K110019

MAR 30 2012

510(k) Summary

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Contact person	Adele Bindon
Date prepared	29 March 2012
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	K073706 MR850 Respiratory Humidifier

Device Description

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

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. A tube connects gas to the chamber input. Another tube connects to the chamber output and enables 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. The humidifier will control the amount of heat provided. 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.

The MR850 Respiratory Humidifier differs from the predicate device by the addition of a new version of software (version 7.25) which includes a humidity compensation feature to the normal heater plate control mode of the modified device. This feature enables the chamber output set temperature to be increased (via a proprietary algorithm) to increase the relative humidity at the patient airway probe position. This is a risk mitigator against specific foreseeable misuse as identified in the Hazard Analysis of the MR850.

Intended use

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 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.

Technological Characteristics

The following technological characteristics of the MR850 Respiratory Humidifier remain the same as the predicate device:

- Design
- Material
- Chemical composition
- Energy source
- Control mechanism
- Operating principle
- Environmental specifications
- Performance specifications
- Dimensional specifications

- Ergonomics of the patient/user interface?

This modification does involve a revision of the software to version 7.25 which will enable the introduction of a risk mitigator and the resolution of factory test issues.

Substantial Equivalence

The modified MR850 Respiratory Humidifier is substantially equivalent to the predicate MR850 Respiratory Humidifier and uses the same method of control and delivery of humidity. In addition, it has:

- The same intended use
- The same operating principle
- The same design
- The same material
- The same mechanism of action
- The same performance.

No modifications to the hardware of the MR850 system have been made with respect to the predicate.

Testing

Testing submitted as part of this 510(k) includes:

- Humidity Performance Testing
- Enthalpy Testing
- Humidity Control Performance Testing

The testing confirmed that the modification to software had no impact on the MR850 meeting the humidity limits and enthalpy limits as established in ISO 8185.

Conclusion

The MR850 Respiratory Humidifier is substantially equivalent to the predicate MR850 Respiratory Humidifier. The information submitted as part of this 510(k) demonstrates that the MR850 Respiratory Humidifier is as safe, as effective and performs as well as the predicate device.

This summary includes only information that is also covered in the body of the 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K110019
Trade/Device Name: Fisher & Paykel Healthcare 850 Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: March 23, 2012
Received: March 26, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number K110019

Device Name Fisher & Paykel Healthcare 850 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)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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