

K061200

RESMED

PRESTIGE Traditional 510(k) Premarket Notification

510(k) Summary – PRESTIGE CPAP System

Date Prepared 10th April, 2006 **JUL 20 2006**

Official Contact Dr Lionel King
V.P., Quality Assurance & Regulatory Affairs
ResMed Ltd
97 Waterloo Road
North Ryde, NSW 2113
Australia
Tel: +61 (2) 9886 5000
Fax: +61 (2) 9878 5517

Classification Reference 21 CFR 868.5905

Product Code 73 BZD

Common/Usual Name Non continuous ventilator (IPPB).

Proprietary Name PRESTIGE CPAP System

Predicate Device(s) S8 Prime (K013909)
S7 Elite (K033841)

Reason for submission New Device

Intended for Use

The PRESTIGE CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). It is intended for use at 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 PRESTIGE CPAP System as a result of the risk analysis and product requirements. All tests confirmed the product met the acceptance criteria. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment of patients with Obstructive Sleep Apnoea (OSA) who weighing more than 66 lb (>30 kg). The new device complies with the applicable standards and 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)

Intended Use

The PRESTIGE CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). It is intended for use at home.

Device Description

The PRESTIGE CPAP System is similar to the predicate devices, (S8 Prime and S7 Elite CPAP System *with H2i*) with a new and improved micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH₂O 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 PRESTIGE CPAP system includes all the clinician and user friendly features of the predicate devices, S8 Prime and S7 Elite CPAP System.

Conclusion

The PRESTIGE CPAP System is substantially equivalent to the Predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 2006

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

Re: K061200

Trade/Device Name: Prestige CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 10, 2006
Received: May 1, 2006

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 Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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: PRESTIGE CPAP System

Indication for Use

The PRESTIGE CPAP system is indicated for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (>30 kg). It is intended for use at home.

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)



Amy Wilson
Department of Anesthesiology, General Hospital,
Infection Control, Dental Devices
Device Number: K061200