510(k) Summary – ResScan™

Date Prepared	23 March 2005
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Classification Reference	21 CFR 868.5895
Product Code	73 BZD
Common/Usual Name	CPAP System / Non continuous Ventilator (with accessory)
Proprietary Name	ResScan™
Predicate Device(s)	ResScan™ (K034033) S8 Pioneer CPAP System (K041209)
Reason for submission	Expanded indication; change in design
Indications for Use	The ResScan™ software is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResScan™ is used to download and view therapy data, as well as store therapy information and print reports. ResScan™ also provides functionality for setting flow generator parameters.

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 new version of ResScan 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. ResScan has not altered the safety and effectiveness when used for patient compliance management as an adjunct with ResMed flow generators that have software incorporating proprietary communication protocol. The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notifications, November 1993.
- FDA reviewer's and industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998.

Intended Use

The ResScan™ software is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResScan™ is used to download and view therapy data, as well as store therapy information and print reports. ResScan™ also provides functionality for setting flow generator parameters.

Device Description

The performance and functional characteristics of ResScan includes all the user friendly features of the predicate device.

ResScan allows the clinician to,

- download and view data from a ResMed Flow Generator
- store patient details and downloaded treatment data
- create reports on patient details and downloaded treatment data
- transfer treatment parameters to a ResMed Flow Generator

Sumathy Ramesh
Manager, Regulatory Affairs
ResMed.

March 23, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2005

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

Re: K050775
Trade/Device Name: ResScan™
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 24, 2005
Received: March 28, 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.

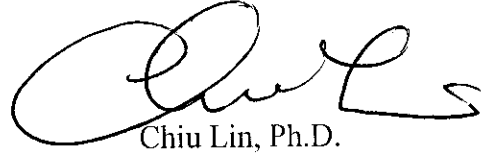
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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) 276-0115. 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):

Device Name: ResScan™

Indications for Use:

The ResScan™ software is intended to be used by clinicians with ResMed flow generators that have software incorporating ResMed's proprietary communication protocol. ResScan™ is used to download and view therapy data, as well as store therapy information and print reports. ResScan™ also provides functionality for setting flow generator parameters.

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)

Ann Nelson

...vision Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K050775