

**510(k) Summary - S8 Prime CPAP System**

K0338A1

Date Prepared	Dec 5 <sup>th</sup> , 2003
Official Contact	Dr Lionel King V.P., 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	BZD - Non-Continuous Ventilator
Common/Usual Name	CPAP System
Proprietary Name	S8™ Prime CPAP System
Predicate Device(s)	ResMed, S7™ Elite CPAP System <i>with</i> ResLink (K024191) ResMed, Sullivan III (K930656)
Reason for submission	New Device
Indications for Use	The S8 Prime CPAP System is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Prime CPAP System is intended for home and hospital use.

## Substantial Equivalence

The new device has the following similarities to the previously cleared predicate device(s).

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

Design and Verification activities were performed on the S8 PRIME 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 OSA in adults. The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Reviewer Guidance for Premarket Notifications, November 1993
- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA reviewer's and industry, Guidance for the content of premarket submissions for software contained in medical devices, May 1998

## Intended Use

The S8 Prime CPAP System is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Prime CPAP System is intended for home and hospital use.

## Device Description

The S8 Prime CPAP System is similar to the predicate devices, (Sullivan III and S7 Elite CPAP System) it is smaller and lighter, with a new and improved micro-processor controlled blower system that generates Continuous Positive Airway Pressure (CPAP) from 4-20 cmH<sub>2</sub>O as required to maintain an "air splint" for effective treatment of OSA. The system comprises the Flow Generator, patient tubing, mask (patient interface) and Smart Card (SC) Module or DB9 Adapter for receiving and sending data.

The performance and functional characteristics of the S8 PRIME CPAP system includes all the clinician and user friendly features of the predicate devices, Sullivan III and S7 Elite CPAP System.



Dr Lionel King  
V.P., Regulatory Affairs  
ResMed.

Friday, December 05, 2003



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 10 2004

ResMed Ltd.  
C/O Mr. David D'Cruz  
VP Regulatory & Clinical Affairs US  
ResMed Corp.  
14040 Danielson Street  
Poway, CA 92064-6857

Re: K033841  
Trade/Device Name: ResMed S8 Prime CPAP System  
Regulation Number: 21 CFR 868.5905  
Regulation Name: Ventilator, Non-Continuous (Respirator)  
Regulatory Class: Class II  
Product Code: BZD  
Dated: December 5, 2003  
Received: December 10, 2003

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

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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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.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

## Indications for Use

510(k) Number (if known): K033841

Device Name: S8 Prime CPAP System

Indications For Use: The S8 Prime CPAP System is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The S8 Prime CPAP System is intended for home and hospital use.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

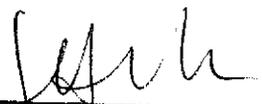
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number:   K033841  

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