K080797

510(k) Summary – HumidAire 2i™

[As required by 21 CFR 807.92(c)]

JUL - 9 2008

Date Prepared	14th March 2008
Official Contact	Dr Lionel King V.P., Global Quality Assurance & Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2021
Classification Reference	21 CFR 868.5450 (Class II device)
Product Code	73 BTT
Common/Usual Name	Humidifier, respiratory gas, (direct patient interface)
Proprietary Name	HumidAire 2i™
Predicate Device(s)	AutoSet Spirit™ with H2i (K013843) - Primary VPAP ADAPT™ with H2i (K051364)
Reason for submission	New Device

Intended Use

The HumidAire 2i is indicated for the humidification of the air delivered from a ResMed compatible CPAP therapy device.

The HumidAire 2i is intended for single patient re-use in the home environment and multi-patient re-use in a hospital / institutional environment.

The HumidAire 2i is for use only as recommended by a physician.

Device Description

ResMed's HumidAire 2i™ is a humidifier designed to humidify the air delivered to the airway during continuous positive airway pressure (CPAP), automatic positive airway pressure (APAP) and bilevel therapy.

The HumidAire 2i™ is designed to form a single heated humidification unit when attached to a CPAP, APAP or bilevel device.

The HumidAire 2i™ is intended for single patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment.

Substantial Equivalence

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

- Similar intended use (modified only to include multiple patient re-use)
- Same operating principle
- Same technologies
- Same manufacturing process

Design and Verification activities were performed on the HumidAire 2i™ as a result of the risk analysis and product requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate device. The disinfection of the HumidAire 2i for re-use in a hospital/sleep lab environment has not altered the safety and effectiveness when used primarily in the management of patients with Obstructive Sleep Apnea (OSA).

The HumidAire 2i complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- Reviewer Guidance for Premarket Notification Submissions, November 1993, ARDB, CDRH, FDA
- Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft
- FDA Reviewer Guidance: "Labeling reusable medical devices for reprocessing in health care facilities" (Office of device evaluation, April 1996)
- FDA Heated Humidifier Review Guide

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
14040 Danielson Street
Poway, California 92064-6857

Re: K080797
Trade/Device Name: HumidAire 2i™
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: June 5, 2008
Received: June 27, 2008

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.

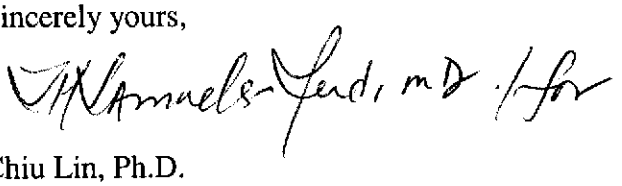
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indication for Use

510(k) Number (if known):

Device Name: **HumidAire 2i™**

Indication for Use

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Prescription Use ___X___ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

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