K123557

MAR 1 4 2013

510(k) Summary

Date Prepared	16-November-2012 (Amended on 11-Mar-2013)
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Official Contact	Jim Cassi Vice President Quality Assurance Americas ResMed Corp 9001 Spectrum Center Boulevard San Diego, CA 92123 +1 858 836 6081 Jim.Cassi@resmed.com
Device name	EasyCare Online
Product code	73 MNS (Primary) 73 BZD (Secondary)
Classification reference	(Accessory to) Ventilator, Non-Continuous (Respirator) (21 CFR 868.5905, Product Code 73 BZD) (Accessory to) Ventilator, Continuous, Non-Life-Supporting (21 CFR 868.5895, Product Code 73 MNS)
Predicate devices	EasyCare Online (K093684) ResScan (K113815)
Reason for submission	Indications for use have been expanded.

5.1 Intended Use

EasyCare Online transfers and displays to clinicians, usage and therapeutic information that has been transmitted remotely from the patient's flow generator located in the home. EasyCare Online also provides remote settings capabilities.

EasyCare Online is intended to support the standard follow-up care of patients that have been prescribed a compatible ResMed flow generator for the treatment of obstructive sleep apnea or respiratory insufficiency.

5.2 Basis for Determination of Substantial Equivalence

This modified EasyCare Online has the following similarities to the previously cleared predicated devices:

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing (deployment) process

The modified EasyCare Online implemented changes to provide compatibility with the VPAP ST-A (K113288) flow generator, a device indicated for patients with respiratory insufficiency, with FDA product code 73 MNS. This addition modified the Intended Use Statement, as the condition of respiratory insufficiency was added. This change does not affect the safety and efficacy of the device, as the interface with the VPAP ST-A uses the existing data types and communications mechanisms that are utilised to interface with the flow generators already supported by the predicate devices. The modified device is substantially equivalent to the predicate devices EasyCare Online (K093684) and ResScan (K113815) which includes compatibility with S9 AutoSet, cleared under K091947; VPAP III ST-A, cleared under K033276; and Stellar, cleared under K103167.

Design and non-clinical verification activities were performed on EasyCare Online as a result of the risk analysis and design process. Verification testing included end-to-end testing to verify data transfer integrity between the flow generator and EasyCare Online. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that new version of EasyCare Online is substantially equivalent to the predicate device. The new version of EasyCare Online has not altered safety or effectiveness.

5.3 Device Description

EasyCare Online is a web application that can transfer, store, manage and display usage and therapy data from ResMed flow generators. The data is transferred from the flow generators either wirelessly through a communications module or with the aid of an SD card, to a central database and then displayed in a clinician computer, through a web application.

EasyCare Online is used to monitor and optimize the therapy of patients diagnosed with sleep apnea or respiratory insufficiency, who are using a ResMed therapy device. The application enables patient usage data to be shared across several different user groups for the primary purpose of monitoring patient compliance. Clinical users, Home Medical Equipment (HME) providers and other healthcare specialists can access data to monitor patient compliance. Also, clinical users and HMEs are able to address any non-compliance issues in a timely manner and provide the necessary patient support, including the modification of device settings.

5.4 Conclusion

The modified version of EasyCare Online is substantially equivalent to the predicate devices, EasyCare Online (K093684) and ResScan (K113815).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 14, 2013

Jim Cassi
ResMed LTD
Vice President Quality Assurance Americas
9001 Spectrum Center Boulevard
SAN DIEGO CA 92123

Re: K123557
Trade/Device Name: EasyCare Online
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, continuous, non-life-supporting
Regulatory Class: Class II
Product Code: MNS
Dated: February 11, 2013
Received February 11, 2013

Dear Mr. Cassi:

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,

Kwame O. Ulmer for

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

Enclosure

Indications for Use Statement

510(k) Number: K123557

Device Name: EasyCare Online

Indications for Use:

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Prescription Use x and / or Over the counter use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Albert E. Moyal -S

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000593331, cn=Albert E. Moyal -S 2013.03.14 17:38:07 -04'00'

for LS

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

510(k) Number: _____