

K131957

5 510(k) Summary

Fisher & Paykel **HEALTHCARE**

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Date prepared	8 November 2013
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Trade name	MR810 System
Common name	Respiratory gas humidifier
Classification name	Respiratory gas humidifier II (21 CFR §868.5450), product code BTT
Predicate devices	K953392 HC500 Servo-Controlled Heated Respiratory Humidifier K100554 880 Respiratory Humidification System

DEC 04 2013

5.1 Device Description

The Fisher & Paykel Healthcare MR810 System is designed to condition respiratory gases for patients by raising the delivered water vapor content (humidity) and temperature of the gases.

The MR810 System consists of the following components:

- MR810 Respiratory Humidifier
- Accessories:
 - Breathing circuit (i.e. 900MR810 Adult Single Limb Circuit, 900MR810E Adult Dual Limb Circuit)
Note: The 900MR810 and 900MR810E breathing circuits have identical heated inspiratory limbs, however the 900MR810E also includes an expiratory limb (unheated) and a Y-piece (which connects the inspiratory and expiratory limbs).
 - Humidification chamber (as cleared in K934140 and K913368).

The device consists of an electrically powered heat controller, utilizing a microprocessor with embedded software, to control a heating element which transfer heat to the water in a humidification chamber and control power to the heated inspiratory limb of the breathing circuit.

A dryline tube (part of the breathing circuit) transports respiratory gases from a gas source (e.g. ventilator) to the humidification chamber where the gases are heated and humidified.

The inspiratory limb of the breathing circuit transports the heated and humidified gases from the humidification chamber to the patient. The inspiratory tube of the 900MR810 and 900MR810E breathing circuits is electrically heated by means of a heaterwire placed internally to the tube, which is controlled by the MR810 respiratory humidifier.

The MR810 respiratory humidifier also includes a built-in heaterwire adaptor. The heaterwire adaptor makes an electrical connection with the heated inspiratory limb of the breathing circuit for the purpose of powering the heated limb. The heater wire adaptor incorporates an ambient (room) temperature sensor and a chamber temperature sensor. The heaterwire adaptor also includes an embedded LED to visually indicate that the heated breathing circuit has been connected correctly.

The expiratory limb of the breathing circuit transports expired gas from the patient when a return flow of expired gases from the patient to the gas source is required (the 900MR810E Adult Dual Limb Breathing Circuit should be used as it includes an expiratory limb).

5.2 Intended Use

The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent non-invasive ventilator system or a continuous gas flow system.

The MR810 System is intended for non-invasive therapies only. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive ventilation is beneficial to prevent drying of the patient airways.

The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.

5.2.1 Indications for Use Comparison

The indications for Use Statements of the subject device, MR810 System, and the predicate device, HC500 Servo-Controlled Heated Respiratory Humidifier (K953392) are identical with the exception of the following:

- The subject device identifies compatible ventilators by function/intended purpose rather than examples of device types;
- The subject device is intended for use for non-invasive therapy only, whereas the predicate device is intended for use for both non-invasive of invasive therapies.

Refer to Table 1 for a side-by-side comparison of the Indications for Use Statements of the subject and predicate devices.

Table 1 Comparison of MR810 and HC500 Indications for Use

Device feature	MR810	HC500 (predicate)	Comment
Indications for use	The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent non-invasive ventilator system or a continuous gas flow system.	The intended use of the HC500 is to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using an artificial ventilation system. This includes use with systems such as portable volume ventilation systems, pressure support ventilation and continuous positive airway pressure (CPAP) devices.	Identical intended use – identification of all artificial ventilator systems that the MR810 System is to be used with using the systems' function/intended purpose rather than examples of device types.
		These systems may bypass the patient airway (using an endotracheal tube)	The subject device (MR810 System) is not recommended for invasive therapy (i.e. for patients with bypassed airways).

The MR810 System is intended for non-invasive therapy only.	or use mask ventilation.	Identical therapy – addition of the term 'non-invasive therapy' to describe 'mask ventilation'.
	Providing heat and humidification to these gases counteracts the effects of bypassing the nose, pharynx and trachea, where this function would not normally be carried out by the body.	The subject device (MR810 System) is not recommended for invasive therapy (i.e. for patients with bypassed airways).
Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive ventilation is beneficial to prevent drying of the patient airways.	Addition of heat and humidity to the supply of cold and dry respiratory gases provided through mask ventilation is similarly beneficial to prevent drying of the patient airways.	Identical operating principle – use of the term 'non-invasive therapy' to describe 'mask ventilation' to be consistent with the therapy statement above ('...intended for non-invasive therapy only').
The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.	The HC500 is primarily intended for a home-use situation, typically for patients requiring long-term respiratory assistance of a non-critical nature (i.e. not requiring hospital or intensive care levels of attention).	The environment for use of the subject device (MR810 System) has been extended to include hospital and long term care facilities, under the prescription of a qualified medical professional.

