K132017

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5 510(k) Summary

Fisher & Paykel HEALTHCARE

15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Contact person/submitter	Elizabeth Goldstein
Date prepared	26 March 2014
Contact details	Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0148
Trade name	HC550 System
Common name	Respiratory gas humidifier
Classification name	Respiratory gas humidifier II (21 CFR §868.5450), product code BTT
Predicate device	K073706 Respiratory Humidifier, Model 850

5.1 Device Description

The Fisher & Paykel Healthcare HC550 System is designed to condition gases for patients by raising the delivered water vapor content (humidity) and temperature of the gases.

The HC550 System consists of the following components:

- HC550 Respiratory Humidifier
- Accessories:
    a) Breathing circuit (compatible adult breathing circuits as cleared in K983112, K020332, K034026, K103767, K122432)
    b) Humidification Chamber (as cleared in K934140[1] and K913368)
    c) Heaterwire Adaptor (as cleared in K073706)
    d) Temperature/Flow Probe (as cleared in K983112)
    e) RT008 Air Entrainer (optional oxygen therapy accessory) (as cleared in K953711)

The device 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 humidification chamber.

A dryline tube (part of the breathing circuit) transports respiratory gases from a flow 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 may be electrically heated by means of a heater-wire placed internally to the tube, which is controlled by the HC550 respiratory humidifier.

The expiratory limb of the breathing circuit transports expired gas from patient. In the case of a dual-heated breathing circuit, this limb may also be heated in the same manner as the inspiratory limb.

If a heated breathing circuit is used, the heaterwire adaptor provides electrical energy from the respiratory humidifier to the heaterwire in the breathing circuit.

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

Note 1: The MR290 Autofeed Humidification Chamber was originally cleared for market under K934140. Since clearance, there have been two changes to the materials used to construct the device. The device, as currently constructed (i.e. with materials which have been modified since clearance under K934140) has been cleared for market under K131957.

5.2 Intended Use

HC550 System:

The Fisher & Paykel HC550 System is designed for use with artificial ventilation systems. Portable volume ventilation systems, pressure support ventilation and Continuous Positive Airway Pressure (CPAP) systems may incorporate an HC550 to provide therapeutic levels of warm humidified air to adult patients with artificial airways or through mask ventilation.

The operating flow range is 5 to 120L/min depending on the patient interface.

The HC550 is designed for use in long term care facilities or the home under the prescription of a qualified medical professional.

5.2.1 Intended Use Comparison

The intended uses of the subject device, HC550 System, and the predicate device, MR850, are identical with the exception of the following:

- The environment for use.

Table 1 provides a comparison of the intended use of the HC550 and MR850, where differences are highlighted in gray.

Table 1 HC550 and MR850 intended use comparison summary

Device feature	HC550 (modified)	MR850 (predicate)
Purpose and function	Addition of therapeutic levels of heat & humidity to inspired respiratory gases	Addition of therapeutic levels of heat & humidity to inspired respiratory gases
Patient population	Patients requiring mechanical ventilation or positive pressure breathing assistance, via face non-invasive or invasive	Patients requiring mechanical ventilation or positive pressure breathing assistance, via face non-invasive or invasive
Environment for use	Long term care facilities or the home *Note: The power output of the HC550 has been software limited for home use. Refer to §5.3.*	Hospital

5.3 Technological Characteristics Comparison

The electrical hardware of the subject device, HC550 System, and the predicate device, MR850, are *identical* and therefore the HC550 System is physically and electrically compatible with accessories designed for the MR850 system. However, although the MR850 may be used with adult, infant or neonatal breathing circuits, the HC550 System is being submitted for use with adult breathing circuit accessories.

Table 2 provides a comparison of the accessories for the HC550 and MR850, where differences are highlighted in gray.

