K053205

510(k) Summary – ResTraxx Data Center

FEB 3 2006

Date Prepared	1st November, 2005
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 97 Waterloo Road North Ryde, NSW 2113 Australia Tel: +61 (2) 9886 5000 Fax: +61 (2) 9878 5517
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Noncontinuous ventilator (IPPB).
Proprietary Name	ResTraxx Data Center System
Predicate Device(s)	ResTraxx Data Center System (K051314)
Reason for submission	Additional Indications

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, VPAP III & S8 Series CPAP Systems, positive airway pressure flow generators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

ResMed Limited
C/O Mr. David D'Cruz
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K053205
Trade/Device Name: ResTraxx Data Center
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 1, 2005
Received: November 16, 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

Indication for Use

510(k) Number (if known): K053205

Device Name: ResTraxx Data Center

Indication for Use

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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)

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