K034033

MAY - 5 2004

510(k) SUMMARY—ResScan

Submitter Name:	ResMed Corp.
Submitter Address:	14040 Danielson Street, Poway CA 92064-6857 USA
Contact Person:	David D'Cruz, VP Regulatory & Clinical Affairs US
Phone Number:	(858) 746 2238
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Date Prepared:	April 30, 2004
Device Trade Name:	ResScan™
Device Common Name/ Classification Name:	Data download and display software
Predicate Devices:	AutoScan™ software (K024191)
Device Description:	The ResScan software with its capabilities of data collection and display of patient information provides an adjunct for patient compliance management. ResScan allows the clinician to download and view data from a ResMed CPAP or Bilevel device. The data displayed will depend on the ventilator used. Parameters displayed may include one or more of the following: • usage (hrs: min); • respiratory rate (breaths/min); • tidal volume (L/min); • leak (L/min); • minute ventilation (L/min); • apnea and hypopnea index including apnea index (AI), hypopnea index (HI) and AHI (events/hr); • oxygen saturation SpO_2 (%); • pulse rate (bpm); The software allows the creation of reports on patient details, and downloaded treatment data. ResScan displays data as retrieved. Data processing in ResScan is limited to computing the statistics (e.g., median) on retrieved data. The software operates under Windows 98SE, Windows 2000 SP2, Windows NT4 SP6, Windows XP, and is available on CD-ROM.

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.

The ResScan software cannot be used to set or change ventilator parameters, or to modify the operation/ function of the ventilator.

Device Technological Characteristics and Comparison to Predicate Device(s):

The ResScan software is based on the previously cleared predicate device ResMed's AutoScan software.

The ResScan software is used to download therapy data previously generated or logged by a ResMed ventilator on an IBM compatible computer and to allow the clinician to download, view, and store data, and print reports. The software operates under various Windows operating systems. These features are consistent with and comparable to the predicate device.

Performance Data:

The ResScan software was tested in accordance with the recommendations of the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 29, 1998) and the General Principles of Software Validation (January 11, 2002).

The ResScan software passed all tests.

Conclusion:

The ResScan software complies with the requirements for functionality, safety and effectiveness, and it is substantially equivalent to the predicate device AutoScan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Resmed Limited
c/o David D'Cruz
Resmed Corporation
14040 Danielson St.
Poway, CA 92064-6857

Re: K034033
Trade/Device Name: ResScan
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 6, 2004
Received: April 9, 2004

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.

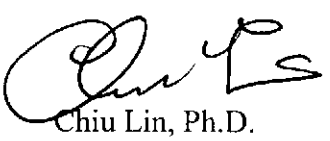
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Center for Devices and
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Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K034033

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.

Prescription Use **Rx only** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

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