Table 2 HC550 and MR850 accessories comparison summary

Device feature	HC550 (modified)	MR850 (predicate)
Humidification chamber	Fisher & Paykel Healthcare humidification chambers	Fisher & Paykel Healthcare humidification chambers
Breathing circuit - Adult	• Single-heated • Dual-heated • Non-heated	• Single-heated • Dual-heated • Non-heated

Device feature	HC550 (modified)	MR850 (predicate)
Breathing circuit – Infant/Neonatal	None	• Single-heated • Dual-heated • Non-heated
Electrical adaptor	Fisher & Paykel Healthcare Dual Limb Smart Adaptor and Single Limb Smart Adaptor	Fisher & Paykel Healthcare Dual Limb Smart Adaptor and Single Limb Smart Adaptor
Temperature / flow probe	Fisher & Paykel Healthcare Temperature / Flow Probes	Fisher & Paykel Healthcare Temperature / Flow Probes
Oxygen therapy	RT008 Air Entrainer	RT008 Air Entrainer
Mounting accessories	Fisher & Paykel Healthcare ventilator brackets	Fisher & Paykel Healthcare ventilator brackets

The HC550 and MR850 have *identical* physical characteristics, with minor aesthetic differences.

Table 3 provides a comparison of the physical descriptions of the HC550 and MR850, where differences are highlighted in gray.

Table 3 HC550 and MR850 physical descriptions comparison summary

Device feature	HC550 (modified)	MR850 (predicate)
Height	140 mm (5.5 in)	140 mm (5.5 in)
Weight	2.8 kg (6.2 lb)	2.8 kg (6.2 lb)
Finger guard (color)	White	Blue
Lens (Button location and opacity)	2 button design Opaque display	3 button design Clear display

The heating hardware and electrical specifications of the HC550 and MR850 are *identical*, however the power has been software limited for use in the home.

Table 4 provides a comparison of the functional characteristics of the HC550 and MR850, where differences are highlighted in gray.

Table 4 HC550 and MR850 functional characteristics comparison summary

Device feature	HC550 (modified)	MR850 (predicate)
Heater-plate	Aluminum 100 mm Ø	Aluminum 100 mm Ø
Voltage	115 Vac	115 Vac
Frequency	50 or 60 Hz	50 or 60 Hz
Current	2.0 A maximum	2.0 A maximum
Power	150 W (Software limited to 105W)	150 W

5.4 Non-Clinical Tests

The HC550 is compliant with the same product standards (or equivalent product standards) as the predicate device, MR850.

Table 5 provides a comparison of the product standards for the HC550 and MR850.

Table 5 HC550 and MR850 functional characteristics comparison summary

Standard	HC550 (Modified device)	MR850 (Predicate device)
ISO 8185: 1997	Compliant with ISO 8185:1997	Compliant with ISO 8185:1997
IEC 60601-1: 1988	Compliant with IEC 60601-1:1998 +A1:1991 +A2:1995	Compliant with IEC 60601-1:1998 +A1:1991 +A2:1995
IEC 60601-1-2	Compliant with IEC 60601-1-2:2007	Compliant with IEC 60601-1-2:2001

Compliance of the subject device, HC550 System, and the predicate device, MR850, 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 (i.e. to heat and humidify gases) and substantial equivalence to the predicate device, MR850. As summarized in Table 6 below, the humidity output of both the subject device, HC550 System, and the predicate device, MR850, meets the performance requirements and the enthalpy requirements as specified in ISO 8185:2007 and therefore the performance of the devices is substantially equivalent.

Table 6 HC550 and MR850 functional characteristics comparison summary

Standard	HC550 (Modified device)	MR850 (Predicate device)
Humidity performance (for non-invasive mode)	≥ 10 mg/L over the recommended flow ranges (as required by ISO 8185)	≥ 10 mg/L over the recommended flow ranges (as required by ISO 8185)
Humidity performance (for invasive mode)	≥ 33 mg/L over the recommended flow ranges (as required by ISO 8185)	≥ 33 mg/L over the recommended flow ranges (as required by ISO 8185)
Enthalpy	< 194 kJ/kg dry gas (as required by ISO 8185)	< 194 kJ/kg dry gas (as required by ISO 8185)

5.4.1 Biocompatibility

The HC550 System was assessed for biocompatibility in accordance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing* and 510(k) Memorandum - #G95-1 *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'.*

The method of assessing biocompatibility of the subject device, HC550 System, is *identical* to the method of assessing biocompatibility of the predicate device, MR850.

