K030797

510(k) Summary

MAR 1 0 2004

S7™ Elite and AutoSet® Spirit™ CPAP Systems with SomnoTraxx™ System™

Date Prepared	November 21, 2003
Official Contact	David D'Cruz VP, US Clinical and Regulatory Affairs ResMed Corp. 14040 Danielson St Poway, CA 92064 (858) 746-2238
Classification Reference	21 CFR 868.5905
Product Code	BZD - Non-Continuous Ventilator
Common/Usual Name	CPAP System
Proprietary Name	**S7™ Elite and AutoSet® Spirit™ CPAP Systems with SomnoTraxx™ System™**
Predicate Device(s)	ResMed, S7™ Elite CPAP System (K013909) ResMed, AutoSet® Spirit™ CPAP System (K013843) HomMed Sentry III Patient Monitoring System with Card Reader K014025 HomMed Central Station K020184
Reason for Submission	Modified design - additional accessory
Indications for Use	The SomnoTraxx System is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by providing wireless transmission and display of usage and therapeutic information. It is intended for home use only in conjunction with ResMed S7 Elite and AutoSet Spirit CPAP Systems Positive Airway Pressure flow generators. SomnoTraxx System is not intended to provide automated treatment decisions nor to be used as a substitute for a competent healthcare professional's judgment. All patients' medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional. The S7 Elite and AutoSet Spirit CPAP Systems are indicated for the treatment of obstructive sleep apnea (OSA) in adult patients.

Description

The S7™ Elite (K013909) and AutoSet® Spirit™ (K013843) CPAP Systems are microprocessor controlled blower-based systems that generate Continuous Positive Airway Pressure (CPAP) from 4-20 cmH2O as required to maintain an "air splint" for effective treatment of Obstructive Sleep Apnea (OSA).

The system includes the flow generator, patient tubing and a mask (patient interface). For additional humidification, several humidifiers, including the integrated HUMIDAIRE 2i, are designed to be compatible with the flow generators. AutoScan software allows viewing of flow-generator stored treatment data via a PC, transmitting the data using a direct connection or a modem.

Description of Device Modifications

The SomnoTraxx™ System is designed to be used with ResMed's S7™ Elite and AutoSet® Spirit™ CPAP Systems for the transfer, storage, retrieval and display of stored information from the flow generators to the clinician, via wireless transmission and web-based access. Access to the data is limited to subscribers of the system. There is no patient access to the system.

The SomnoTraxx™ System is comprised of two distinct components, the ResTraxx™ and the Server System. Data are extracted from the flow generator, transmitted via a wireless network, stored in a database, transmitted via the Internet and displayed for review by a healthcare provider. Both components must be present in order for the SomnoTraxx™ System to function.

ResTraxx™ – ResTraxx™ is an optional wireless module designed to attach to a ResMed S7™ Elite or AutoSet® Spirit™ flow generator using a docking mechanism. This mechanism allows the device to be electrically connected via the existing 15-pin expansion port located at the rear of the flow generator. When attached, the ResTraxx™ can automatically collect usage and therapeutic information stored within the flow generator's memory.

The ResTraxx™ sends and receives information utilizing existing messaging networks providing wireless coverage to large portions of the US population.

Server System – The Server System consists of several functional software modules that are designed to retrieve information from flow generators through the ResTraxx™ and a wireless messaging network, store the information in a database and provide a secure interface into the system allowing users (not patients) to schedule information retrieval and view the results.

Substantial Equivalence

The modified device has the following similarities to the previously cleared devices:

- Similar intended use
- Similar operating principles
- Similar technologies
- Same manufacturing processes

Design Verification and Validation were performed on the S7 Elite™ & AutoSet® Spirit™ CPAP Systems with SomnoTraxx™ System, in accordance with the risk analysis and product requirements. All tests confirmed the product meets the acceptance criteria. ResMed has determined that the modified design has no impact on the safety and effectiveness of the device. The S7™ Elite& AutoSet® Spirit™ CPAP system with SomnoTraxx™ System is equivalent to the S7™ Elite& AutoSet® Spirit™ CPAP system without SomnoTraxx™System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2004

Mr. David D'Cruz
ResMed Corporation
VP, Regulatory Affairs
14040 Danielson Street
Poway, California 92064-6857

Re: K030797
Trade/Device Name: S7 Elite and AutoSet Spirit CPAP Systems with Somno Traxx System
Regulation Number: 868.5905
Regulation Name: Non-Continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: January 8, 2004
Received: January 12, 2004

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.

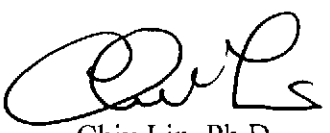
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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 (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 (Revised)

510(k) Number (if known): K030797

Device Name
S7™ Elite and AutoSet® Spirit™ CPAP Systems with SomnoTraxx™ System

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) XXX OR Over-The-Counter Use _____

(Optional Format 1-2-96)

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

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