K102586

MAR 18 2011

510(k) Summary – S9 VPAP Adapt

Date Prepared	21st Feb, 2011
Official Contact	David D'Cruz VP, US Medical and Regulatory Affairs ResMed Corp 9001 Spectrum Center Blvd. San Diego CA 92123 USA Tel: (858) 836-5984 Fax: (858) 836-5522
Classification Reference	21 CFR 868.5905
Product Code	73 BZD
Common/Usual Name	Non continuous ventilator (IPPB).
Proprietary Name	S9 VPAP Adapt
Predicate Device(s)	VPAP Tx (K092186) S8 Aspen with H4i Plus (K091947) VPAP Adapt (K051364)
Reason for submission	New Device

Indication for Use

The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.

Substantial Equivalence

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

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

Design and Verification activities were performed on the S9 VPAP Adapt System as a result of the risk analysis and design requirements. All tests (predicate bench testing) 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), central and/or mixed apneas, or periodic breathing who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notification Submissions (November 1993)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

Predicate bench testing and clinical studies were used to show substantial equivalence between the S9 VPAP Adapt and VPAP Tx system (K092186).

Device Description

S9 VPAP Adapt System (S9 VPAP Adapt *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 S8 Aspen with H4i Plus (K091947) and contains a Micro-processor controlled blower system that generates controlled positive airway pressure between 3-25 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 S9 VPAP Adapt is a flow generator device designed to provide adaptive servo-ventilation therapy (ASV) to stabilize a patient's ventilation during sleep. The device continually measures the patient's instantaneous ventilation, and calculates a target ventilation based on to the patient's recent average. It then adjusts the degree of pressure support to servo-control the patient's ventilation to at least equal the target ventilation.
Therapy modes contained in the S9 VPAP Adapt are CPAP, CPAP with EPR, and Auto Servo Ventilation (ASV). Therapy modes come from the VPAP Tx system (K092186) and VPAP Adapt (K051364).

The functional characteristics of the S9 VPAP Adapt system includes all the clinician and user friendly features of the predicate devices.

Conclusion

The S9 VPAP Adapt is substantially equivalent to the Predicate devices, VPAP Tx system (K092186), VPAP Adapt (K051364) and S8 Aspen with H4i Plus (K091947).

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
V.P., Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

MAR 18 2011

Re: K102586
Trade/Device Name: S9 VPAP Adapt
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 21, 2011
Received: March 11, 2011

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. 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,

for

Anthony 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: S9 VPAP Adapt

Indication for Use.

The S9 VPAP Adapt is indicated for the treatment of patients weighing more than 66 lb (30 kg) with obstructive sleep apnea (OSA), central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.

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)

Page 1 of 1

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102586