K020332

Fisher & Paykel HEALTHCARE

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510(K) Summary

Contact person	Brett Whiston
Date prepared	4 April 2003
Trade name	MR850 Respiratory Humidifier
Common name	Respiratory Humidifier
Classification name	Respiratory Gas Humidifier (21 CFR § 868.5450)
Predicate device	MR850 Respiratory Humidifier, K983112 Airlife Breathing Circuit, K000697

Description of device

The MR850 Humidifier is a Respiratory Gas Humidifier (heated pass-over type) according to 21 CFR §868.5450. Heat is used to provide evaporated water content to dry breathing gases. Heated breathing tubes are also utilized in order to increase operating efficiency and reduce excessive water and heat loss.

The MR850 has a thermoplastic enclosure with dimensions of 140 mm high × 135 mm wide × 173 mm deep, and weighs 2.8 kg. A heater plate is positioned in the top of the unit, where the enclosure rim and finger guard allow a humidification chamber to be added. Temperature probe and heater wire connection sockets are on the right side of the unit. A serial data interface port is located in the underside of the unit, with a mounting bracket at the back of the device.

The unit controls and displays are located on the front panel. Controls consist of power, operating mode and alarm mute buttons. A setup / alarm display indicates if a part of the equipment is incorrectly installed, or type of alarm condition occurring.

Accessories for the MR850 Humidifier include humidification chambers, breathing circuits, electrical adaptors and temperature / flow probes.

The chamber slides on to the heater plate and contains the water supply for adding humidity to breathing gases. The breathing circuit transports gases to the patient, and includes sections for connection from ventilator to humidifier, inspiratory limb to the patient, and expiratory limb for return to the ventilator. Heated wires in the inspiratory and expiratory limbs prevent condensation. The electrical adaptor supplies power to the heated wires. The temperature / flow probe has sensors at the chamber and patient airway ends of the inspiratory section for heater control.

The MR850 Humidifier has two operating modes. Intubated Mode is used for patients who have bypassed upper airways, and delivers humidified gas to the patient at 37 °C (body temperature). Mask Mode is used for patients receiving breathing gases via a face mask, and delivers humidified gas to the patient at 31 °C. The MR850 Humidifier monitors temperature, flow parameters and equipment integrity, in order to maintain stable performance conditions. It will also notify the user of high delivered temperature, inadequate delivered humidity, or incorrect equipment set-up conditions.

Intended use

The MR850 Humidifier is intended to add moisture to, and to warm, the breathing gases for administration to a patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed.

This may be indicated for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. These gases may be delivered by face mask or through bypassing the upper airways, for example use of an endotracheal tube.

Technological Characteristics Summary

The technological characteristics of the MR850 Humidifier are equivalent to the predicate devices.

The MR850 is equivalent to the MR730 and HC500 Humidifiers in terms of: type (heated passover humidification), configuration (chamber, heated wire breathing circuits, dual-sensor temperature probe), power usage (same heater system ratings), performance (same temperature and humidity output), control method (electronic and PID algorithm microprocessor), and uses equivalent materials and some common components.

The MR850 is equivalent to the 7200 Ventilator in terms of the use of heated-wire flow-sensing technology for respiratory gas flow-sensing purposes.

Discussion of the Non-Clinical Tests

Non-clinical testing of the MR850 Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance capacity and accuracy.

The MR850 meets the requirements of the IEC 60601-1 and IEC 60601-1-2 electro-medical and EMC standards, and the relevant USA deviations to these in UL 2601-1. It meets the mechanical, electrical and environmental testing requirements of the 1993 FDA Reviewer Guidance for Premarket Notification Submissions. It complies with performance and safety requirements of the ISO 8185 and ASTM F1690 (USA) particular standards for Humidification Systems with the exception of clauses 51.6.2 and 51.7.

Discussion of the Clinical Tests

Clinical verification studies on the MR850 Humidifier demonstrated the safety, effectiveness and performance of the device. The humidifier was able to provide required temperature and humidification output across a variety of respiratory gas therapies. It required a low level of user intervention and had reduced susceptibility to user error factors. Modified technological components fulfilled their purpose of safety and effectiveness improvements, and did not introduce further hazards to user or patient.

Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the MR850 Humidifier indicates that it meets design and performance functional requirements. Clinical verification studies demonstrate the successful use of the humidifier and its ability to provide effective humidity levels. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from the particular standard for humidification systems.

This information indicates that the MR850 Humidifier is equivalent to or better than the predicate devices in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Mr. Brett Whiston
Regulatory Affairs
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Auckland, New Zealand

Re: K020332
Trade/Device Name: MR 850 Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: April 4, 2003
Received: April 8, 2003

Dear Mr. Whiston:

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

Indications for use statement

510(k) Number K020332

Device Trade Name Respiratory Humidifier

The Fisher & Paykel Healthcare MR850 Humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases.

The heated-wire breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas, to reduce condensation. They are accessories for the Fisher & Paykel Healthcare MR850 Respiratory Gas Humidifier. The RT130 is used for flow rates between 0.3 and 4 L/min, and the RT131 is for flow rates greater than 4 L/min, for neonatal patients.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Dazarak

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

510(k) Number: K020332

Prescription Use ✓
(per 21 CFR 801.109)