5 510(K) SUMMARY

K073706

MAR 31 2008

Fisher & Paykel Healthcare Limited
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Contact person Adele Bindon

Date prepared 21 December 2007

Trade name MR850 Respiratory Humidifier

Common name Respiratory Gas Humidifier

Classification name Respiratory Gas Humidifier
II (21 CFR § 868.5450), product code BTT

Predicate device K033710 Fisher & Paykel Healthcare MR850 Respiratory Humidifier

5.1 Description

The MR850 Respiratory Humidifier is designed to condition the ventilatory gases for patients requiring assisted breathing, by raising the water vapor content and temperature of the gases delivered to patients.

It consists of an electrically powered heat controller, utilizing a microprocessor with embedded software, to control a heating element that transfers heat to the water in a chamber. Breathing tubes enable the humidified gas to be transported to the patient. Depending on the chosen configuration, these tubes may be electrically heated, by means of a heater-wire placed internally to the tubes, to minimize the loss of humidity. An electrical adaptor provides electrical energy from the humidifier to the heater-wire in the breathing circuit and incorporates protection circuitry to prevent voltage and current transients on the heater-wire.

Temperature probes in the gas path provide feedback on temperature and flow of the gas to regulate temperature and humidity to the patient.

5.2 Intended use

Gases available for medical use do not contain sufficient moisture and heat, which may damage or irritate the respiratory tract by desiccation in patients whose supraglottic airways have been bypassed.

Heated humidification, as provided by the MR850 Respiratory Humidifier, may be used for patients requiring mechanical ventilation, positive pressure breathing assistance, or general medical gases. The MR850 humidifier is to be used on patients who are in the hospital/institutional environment.

5.3 Technological characteristics comparison

The modified MR850 Respiratory Humidifier is substantially equivalent to the predicate MR850 humidifier and uses the same method of control and delivery of humidity.

The MR850 Respiratory Humidifier differs from the predicate device in the electrical adaptor for the heated breathing circuit. In the predicate system, the heater-wire adaptor is simply an electrical connection to provide power to the heater-wires in the breathing tubes. In the modified MR850 system, the electrical heater-wire adaptor incorporates surge and over-current protection circuitry.

In the event of a surge condition, the adaptor disconnects the heater-wire for a period of time which is dependent on the transient magnitude (for up to 4 seconds), to minimize the risks associated with such fault conditions. As the MR850 humidifier detects the presence of a heater-wire, if the heater-wire remains disconnected during a detection cycle, then the humidifier will illuminate the warning indicators and audibly alarm for the duration of the disconnection, thus alerting the user to abnormal operating conditions. Once the heater-wire is reconnected, normal operation resumes.

In the event of an over-current condition (such as an incompatible heated circuit or a fault condition such as a short-circuit), the heater-wire is disconnected for a fixed period of 4 seconds. When the heater-wire is reconnected (and should the over-current condition persist) the heater-wire is disconnected again, and the humidifier continues to alarm, thus minimizing the risk associated with such a fault condition.

5.4 Non-clinical tests

Testing of the MR850 Respiratory Humidifier was compared to the MR850 (predicate) humidifier for performance and safety. These tests show that the MR850 Respiratory Humidifier has substantial equivalence to the MR850 (predicate) humidifier.

5.5 Conclusion

The MR850 Respiratory Humidifier is substantially equivalent to the MR850 (predicate) humidifier. The comparison of features, performance, and intended use demonstrate that the MR850 Respiratory Humidifier is at least as safe and effective for its intended purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2008

Ms. Adele Bindon
Regulatory Affairs Manager - RH
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14-348, Panmure
Auckland,
NEW ZEALAND

Re: K073706
Trade/Device Name: Fisher & Paykel Healthcare MR850 Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: February 27, 2008
Received: March 3, 2008

Dear Ms. Bindon:

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.

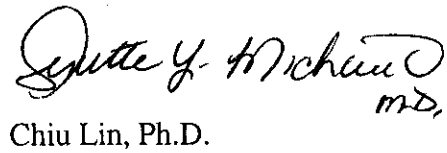
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

4 INDICATIONS FOR USE STATEMENT

510(k) Number

Device Name Fisher & Paykel Healthcare MR850 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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

)10(k) Number: K073706