K030090

JAN 2 4 2003

SECTION 10

510(K) SUMMARY

Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Proprietary Name	H2 Heated Humidifier
Common/Usual Name	Respiratory Gas Humidifier
Classification Reference	21 CFR 868.5450
Classification	Class II
Appropriate Classification Panel	*Anesthesiology Devices*
Product Code	BTT – Humidifier, Respiratory Gas, (Direct Patient Interface)
Predicate Devices	*Respironics Heated Humidifier* (K012633) Fisher & Paykel HC100 Heated Humidifier (K915460)
Reason for submission	*Additional or expanded indications*

Substantial Equivalence

This premarket notification submission demonstrates that the H2 Heated Humidifier is substantially equivalent to a combination of the Respironics Heated Humidifier (K012633) and the Fisher & Paykel HC100 Heated Humidifier (K915460). The software in the H2 Heated Humidifier is unchanged from the software provided in K012633.

The design of the humidifier was verified through the use of design verification and validation testing. The Hazards Control Measures Traceability Matrix provided in Appendix B of the Risk Analysis assured that all hazards identified by the risk analysis were successfully mitigated.

This submission is seeking to extend the existing claims of the humidifier to include patients using mask applied positive pressure ventilation.

Indications for Use

The Respironics H2 Heated Humidifier is an accessory for positive pressure ventilation systems to provide moisture to the patient circuit.

It is intended for use with adult patients (> 30 kg), in the home or hospital/institutional environment, who use mask-applied positive pressure ventilation therapy.

Device Description

The H2 Heated Humidifier is a microprocessor-controlled system that has been designed to moisten and warm the air from a positive pressure ventilation device and thus help to compensate for the drying effect. The device is intended for use with the standard patient circuit that is used to connect the device to the patient interface (mask) and to the positive pressure ventilation device.

It is a Respiratory Gas Humidifier (heated Passover type) according to 21 CFR 868.5450. Heat is used to provide an evaporated water content to dry breathing gases.

The H2 Heated Humidifier has a thermoplastic enclosure with dimensions of 5.5 in. high x 6.5 in. wide x 5.25 in. deep and weighs 1.24 lbs. (without the chamber fitted), 1.63 lbs. (with the chamber fitted), and 2.5 lbs. (with the chamber fitted and filled with water). The unit is compromised of a metal heater plate that is controlled from control electronics, contained in a plastic enclosure that is directly supplied with AC power. The heater plate is positioned in the front of the unit. The humidification chamber slides onto the heater plate and is held in place by a rim on the enclosure. The unit controls are located on the top panel.

Accessories for the H2 Heated Humidifier include humidification chambers, breathing tubing and mounting arrangements.

During the review of the Respironics Heated Humidifier (K012633) submission, a baffle was added to the inlet of the humidifier water chamber in order to minimize the amount of water being blown out of the humidifier at high flow conditions. Without the baffle, a positive pressure ventilation device operating at pressures > 20 cm H_2O and flows < 325 LPM would cause the water in the chamber to splash and enter the outlet of the water chamber into the patient tubing. Verification testing has

demonstrated that the addition of the baffle to the inlet of the water chamber mitigated the water turbulence, which caused the water to spill into the patient circuit, observed at 30 cm H_2O under normal operating conditions and at 40 cm H2O under single fault conditions.

The software in the H2 Heated Humidifier is unchanged from the software provided in K012633.

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

Respironics, Incorporated
C/O Mr. Ned Devine, Jr.
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K030090
Trade/Device Name: H2 Heated Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: January 10, 2003
Received: January 10, 2003

Dear Mr. Devine:

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

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): K030090

Device Name: H2 Heated Humidifier

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The Respironics H2 Heated Humidifier is an accessory for positive pressure ventilation systems to provide moisture to the patient circuit.

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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)

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

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