5.3 Technological Characteristics Comparison

5.3.1 Comparison to HC500 (K953392)

The subject device, MR810 System, and the predicate device, HC500 Servo-Controlled Heated Respiratory Humidifier (K953392), control the heaterplate temperature identically, however the related user controls (i.e. buttons) have been simplified in the subject device. Refer to Table 2 for a side-by-side comparison of the technological characteristics of the subject device, MR810 System, and the predicate device, HC500 Servo-Controlled Heated Respiratory Humidifier (K953392).

Table 2 Comparison of the MR810 and HC500 Technological Characteristics

Device Feature	MR810	HC500 (predicate)	Comment
Heaterplate temperature control	MR810 controls heaterplate temperature by adjusting delivered power.	HC500 controls heaterplate temperature by adjusting delivered power.	Identical

Device Feature	MR810	HC500 (predicate)	Comment
Switchable Heaterwire mode	Connection of compatible heated circuit changes operating mode to Heaterwire mode.	Front panel button ("Heaterwire" button) switches operating mode between Heaterwire mode and Non-Hose Heated mode	Heaterwire mode is the recommended mode of operation for the MR810. Disconnection of compatible heated circuit changes mode to Non-Hose Heated mode.
Patient-end set temperature: Heaterwire mode	Temperature setting: LOW: 28 to 29°C MED: 28 to 30°C HIGH: 31 to 32°C (Flow 5 to 20 L/min) Heaterplate maximum temperature: ≤ 70 °C (Software limit)	32 to 39 °C (dial allows intermediate values to be set). (Flow <30 L/min) Heaterplate maximum temperature: ≤ 100 °C (Software limit)	MR810 patient temperature is dependent on both ambient temperature and Temperature Setting HC500 maximum heaterplate temperature is set by solder pads on the PCB. Optional limits of 50, 80 and 90°C can be set.
Heaterplate set temperature:	Temperature setting: LOW: 45°C MED: 60°C HIGH: 70°C	Adjustable in the range 45 to 80 °C	MR810 controls to a fixed value for the heaterplate temperature dependent on the Temperature Setting

5.3.2 Comparison to MR880 (K100554)

The subject device, MR810 System, and the predicate device, MR880 Respiratory Humidification System (K100554), set the power delivered to the heaterwire identically (i.e. using an ambient sensor). The subject device controls the desired heaterplate setpoint to maintain the chamber output temperature whilst the predicate device controls the chamber output temperature directly.

Refer to Table 3 for a side-by-side comparison of the technological characteristics of the subject device, MR810 System, and the predicate device, MR880 Respiratory Humidification System (K100554).

Table 3 Comparison of the MR810 and MR880 Technological Characteristics

Device feature	MR810	MR880 (predicate)	Comment
Ambient (room) temperature sensor	Over moulded feature on heaterwire adapter	Over moulded feature on heaterwire adapter	Identical.
Heaterwire control using ambient sensor	MR810 uses ambient temperature to set the power delivered to the heaterwire	MR880 uses ambient temperature to set the power delivered to the heaterwire.	Identical. Sensor used to set delivered power to the heaterwire contained in inspiratory limb

Device feature	MR810	MR880 (predicate)	Comment
Chamber output control	MR810 controls heaterplate temperature to maintain desired chamber output temperature.	MR880 controls chamber output temperature.	MR880 controls chamber output temperature directly.
Breathing circuit - Adult	<ul style="list-style-type: none"> Single-heated breathing circuits (i.e. 900MR810, 900MR810E) Length: 1.5m (60") Diameter: 22mm (0.9")	<ul style="list-style-type: none"> Single-heated breathing circuits (i.e. RT241) Length: 1.8m (70.9") Diameter: 10.6mm (0.4")	<p>The MR810 and MR880 Systems are both offered with single-heated breathing circuit options only.</p> <p>The breathing circuits used with the MR880 System are longer and narrower than those used with the MR810, however both circuits are single-heated and are fitted with standard 22mm connectors as per ISO 5356-1.</p>

5.4 Non-Clinical Tests

The MR810 System is compliant with the same product standards as the previously cleared HC500 Servo-Controlled Heated Respiratory Humidifier (K953392) as follows:

