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510(k) Summary – ResTraxx System

Date Prepared	12th March, 2007
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2021
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	ResTraxx System
Predicate Device(s)	ResTraxx Data Center (K053205)
Reason for submission	Change to Indications for Use

Substantial Equivalence

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

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

Design and Verification activities were performed on the ResTraxx System with the inclusion of the VPAP Malibu (K062291) as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device. The inclusion of the VPAP Malibu as another CPAP (73 BZD) device with the ResTraxx System has not altered the safety and effectiveness when used in the management of Obstructive Sleep Apnea (OSA) in patients. 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)

Intended Use

ResTraxx System 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 wirelessly transmitted from the patient's home to the care giver.

It is intended to be used in the home only and with compatible S7 Elite, AutoSet Spirit, AutoSet Respond, S8 Series CPAP Systems, VPAP III, VPAP III ST and VPAP Malibu positive airway pressure flow generators.

Device Description

The performance and functional characteristics of the ResTraxx System includes all the user features of the predicate device, ResTraxx Data Center System (K053205).

ResTraxx System is designed to function with ResMed OSA treatment devices for the transfer, storage, retrieval and display of stored information from the flow generator to the clinician's PC, via wireless transmission and web-based access. Access to the data is limited to subscribers of the system. Patients cannot access the system.

The ResTraxx System comprises two distinct components, the wireless transmitter/receiver located on the flow generator (referred to as, ResTraxx or S8 ResTraxx) and the web-based application, referred to as ResTraxx Online. Data taken from the flow generator is transmitted via a wireless network, stored in the ResTraxx Online database, transmitted via the Internet and displayed on the Clinical reviewer's PC.

ResTraxx™ and S8 ResTraxx™ – are wireless modules designed to attach to a compatible ResMed flow generator using a docking mechanism. 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 ResTraxx or S8 ResTraxx can automatically collect patient and machine information stored within the flow generator's memory. The ResTraxx and S8 ResTraxx sends information utilizing existing messaging networks providing wireless coverage to large portions of the USA population (The VPAP Malibu uses the ResTraxx model).

ResTraxx Online – consists of several functional software modules that are designed to retrieve information from ResMed flow generators through ResTraxx or S8 ResTraxx via a wireless messaging network, store the information in a database and provide a secure interface into the system, allowing users to schedule information retrieval and view patient and machine information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K070746
Trade/Device Name: ResTraxx System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 2, 2007
Received: July 2, 2007

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.

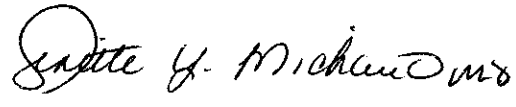
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

RESMED

Indication for Use

510(k) Number (if known): K070746

Device Name: ResTraxx System

Indication for Use

ResTraxx System 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 wirelessly transmitted from the patient's home to the care giver.

It is intended to be used in the home only and with compatible S7 Elite, AutoSet Spirit, AutoSet Respond, S8 Series CPAP Systems, VPAP III, VPAP III ST and VPAP Malibu positive airway pressure flow generators.

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

510(k) Number: K070746