510(k) Summary – VPAP Auto System

JAN 13 2009

K082605

Date Prepared	1st Sep, 2008
Official Contact	Dr Lionel King V.P., Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia Tel: +61 (2) 8884 2243 Fax: +61 (2) 8884 2000
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	VPAP Auto System
Predicate Device(s)	VPAP Auto (K071171) Fisher and Paykel, HC604 CPAP Humidifier (K041900)
Reason for submission	New Technology

Indication for Use

The VPAP Auto system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). The optional integrated HumidAire 3i is indicated for humidification of the air delivered from the VPAP Auto device. The VPAP Auto system and HumidAire 3i are intended for use in the hospital and home.

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Same intended use
- Similar operating principle
- Similar technologies
- Same manufacturing process

Design and Verification activities were performed on the VPAP Auto System as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment for patients with Obstructive Sleep Apnoea (OSA) who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)

Device Description

The VPAP Auto System is similar to the predicate device, (VPAP Auto *with* HumidAire 3i (K071171)) with a new and improved power supply and heater controller for the HumidAire 3i. Micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH_2O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the flow generator, patient tubing, mask (patient interface) and humidifier.

The performance and functional characteristics of the VPAP Auto system includes all the clinician and user friendly features of the predicate devices.

Conclusion

The VPAP Auto System 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

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

JAN 13 2009

Re: K082605
Trade/Device Name: VPAP Auto System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 6, 2009
Received: January 8, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Division 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): K082605

Device Name: VPAP Auto System

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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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K082605