Table 3 Comparison of MR810 and HC500 Standards

Standard	MR810	HC500 (Predicate device)	Comment
ISO 8185: 1997 Humidifiers for medical use - General requirements for humidification systems	Compliant with ISO 8185:1997	Compliant with ISO 8185:1997	Identical
IEC 60601-1: 1988 Medical Electrical Equipment - Part 1: General Requirements for Safety, Amendment 1, 1991, Amendment 2, 1995	Compliant with IEC 60601-1:1998 +A1:1991 +A2:1995	Compliant with IEC 60601-1:1998 +A1:1991 +A2:1995	Identical
IEC 60601-1-2: 2001 Medical electrical equipment. Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility - requirements and tests, Amendment 1	Complaint with IEC 60601-1-2:2001	Complaint with IEC 60601-1-2:2001	Identical

The MR810 System is compliant with the same product standards as the previously cleared MR880 Respiratory Humidification System (K100554) as follows:

Table 4 Comparison of MR810 and MR880 Standards

Standard	MR810	MR880 (predicate)	Comment
ISO 5367:2000 Breathing tubes intended for use with anaesthetic apparatus and ventilators	Single-heated breathing circuit accessories (i.e. 900MR810, 900MR810E) compliant with ISO 5367:2000	Single-heated breathing circuit accessories (i.e. RT241) compliant with ISO 5367:2000	Identical

Compliance of the subject device, MR810 System, and the:

- Predicate device HC500 Servo-Controlled Heated Respiratory Humidifier (K953392); and
- Single-heated breathing circuit accessories provided with the MR880 Respiratory Humidification System (K100554)

to the same device standards supports substantial equivalence of these products.

In addition, testing to ISO 8185:2007, the particular standard for humidification systems, supports performance of the subject device in accordance with the intended use and substantial equivalence to the predicate device HC500 Servo-Controlled Heated Respiratory Humidifier (K953392).

As summarized in Table 5 below, the humidity output of both the subject device, MR810 System, and the predicate device, HC500 Servo-Controlled Heated Respiratory Humidifier (K953392), is >10 mg/L and the enthalpy is of both the subject and predicate devices is <194 kJ/kg dry gas and therefore the performance of the devices is substantially equivalent.

Note: ISO 8185 requires that the predicate device also meet additional performance requirements for humidification systems intended for use with bypassed airways. These additional requirements are not applicable to the subject device as it is intended for non-invasive use only.

Table 5 Comparison of MR810 and HC500 humidification system performance as per ISO 8185:1997

Device feature	Requirement	MR810	HC500 (predicate)	Comment
Humidity performance, Heaterwire mode – for non-invasive use	≥ 10 mg/L (as required by ISO 8185:1997 for all humidification systems)	> 10 mg/L Flow: 5 to 60 L/min	> 10 mg/L Flow: 5 to 60 L/min	Identical

Device feature	Requirement	MR810	HC500 (predicate)	Comment
Humidity performance, Heaterwire mode – for invasive use (i.e. patients with bypassed airways)	≥ 33 mg/L (as required by ISO 8185:1997)	Not applicable – the MR810 System is intended for non-invasive use only	≥ 33 mg/L	The MR810 not intended for use with bypassed airways and therefore the humidity performance requirements (as per ISO 8185) are different
Enthalpy	< 194 kJ/kg dry gas (as required by ISO 8185:1997 for all humidification systems)	< 194 kJ/kg dry gas	< 194 kJ/kg dry gas	Identical

5.5 Clinical Tests

Not applicable – no clinical testing was performed with respect to the MR810 System.

5.6 Conclusion

The comparison of the intended use and temperature control system demonstrate that the MR810 System is substantially equivalent to the predicate device, Fisher & Paykel Healthcare HC500 Servo-Controlled Heated Respiratory Humidifier (K953392), and the comparison of the temperature sensor and hardware control demonstrate that the MR810 System is substantially equivalent to the predicate device, Fisher & Paykel Healthcare 880 Respiratory Humidification System (K100554). In addition, bench testing demonstrates that the MR810 System conforms to the particular standard for humidification systems, ISO 8185, supporting performance in accordance with the intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 4, 2013

Fisher & Paykel Healthcare
Ms. Elizabeth Goldstein
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Re: K131957
Trade/Device Name: MR810 System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: October 31, 2013
Received: November 4, 2013

Dear Ms. Goldstein:

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 contact 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>. 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,

Erin  Keith

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131957

Device Name
MR810 System

Indications for Use (Describe)

The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent non-invasive ventilator system or a continuous gas flow system.

The MR810 System is intended for non-invasive therapies only. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive ventilation is beneficial to prevent drying of the patient airways.

The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

James J. Lee

Digitally signed by James J. Lee

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