K030843

AUG 15 2003

510(k) SUMMARY— VPAP III

Date Prepared	10th March 2003
Official Contact	Dr Lionel King ResMed Ltd 97 Waterloo Road North Ryde NSW 2113 Australia Tel: + 61 (2) 9886 5000 Fax: + 61 (2) 9878 5517
Device Trade Name	VPAP III™
Device Common Name	CPAP and Bi-level Flow Generator
Classification Name	BZD Noncontinuous Ventilator
Predicate Devices	S7 Elite CPAP System (K013909) VPAP II ST Nasal VPAP System (K961783)
Reason for Submission	Modified design, additional therapy mode
Indications for use	The VPAP III™ is intended for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The optional integrated humidifier (HUMIDAIRE® 2i™) is indicated for the humidification and warming of air from the VPAP III™ flow generator. The VPAP III™ flow generator and HUMIDAIRE 2i™ are for home and hospital use.

Device Description

The VPAP III is a microprocessor-controlled blower-based positive airway pressure flow generator for the treatment of OSA. The device is based on the S7 Elite with an additional therapy mode (bi-level), derived from the VPAP II ST, to provide pressure relief during exhalation. The flow generator is used in combination with patient tubing and a mask. For additional humidification, an optional integrated humidifier, the HUMIDAIRE 2i, is compatible with the flow generator.

Substantial Equivalence

The modified device has the following similarities to the previously cleared devices:

- Same Intended Use
- Same Operating Principle
- Same Technologies
- Same Manufacturing Line

Design Verification and Validation tests were performed on the VPAP III flow generator, in accordance with the risk analysis and product requirements. All tests confirmed that the modifications have had no impact on the safety or effectiveness of the device. In summary, the device in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2003

ResMed Limited
Senior Director of QA/RA
C/O Roger Kotter
14040 Danielson Street
Poway, California, 92064-6857

Re: K030843
Trade/Device Name: VPAP III
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 13, 2003
Received: June 16, 2003

Dear Mr. Kotter:

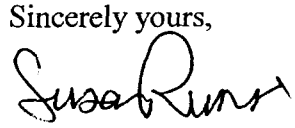
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030843

Device Name: VPAP III™

Indications for Use:

The VPAP III™ is intended for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The optional integrated humidifier (HUMIDAIRE® 2i™) is indicated for the humidification and warming of air from the VPAP III™ flow generator. The VPAP III™ flow generator and HUMIDAIRE 2i™ are for home and hospital use.

(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: K030843

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)