DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2004

Mr. David D' Cruz
Vice President Regulatory & Clinical Affairs US
Resmed Corporation
14040 Danielson Street
Poway, CA 92064-6857

Re: K033276
Trade/Device Name: Resmed VPAP III-STA
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: May 17, 2004
Received: May 19, 2004

Dear Mr. D'Cruz:

This letter corrects our substantially equivalent letter of June 7, 2004, regarding the VPAP III-STA. Our letter identified the regulation number as 868.5905 and the product code as BZD. This is in error; the regulation number is 868.5895 and the correct product code is MNS as indicated above.

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.

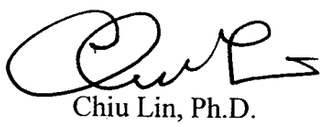
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-5613. 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.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE

510(k) Number (if known): K033276

Device Name: VPAP III - ST A

Indications for Use:

The VPAP III ST-A system is intended to provide non-invasive ventilation for patients with respiratory insufficiency or obstructive sleep apnea (OSA), in the hospital or home.

(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: K033276

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

JUN - 7 2004

K033276

510(k) SUMMARY—VPAP III ST-A

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
Fax Number:	(858) 746 2915
Date Prepared:	June 3, 2004
Device Trade Name:	VPAP III ST-A
Device Common Name/ Classification Name:	Variable Positive Air Pressure (VPAP) System / Continuous Ventilator, Non-life-support
Predicate Devices:	VPAP II ST-A (K974417)
Device Description:	The VPAP III ST-A provides a mode of non-invasive positive pressure ventilation (NPPV) called Pressure Support with PEEP, which delivers two treatment pressures (bi-level ventilation). A higher pressure is applied when the patient inhales - IPAP or inspiratory positive airway pressure, and a lower pressure is applied when the patient exhales - EPAP or expiratory positive airway pressure, sometimes referred to as PEEP or positive end-expiratory pressure. The difference between the two treatment pressures represents the amount of pressure support provided to the patient.
Intended Use:	The VPAP III ST-A system is intended to provide non-invasive ventilation for patients with respiratory insufficiency or obstructive sleep apnea (OSA), in the hospital or home.

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

The VPAP III ST-A is a flow-cycled, pressure-limited ventilator. A blower assembly generates airway pressure. A flow sensor and a pressure sensor in the patient airway feed data on measured flow and pressure into a microprocessor controller, which in turn regulates the blower assembly. A user interface displays clinical data and enables the user to set and adjust certain clinical parameters.

The VPAP III ST-A has a CPAP mode in which a fixed pressure is delivered, and three bi-level operating modes which determine how the changes between IPAP and EPAP pressures are made: Spontaneous, Spontaneous/Timed and Timed.

The VPAP III ST-A is fitted with alarms to alert the user to changes that will affect the treatment. Some of the alarms are pre-set (fixed), others are user adjustable.

VPAP III ST-A is substantially equivalent to the VPAP II ST-A. The two ventilators have the same intended use, operating principle, technological characteristics and manufacturing process. The materials used in the air path are either predicate materials (previously cleared for the same intended use) or have been tested and found compliant with the biocompatibility requirements.

The main differences between the modified device VPAP III ST-A and the VPAP II ST-A are:

- A new enclosure design for VPAP III ST-A - comparable in size and shape with that of the VPAP II ST-A;
- Additional LCD display in the User Interface of the VPAP III ST-A.

  VPAP II ST-A requires an external Universal Control Unit (UCU) in order to display therapy configuration and treatment data. VPAP III ST-A has the ability to display such data on the ventilator itself via an LCD.
- A new power supply unit (PSU), which can be used across the ResMed product range; the new PSU is a switching mode power supply, i.e., it has the same principle of operation as the VPAP II ST-A power supply.

  The VPAP III ST-A can also be run from a 12V battery via a DC-DC (12V/ 24V) converter in the event of mains power not being reliable. The VPAP III ST-A is however **not** intended for transport use as defined in section 5.5 of the FDA Draft Reviewer Guidance for Ventilators (July 1995).
- A new blower motor, which can supply operating pressure up to 30 cmH_2O, having the same principle of operation as the VPAP II ST-A blower motor;
- New flow sensor with superior accuracy at low flow values, and new microprocessor controller with superior processing power and more competitive price;

  VPAP II ST-A has one flow sensor and two pressure sensors, the second pressure sensor having its own alarm microprocessor controller and acting as backup in the event that the first pressure sensor fails. VPAP III ST-A has a flow sensor and one pressure sensor, the microprocessor controller checks every 50ms that the pressure sensor works properly thus eliminating the need for a backup pressure sensor with its own microprocessor controller.

  VPAP III ST-A compensates for pressure drop in the air tubing, whereas VPAP II ST-A does not.
- When a humidifier is used, the pressure sensing point for VPAP II ST-A and VPAP III ST-A is before the humidifier, except that when an integrated humidifier (H2i) is used with VPAP III ST-A the pressure sensing point was moved after the humidifier to compensate for the pressure drop in the humidifier and ensuring a more accurate control of the mask pressure.
- VPAP II ST-A has an analog breath detection circuit and fixed thresholds for triggering and cycling. The VPAP III ST-A breath detection is software-based, and the device has adjustable sensitivity levels - Low, Medium and High - for triggering and cycling thresholds.
- VPAP II ST-A has a single generic vent pressure-flow compensation characteristic estimated in hardware. VPAP III ST-A has a range of vent pressure-flow compensation characteristics for different mask types, calculated more accurately by software based on the known mask pressure.
- Leak management for VPAP II ST-A is implemented in hardware. Leak in VPAP III ST-A is calculated more accurately by software taking into consideration the fact that leak rate depends on pressure.

- The rise time, i.e., the time taken to for the pressure to increase from EPAP to IPAP can be adjusted in VPAP III ST-A for increased patient comfort. VPAP II ST-A does not have this feature.
- Additional alarms for VPAP III ST-A;

  VPAP II ST-A has the following alarms: power fail, high pressure and low pressure. System faults, which might cause high or low pressures, and gross leak are reported either by the high-pressure alarm or by the low-pressure alarm, as applicable. VPAP III ST-A has the following alarms: power fail, high pressure and low pressure, mask-off condition, (gross) over pressure, over use (operation outside specification), system fault, non-vented mask, and low minute ventilation.
- VPAP III ST-A incorporates additional compliance statistics compared to VPAP II ST-A.
- VPAP III ST-A has more flexibility in setting the ramp (or delay) time: from 5 to 45 minutes in 5 minutes increments, compared to 5, 10 or 20 minutes for VPAP II ST-A.

Performance Data:

The VPAP III ST-A was tested in accordance with the recommendations of the FDA Draft Reviewer Guidance for Ventilators (July 1995).

The VPAP III ST-A ventilator complies with the following standards: IEC 60601-1; IEC 60601-1-2; IEC 60068-2-27/ -6/ -34; IEC 10993-1; ASTM F 1100-90.

Conclusion:

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