K024191

510(k) SUMMARY— S7™ Elite and AutoSet® Spirit™ CPAP Systems with ResLink™

Date Prepared	December 17th, 2002
Official Contact	David D'Cruz VP 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	S7™ Elite and AutoSet® Spirit™ CPAP Systems with ResLink™
Predicate Device(s)	ResMed, S7™ Elite CPAP System (K013909) ResMed, AutoSet® Spirit™ CPAP System (K013843)
Reason for submission	Modified design; additional accessories
Indications for Use	The S7™ Elite and AUTOSET® SPIRIT™ CPAP System is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The optional integrated humidifier (HUMIDAIRE® 2i™) is indicated for the humidification and warming of air from the S7™ Elite or AUTOSET® SPIRIT™ flow generator device. The S7™ Elite and AUTOSET® SPIRIT™ CPAP System and HUMIDAIRE® 2i™ are for home and hospital use.

Device 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 cmH_2O 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.

ResLink is intended to be used with the ResMed S7 Elite and AutoSet Spirit CPAP systems. ResLink provides collection, storage and transfer of treatment data for review by a clinician. In addition to storing treatment data, ResLink can also store pulse oximetry information if a pulse oximeter is connected to it.

ResLink is designed to attach to the flow generator using a docking mechanism. This mechanism allows the device to be electrically connected via a 15-pin expansion port located at the rear of the flow generator. A removable SmartMedia card (SMC) is inserted into ResLink prior to use. Patient data can then be automatically collected when the flow generator is in use. As instructed by the clinician, the patient will remove the SMC and return to the clinic, where the clinician can download the stored data onto a personal computer (PC). The clinician can view the data using AutoScan® software.

Device Modification
Modifications to the S7 Elite and AutoSet Spirit CPAP Systems consist of the following:

- Inclusion of ResLink as an accessory to the cleared S7 Elite and AutoSet Spirit CPAP systems, which provides additional memory and allows for the collection, storage and transfer of:
  - Data already stored in the flow generators,
  - Data, including pressure and leak, collected by the flow generator at a higher sampling rate than the data that is stored in the predicate flow generator, and
  - Additional data, including minute ventilation, snore index, flattening index, SpO_2, and pulse rate. (Pulse oximetry data is recorded through a separate port in ResLink using a Nonin pulse oximeter.); and

- Updated S7 Elite and AutoSet Spirit software from SX116-0203 to SX116-0302 to enable the flow generator and ResLink to communicate and to provide additional display messages on the flow generator LCD to provide feedback to the user on the correct connection and use of ResLink.

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

- Same Intended Use
- Same Operating Principle
- Similar Technologies
- Similar Manufacturing Process

Design Verification and Validation were performed on the S7 Elite and AutoSet Spirit CPAP Systems with ResLink, 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 and AutoSet Spirit CPAP system with ResLink is equivalent to the S7 Elite and AutoSet Spirit CPAP system without ResLink.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Mr. Roger Kotter
ResMed Ltd.
c/o ResMed Corporation
14040 Danielson Street
Poway, CA 92064-6857

Re: K024191
Trade/Device Name: S7 Elite and AutoSet Spirit CPAP with ResLink
Regulation Number: 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 2, 2003
Received: April 4, 2003

Dear Mr. Kotter:

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.

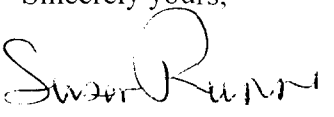
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024191

Device Name: S7™ Elite and AutoSet® Spirit™ CPAP Systems with ResLink™

Indications for Use:

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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: K024191

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

(Optional Format 1-2-96)