K051314

RESMED

510(k) Summary – ResTraxx Data Center

JUL 15 2005

Date Prepared: 5th April, 2005

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Classification Reference: 21 CFR 868.5905

Product Code: 73 BZD

Common/Usual Name: CPAP System / Non continuous Ventilator (with accessory)

Proprietary Name: ResTraxx Data Center System

Predicate Device(s): SomnoTraxx System (K030797)

Reason for submission: New Device

Indications for Use

The ResTraxx Data Center system is intended to augment the standard follow-up care of adult patients diagnosed with obstructive sleep apnea by providing wireless transmission and display of usage and therapeutic information.

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

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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 Data Center System as a result of the risk analysis and product requirements. All tests confirmed the product met the acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device. ResTraxx Data Center system has not altered the safety and effectiveness when used in the management of Obstructive Sleep Apnea (OSA) in adult 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 reviewer's and industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998.

Intended Use

The ResTraxx Data Center system is intended to augment the standard follow-up care of adult patients diagnosed with obstructive sleep apnea by providing wireless transmission and display of usage and therapeutic information.

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

Device Description

The performance and functional characteristics of the ResTraxx Data Center System includes all the user features of the predicate device, SomnoTraxx System (K030797).

The ResTraxx Data Center System is designed to function with ResMed's S7™ Elite, AutoSet® Respond and AutoSet® Spirit™ CPAP Systems and S8 Series CPAP Systems for the transfer, storage, retrieval and display of stored information from the flow generators to the clinician, via wireless transmission and web-based access. Access to the data is limited to subscribers of the system. There is no patient access to the system.

The ResTraxx Data Center System comprises two distinct components, ResTraxx or S8 ResTraxx and the Server System. Data taken from the flow generator is transmitted via a wireless network, stored in the ResTraxx Data Center database, transmitted via the Internet and displayed on the Clinical reviewer's PC.

ResTraxx™ and S8 ResTraxx™ are optional wireless modules designed to attach to a ResMed S7™ Elite, AutoSet® Respond and AutoSet® Spirit™ or S8 Series flow generators respectively 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 US population.

Server System – The Server System consists of several functional software modules that are designed to retrieve information from ResMed flow generators through the ResTraxx or S8 ResTraxx and 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

JUL 15 2005

ResMed Limited
c/o Mr. David D'Cruz
14040 Danielson St.
Poway, California 92064-6857

Re: K051314
Trade/Device Name: Res Traxx Data Center
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 5, 2005
Received: May 20, 2005

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):

Device Name: ResTraxx Data Center

Indication for Use

The ResTraxx Data Center system is intended to augment the standard follow-up care of adult patients diagnosed with obstructive sleep apnea by providing wireless transmission and display of usage and therapeutic information.

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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)

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

510(k) Number: K051314