510(k) Summary – VPAP ST-A

K113288

MAR 2 9 2012

Date Prepared	31st Oct, 2011
Submitter	Greg Dockar Senior Regulatory Affairs Manager
Official Contact	Mr David D'Cruz – V.P., US Medical & Regulatory Affairs ResMed Corp. 9001 Spectrum Center Boulevard, San Diego, CA 92123 Tel: (858) 836-5984
Classification Reference	21 CFR §868.5895
Product Code	73 MNS
Common/Usual Name	Ventilator, continuous, non-life-supporting
Proprietary Name	VPAP ST-A
Predicate Device(s)	ResMed, VPAP ST with H5i (K102513) ResMed, Stellar 150 (K103167) ResMed, VPAP III ST-A (K033276)
Reason for submission	New Device

Indication for Use

The VPAP ST-A is indicated to provide non-invasive ventilation for patients weighing more than 30 lbs (13kg) or more than 66 lbs (30kg) in iVAPS mode with respiratory insufficiency or obstructive sleep apnea (OSA). The VPAP ST-A is intended for use in the hospital or home.

Substantial Equivalence

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

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

Design and Verification activities were performed on the VPAP ST-A System as a result of the risk analysis and design requirements. All bench tests confirmed the product met the predetermined acceptance criteria, this included Pressure, Flow, Pressure Support, Trigger and Cycling, Hypopnea and Apnea tests against the predicate devices using common protocols for both devices. Clinical data for the VPAP ST-A is not required as the predicate devices have been subjected to clinical trial requirements or validated patient simulation models have been used during the bench testing phases. 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)

Non-Clinical Testing:

The VPAP ST-A has been tested to appropriate FDA consensus standards and other applicable requirements passing all test protocols. The VPAP ST-A with and without the integrated heated humidifier (H5i) was designed and tested according to:

- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for safety Medical electrical equipment – General requirements for basic safety and essential performance
- IEC 60601-1-8:2006, Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

Device Description

VPAP ST-A System (VPAP ST-A *with* H5i) is similar to the predicate device(s), using a blower based positive pressure system with an integrated heated humidifier and heater controller. The device platform is similar to the S9 VPAP ST (K102513) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure (CPAP) between 4-20 cmH_2O as required to maintain an "air splint" for effective treatment of OSA and (Bilevel) pressures between 3-30 cmH_2O for the treatment respiratory insufficiency. The system comprises the flow generator, patient tubing, mask (patient interface), alarm functions and integrated humidifier.

Therapy modes contained in the VPAP ST-A are CPAP, Spontaneous, Spontaneous/Timed, Timed, PAC and iVAPS. Therapy modes come from the S9 VPAP ST (K102513) and Stellar 150 (K103167).

The functional characteristics of the VPAP ST-A system includes all the clinician and user friendly features of the predicate devices.

Conclusion

The VPAP ST-A is substantially equivalent to the Predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ResMed Limited
C/O Mr. David D' Cruz
Vice President Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
Kearny Mesa, California 92123

MAR 2 9 2012

Re: K113288
Trade/Device Name: VPAP ST-A
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: MNS
Dated: March 24, 2012
Received: March 28, 2012

Dear Mr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
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):

Device Name: VPAP ST-A

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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)

L Schultheiss

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

510(k) Number: K113288