Revised 510(k) Summary – VPAP Tx

[As required by 21 CFR 807.92 (c)]

Date Prepared	14 December 2011
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Classification Reference	21 CFR 868.5895
Product Code	73 MNS
Common/Usual Name	Ventilator, continuous, non-life-supporting
Proprietary Name	VPAP Tx
Predicate Device(s)	VPAP Tx (K092186)
Reason for submission	New Device

Indication For Use

The VPAP Tx is indicated for the treatment and titration of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing.

The VPAP Tx is intended to be used in a clinical environment.

Substantial Equivalence

The modified VPAP Tx device has the following similarities to the previously cleared predicate devices.

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

The change to the Indication For Use statement is a minor change to include the words "and titration", this minor change has been done for clarity only. Design and Verification activities were performed on the modified VPAP Tx as a result of the risk analysis and design requirements. Endurance testing was not repeated as the change relates to the inclusion of ASVAuto (software change only) and therefore, the test report D251-178 remains valid as supplied in the VPAP Tx (K092186) submission, and is held on file at ResMed. As the VPAP Tx device is technologically identical to the VPAP Tx (K092186), predicate therapy performance verification was directly applicable to the modified VPAP Tx device. ResMed has determined that the modified VPAP Tx device has not altered the safety and effectiveness of treatment for patients with respiratory insufficiency or Obstructive Sleep Apnoea (OSA) who weigh more than 66 lb (>30 kg).

The VPAP Tx complies with the applicable requirements:

- 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)
- 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 60601-1:1988 Ed 2, Medical electrical equipment - Part 1: General requirements for safety

Non-Clinical Testing

Performance testing of VPAP Tx has been conducted using Side-by-Side bench testing methodology to demonstrate that the modified VPAP Tx performs to design input specifications when compared to the VPAP Tx (K092186) clinical trial device. The VPAP Tx met the predetermined pass/fail criteria as defined in the VPAP Tx System Verification Report.

ResMed conducted extensive bench testing using both closed-loop and open-loop test scripts from patient models designed to verify that the ASVAuto algorithm in the VPAP Tx performs to specification. These tests included Adaptive servo-ventilation tests for the ASV functionality, and EPAP response tests to Flow Limitation, Snore and Apnea events for the auto-adjusting EPAP component. The bench test results demonstrated that the VPAP Tx met the predetermined pass/fail criteria.

Clinical Testing

There were 21 subjects who completed the trial, which documented the outcome of Enhanced ASV when compared to the predicate ASV treatment, and to demonstrate the Enhanced ASV is clinically non-inferior in terms of suppressing respiratory events in patients who are treated for central sleep apnea/periodic breathing.

There were no complications or adverse events recorded, as a result of this clinical trial.

Device Description

The modified VPAP Tx device has a similar operating principle, and the same technology and manufacturing process as the VPAP Tx (K092186). The hardware (electromechanical operation and materials) also remain unchanged from the predicate VPAP Tx (K092186). The therapy modes contained in the predicate VPAP Tx (K092186) provides CPAP, Auto-titrating, Bilevel, VAuto and ASV modes to treat OSA and/or respiratory insufficiency, central or mixed apneas or periodic breathing in patients weighing more than 66 lb. The device contains a micro-processor controlled blower system that generates airway pressures as required to maintain an "air splint" for effective treatment of OSA and/or respiratory insufficiency, central or mixed apneas or periodic breathing.

The change to the modified VPAP Tx device includes the addition of the ASVAuto therapy mode. The modified VPAP Tx system comprises the flow generator, patient tubing, mask (patient interface) and optional HumidAire 2i humidifier.

The performance and functional characteristics of the modified VPAP Tx includes all the clinician and user friendly features of the predicate device VPAP Tx (K092186).

Conclusion

The modified VPAP Tx is substantially equivalent to the previously cleared predicate device VPAP Tx (K092186).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
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Resmed Corporation
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MAY 25 2012

Re: K113714
Trade/Device Name: VPAP Tx
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: May 16, 2012
Received: May 24, 2012

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 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

Indication for Use

510(k) Number (if known):

Device Name: VPAP Tx

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

510(k) Number: K113714

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)