2. SAFETY AND EFFECTIVENESS (SUMMARY)

2.1 Indications for Use

The 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 AUTOSET SPIRIT flow generator device. The AUTOSET SPIRIT CPAP System and HUMIDAIRE 2i are for home and hospital use.

2.2 Brief Device Description

The AUTOSET SPIRIT CPAP System is a non-invasive Continuous Positive Airway Pressure (CPAP) system. It includes the following system components:

- Flow generator device,
- Humidifier
- Mask and air tubing,
- Clinical Interface (AutoScan) Software.

The flow generator device incorporates a blower (motor/fan assembly), sensors and processing electronics. The blower supplies pressurized air to the patient via the air tubing and a mask.

The AUTOSET SPIRIT flow generator has two (2) modes of operation:

(i) CPAP Mode

In this mode the flow generator provides a single fixed-pressure as set by the clinician.

(ii) Auto-titrating (AutoSet) Mode

In this mode the pressure is automatically set in response to the patient's breathing patterns.

The AutoScan software allows adjustment of parameter settings and viewing of flow generator-stored treatment data via a PC.

2.3 Substantial Equivalence

This submission demonstrates Substantial Equivalence of the AUTOSET SPIRIT CPAP System (including the integrated humidifier) with the predicate ResMed Sullivan AutoSet CPAP System (K980721) and the predicate ResMed Sullivan HumidAire Heated Humidifier (K971260). (The Sullivan AutoSet CPAP System was cleared for use with the Sullivan HumidAire Heated Humidifier.)

The AUTOSET SPIRIT flow generator and the HUMIDAIRE 2i integrated humidifier are developments from the predicate Sullivan AutoSet flow generator and Sullivan HumidAire devices and share many design features.

The AUTOSET SPIRIT CPAP System has been tested to the following standards and guidance documents:

- EN 60601-1 *Medical electrical equipment. Part 1: General requirements for safety.*
- EN 60601-1-2 *Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility.*
- IEC 529: *1989* *Degrees of protection provided by enclosures (Code IP).*
- ISO 8185:1997 *Humidifiers for medical use - General requirements.*
- PrEN ISO 17510 *Sleep Apnoea Therapy Devices* (1998).
- Reviewer Guidance for Premarket Notification Submissions, November 1993, ARDB, CDRH, FDA.
- FDA *Heated Humidifier Review Guide*, Shelf # 780, 8/30/91 (applicable requirements)

This submission presents the results of this testing, and together with detailed descriptions demonstrate Substantial Equivalence of the AUTOSET SPIRIT CPAP System to the predicate devices.

END – Traditional 510(k) Summary of Safety and Effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Mr. Roger Kotter
Senior Director of QA/RA
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K013843
Trade/Device Name: AUTOSET® CPAP System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 16, 2002
Received: April 19, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.2 Indications for Use

510(k) Number (if known): K013843

Device Name: AUTOSET® SPIRIT™ CPAP System

Indications for Use:

The 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 AUTOSET SPIRIT flow generator device. The AUTOSET SPIRIT CPAP System and HUMIDAIRE 2i are for home and hospital use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

n Sign-Off)
of Dental, Infection Control,
eral Hospital Devices
lumber K013843

Page __ of __