510(k) Summary – AutoSet CS2
[As required by §807.92 (c)]

Submitter Name:	ResMed Corp.
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Phone Number:	(858) 746 2238
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Date Prepared:	May 19, 2005
Device Trade Name	VPAP ADAPT
Device Common Name/ Classification Reference	Bi level Positive Pressure Ventilator/ Continuous Ventilator, Passive Exhalation Port, Non-Critical Care. 21 CFR868.5895
Product Code	73MNS
Predicate Devices:	VPAP III ST-A (K033276)
Reason for submission	New device
Intended Use:	The VPAP ADAPT is intended to provide non-invasive ventilatory support to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

Device Description

The VPAP ADAPT is a non-invasive flow generator device designed to provide adaptive servo-ventilation therapy (ASV) to stabilize a patient's ventilation. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation equal to 90% of the patient's recent average ventilation (time constant 100 seconds). It then adjusts the degree of support to servo-control the patient's ventilation to at least equal the target ventilation.

The VPAP ADAPT is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed) whereas others are clinically selectable. Also, a graphic user interface displays clinical data and enables the user (patient/clinician) to set and adjust certain parameters.

Performance Data

Design and verification activities were performed on the VPAP ADAPT as a result of the risk analysis and product requirements. All tests confirmed that the VPAP ADAPT met the acceptance criteria. The VPAP ADAPT complies with the applicable standards and requirements referenced in the following guidance documents:

- *FDA Draft Reviewer Guidance for Ventilators (July 1995)*
- *FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)*
- *FDA Reviewer's and Industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998*

Substantial Equivalence

The VPAP ADAPT (new device) and the VPAP III ST-A (predicate device) are both positive pressure flow generators comprising of a blower (motor/fan assembly), flow and pressure sensors, and processing electronics. The blower supplies pressurized air to the patient via a mask and air tubing. The VPAP ADAPT has the same intended use as the VPAP III ST-A.

Predicate bench testing and clinical studies were used to show substantial equivalence between the VPAP ADAPT and VPAP III ST-A.

In the predicate bench testing, the minute ventilation and tidal volume produced by VPAP ADAPT and the VPAP III ST-A were measured under various patient breathing efforts. The results show the VPAP ADAPT behaves similar to the predicate device, the VPAP III ST-A.

The findings of the VPAP ADAPT equivalence study demonstrated that the VPAP ADAPT is effective for use in patients with central, mixed apnea or periodic breathing. The primary endpoints were achieved, showing clinically equivalent Apnea/Hypopnea (AHI) and Respiratory-related Arousal Index (RAI) sleep and respiratory parameters between the VPAP ADAPT and VPAP III ST-A devices. Furthermore, the non-equivalent AHI results indicated that the VPAP ADAPT device is superior (statistically significant $p=0.001$) to the VPAP III ST-A device for providing effective therapy. Additionally, all secondary endpoints provided further evidence of the equivalency of the devices.

Conclusion

The VPAP ADAPT is substantially equivalent to the VPAP III ST-A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

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

Re: K051364
Trade/Device Name: VPAP Adapt
Regulation Number: 21 CFR 868.5895
Regulation Name: Bi-Level positive Pressure Ventilator/Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: May 20, 2005
Received: May 31, 2005

Dear D'Cruz:

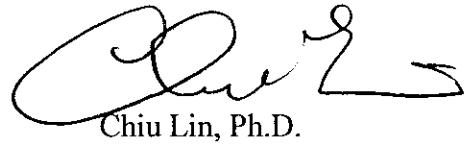
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Indications for Use

510(k) Number (if known):

Device Name:_____VPAP ADAPT

Indications For Use:

The VPAP ADAPT is intended to provide non-invasive ventilatory support to treat adult patients with OSA and Respiratory Insufficiency caused by central and/or mixed apneas and periodic breathing.

Prescription Use __X_____ 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

510(k) Number: K051364