

K032480

510(k) SUMMARY— AutoSet Spirit System

OCT 16 2003

Date Prepared 17th September, 2003

Official Contact Lionel King
Director, Regulatory Affairs
ResMed Ltd
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North Ryde, NSW 2113
Australia
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Classification Reference 21 CFR 868.5905

Product Code BZD - Non-Continuous Ventilator

Common/Usual Name CPAP System

Proprietary Name AutoSet[®] Spirit[™] System.

Predicate Device(s) ResMed, AutoSet[®] Spirit[™] CPAP System (K013843)

Reason for submission Updated Indication for Use

Indications for Use "The AUTOSET SPIRIT self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The AUTOSET SPIRIT self-adjusting sleep apnea system has two treatment modes (auto-titrating and fixed-pressure CPAP).

The optional integrated humidifier (HUMIDAIRE 2i) is indicated for the humidification and warming of air from the AUTOSET SPIRIT flow generator device. The AUTOSET SPIRIT self-adjusting sleep apnea System and HUMIDAIRE 2i are for home and hospital use."

Device Description

The AutoSet Spirit (K013843) CPAP System is a microprocessor controlled blower-based system that self-adjusts the pressure from 4–20 cmH₂O as required to maintain an “air splint” for effective treatment of Obstructive Sleep Apnea (OSA) in adult patients. The system includes the flow generator, patient tubing, integrated humidifier and a mask (patient interface).

Device Modification

Modification to the Indication for Use was made in the User’s and Clinician’s Manuals to more accurately reflect the terminology used in ISO 17510-1:2002, Sleep Apnoea breathing therapy devices undersection 3, Terms and Definitions, sub section 3.16, self-adjusting sleep apnoea breathing therapy devices. The Indication for Use from the predicate submission (K013843) has only been rephrased. This change does not alter the fundamental Indication for Use as cleared by the FDA for the predicate device.

Substantial Equivalence

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

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

The only changes that were made relate to revised wording for the Indications for Use. Therefore, design Verification and Validation were not performed on the AutoSet Spirit System as there are no engineering changes required to the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Mr. David D'Cruz
V.P. U.S. Clinical & Regulatory Affairs
Resmed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K032480
Trade/Device Name: Autoset Spirit System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: July 25, 2003
Received: August 12, 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.

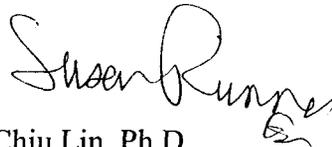
Page 2 – Mr. D’Cruz

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,

A handwritten signature in black ink, appearing to read "Susan Runger". The signature is written in a cursive style with a small flourish at the end.

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

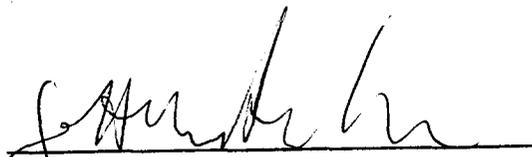
510(k) Number (if known): _____

Device Name: AutoSet® Spirit™ System

Indications for Use:

"The AUTOSET SPIRIT self-adjusting sleep apnea system is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients. The AUTOSET SPIRIT self-adjusting sleep apnea system has two treatment modes (auto-titrating and fixed-pressure CPAP).

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

510(k) Number: K032480

(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)

OR

Over-The-Counter
Use _____

(Optional Format 1-2-96)