow generator located in the patient's home via a secure telemetry network (GSM network).

If the user decides to update treatment parameters in the flow generator, this can be done by sending appropriate commands from the PC to the flow generator via the server and GSM network. The flow generator, via the GSM network, will send confirmation information back to the user once these new settings have been implemented.

All tests confirmed that EasCare Online met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate devices – ResTraxx Online (K083816) for web based wireless transfer and functionality of patient and machine information and ResScan Pro (K082983) for (GUI). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- 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)

No clinical trials were needed to demonstrate Safety and Efficacy. Based upon the Risk Analysis, End-to-End bench testing alone is sufficient as no new features were added that could raise concerns regarding Safety or Efficacy.

Intended Use

EasyCare Online is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's flow generator located in the home to the care giver. EasyCare Online also provides remote settings capabilities.

It is intended to be used by Clinicians in conjunction with ResMed compatible flow generators.

Device Description

General

The performance and functional characteristics of EasyCare Online includes all the user features of the predicate device, ResTraxx Online (K083816).

EasyCare Online is designed to function with ResMed OSA treatment systems for the transfer, storage, retrieval and display of stored information from the flow generator to a centralized server. This information can then be accessed by the clinician where the information can be displayed on the clinician's PC using a web browser application. Flow Generator settings changes, via wireless transmission can also be made from the clinicians PC. Access to the data is limited to subscribers of the system. Patients cannot access the system.

EasyCare Online comprises two distinct components, the wireless transmitter/receiver located on the flow generator and the Server System. Data taken from the flow generator is transmitted via a wireless network and stored on the EasyCare Online database.

Wireless Module

The Wireless Module is similar in size to a mobile phone, it contains a GSM device and some interface hardware and firmware that functions in a similar manner as a mobile phone by transferring data to and from the server and the flow generator. It is designed to attach to a compatible ResMed flow generator using a docking mechanism and is powered via the electrical connection from the flow generator. This mechanism allows the device to be electrically connected via the existing expansion port located at the rear of the flow generator. When attached, the wireless modules can automatically collect patient and machine information stored within the flow generator's memory. The wireless module sends information utilizing existing wireless networks providing coverage to large portions of the US population.

All flow generators capable of being connected to the GSM wireless module and therefore able to transfer patient and machine data to the server are classified as 73 BZD devices.

Server System

The Server System consists of several functional software modules that are designed to retrieve information from ResMed flow generators through the wireless network, store the information in a database and provide a secure interface into the system. The system allows users to schedule information retrieval and view patient and treatment information, including the ability to retrieve existing settings from and apply new settings to the flow generator remotely from the Clinical reviewer's PC.

Conclusion

Based upon the Risk Analysis and results obtained from End-to-End bench testing as detailed in this submission, EasyCare Online is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ResMed Limited
C/O Mr. David D'Cruz
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FEB 2 6 2010

Re: K093684
Trade/Device Name: EasyCare Online
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 20, 2009
Received: November 30, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 Online

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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)

Page 1 of 1

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

510(k) Number: K093689