Fisher & Paykel
HEALTHCARE

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K983117

31 August, 1998

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **MR850 Respiratory Humidifier**
Classification Name: Humidifier, Respiratory Gas (Direct Patient Interface) - 73 BTT Anesthesiology Devices, 21 CFR §868.5450 (Class II)
Predicate Devices: Fisher & Paykel, MR730 Respiratory Humidifier, K913368
Fisher & Paykel, HC500 Respiratory Humidifier, K953392
Fisher & Paykel, MR290 Humidification Chamber, K934140
Puritan-Bennett, 7200 Microprocessor Ventilator, K902506

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The MR850 Humidifier 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. 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 140mm high × 135mm wide × 173mm deep, and weighs 2.8kg. A heaterplate 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 heaterplate 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.

510(k) Summary continued - Fisher & Paykel MR850 Respiratory Humidifier

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 and flow parameters, and equipment integrity, in order to maintain stable performance conditions and notify the user of high delivered temperature, inadequate delivered humidity, or incorrect equipment set-up conditions.

(a)(5) Statement of the 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.

(a)(6) Technological Characteristics Summary

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

(b)(1) 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.

510(k) Summary continued - Fisher & Paykel MR850 Respiratory Humidifier

(b)(2) 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.

(b)(3) 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.

signed: _____ date: 31 August 1998

Chris Mander
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1998

Mr. Chris Mander
Fisher & Paykel Healthcare
25 Carbine Road
P.O. Box 14-348
Panmure, Auckland
NEW ZEALAND

Re: K983112
Respiratory Humidifier - Model MR850
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: August 31, 1998
Received: September 4, 1998

Dear Mr. Mander:

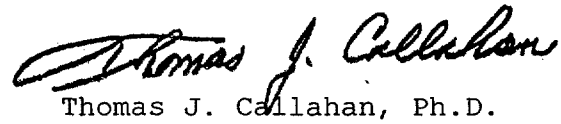
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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[510(k)] Number: K983/02

31 August, 1998

Fisher & Paykel MR850 Respiratory Humidifier

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare MR850 Humidifier is a Respiratory Gas Humidifier as per 73 BTT, 21 CFR §868.5450. It is intended to add moisture to and warm breathing gases for administration to a patient.

The MR850 is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation, positive pressure breathing assistance or general medical gases.
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. Heat is used to increase the water output of the humidifier. Heated breathing tubes are also utilized in order to increase operating efficiency and reduce excessive water and heat loss.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marianne Daniels 11-9-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983/02

Prescription Use ✓
(Per 21 CFR §801.109)