All equivalent components of the HC550 and MR850 Systems have been assessed as having *identical* patient contact and duration of contact. All patient-contacting accessories which are accessories to the subject device, HC550 System, are also accessories to the predicate device, MR850, i.e. all patient-contacting devices are *identical* and no new patient-contacting accessories are being presented as part of this 510(k) submission.

A summary of the biocompatibility assessments of the HC550 and MR850 is provided in Table 7 below.

System component	Summary of biocompatibility – HC550 (Modified device)	Summary of biocompatibility – MR850 (Predicate device)	Comments
Respiratory humidifier	Non-patient contact device (no biocompatibility testing required)	Non-patient contact device (no biocompatibility testing required)	*Identical*
Breathing circuit accessories	External communicating device (tissue/bone/dentin); permanent contact	External communicating device (tissue/bone/dentin); permanent contact	*Identical* All breathing circuits recommended for use with the HC550 and/or MR850 have been previously cleared. Biocompatibility testing for breathing circuit

			accessories is as per the relevant 510(k) submissions. Refer to 510(k) K983112, K020332, K122432.
Humidification chamber accessories	External communicating device (tissue/bone/dentin); permanent contact	External communicating device (tissue/bone/dentin); permanent contact	*Identical* All humidification chambers recommended for use with the HC550 and/or MR850 have been previously cleared. Biocompatibility testing for humidification chamber accessories is as per the relevant 510(k) submissions. Refer to 510(k) K934140[1], K913368. Note 1: The MR290 Autofeed Humidification Chamber was originally cleared for market under K934140. Since clearance, there have been two changes to the materials used to construct the device. The device, as currently constructed (i.e. with materials which have been modified since clearance under K934140) has been cleared for market under K131957.
Temperature / flow probe accessories	• Primarily non-patient contact • Flow probe stem is an external communicating device (tissue/bone/dentin); permanent contact	• Primarily non-patient contact • Flow probe stem is an external communicating device (tissue/bone/dentin); permanent contact	*Identical* All temperature/flow probes recommended for use with the HC550 and MR850 have been previously cleared. Biocompatibility testing for temperature/flow probe accessories is as per the relevant 510(k) submissions. Refer to 510(k) K983112.
Heater wire adaptor accessories	Non-patient contact device (no biocompatibility testing required)	Non-patient contact device (no biocompatibility testing required)	*Identical*

5.5 Clinical Tests

Not applicable – no clinical testing was performed with respect to the HC550 System.

5.6 Conclusion

A comparison of the physical and functional characteristics and biocompatibility demonstrates technological equivalence, where only minor differences between the devices exist for aesthetic purposes a revised environment for use. In addition, the subject device is being presented with adult accessories only, whereas the predicate device is presented with adult and infant/neonatal accessories. The aforementioned differences do not affect safety or effectiveness of the subject device. The comparison of the intended purpose/function of the HC550 to the MR850 demonstrates that the systems are substantially equivalent in terms of clinical purpose.

Performance of these devices is supported by bench testing, which demonstrates equivalent performance in accordance with the particular standard for humidification systems, ISO 8185.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

Fisher & Paykel Healthcare Ltd.
Elizabeth Goldstein
Regulatory Affairs Specialist
15 Maurice Paykel Place
East Tamaki
Auckland, New Zealand

Re: K132017
Trade/Device Name: HC550 System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: February 16, 2014
Received: February 18, 2014

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,

FOR

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132017

Device Name
HC550 System

Indications for Use *(Describe)*
Indications for Use:

HC550 System:
The Fisher & Paykel HC550 System is designed for use with artificial ventilation systems. Portable volume ventilation systems, pressure support ventilation and Continuous Positive Airway Pressure (CPAP) systems may incorporate an HC550 to provide therapeutic levels of warm humidified air to adult patients with artificial airways or through mask ventilation.
The operating flow range is 5 to 120L/min depending on the patient interface.
The HC550 is designed for use in long term care facilities or the home 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)*

Tejashri Purohit-Sheth,
M.D.
Clinical Deputy Director
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