# 5 510(k) Summary

K100554

MAY 2 8 2010

Fisher & Paykel HEALTHCARE

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| **Contact person** | Ivy Cheng |
| **Date prepared** | 4 February 2010 |
| **Trade name** | 880 Respiratory Humidification System |
| **Common name** | Respiratory Gas Humidifier |
| **Classification name** | Respiratory Gas Humidifier<br>II (21 CFR § 868.5450), Product Code BTT |
| **Predicate device** | K073706 Fisher & Paykel Healthcare MR850 Respiratory Humidifier |

## 5.1 Description

The 880 Respiratory Humidification System (880 System) is designed to condition gases for patients by raising the delivered water vapor content and temperature of the gases.

The 880 System consists of the following components:

- MR880 Respiratory Humidifier (MR880)
- Accessories:
    a) RT241 Heated Delivery System
    b) 900MR441 Adaptor

The MR880 is 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 (chamber).

An unheated tube connects a gas source to the chamber input port. The chamber output port is connected to a heated inspiratory tube designed for exclusive use with the MR880. The gas is heated by means of a heaterwire placed internally within the heated inspiratory tube and enables the humidified gas to be transported to the patient whilst simultaneously minimizing the loss of humidity as condensation.

The MR880 controls the amount of heat provided to the chamber and the power to the heaterwire in the heated inspiratory tube via a proprietary algorithm.

Sensors external and internal to the gas path provide feedback on ambient room temperature, gas flow and gas temperature to regulate temperature and humidity delivery to the patient.

## 5.2 Intended use

The 880 System is intended to be used to warm and humidify breathing gases delivered to spontaneously breathing patients requiring assisted breathing and / or mucosal humidification. The system is intended to be used in a hospital environment by trained healthcare providers.

The 880 System is designed for use with an air-oxygen mix, up to 100% oxygen, provided by an external flow source. The flow may be from 5 L/min to 45 L/min depending on the type of patient interface.

## 5.3 Technological characteristics comparison

The 880 System is substantially equivalent to the predicate MR850 Respiratory Humidification System (850 System) in its method of controlling the chamber output temperature. It differs from the predicate in its method of controlling the delivered gas temperature.

In the predicate 850 System, the heaterwire adaptor is simply an electrical connection to provide power to the heaterwire in the heated inspiratory tube. A separate temperature probe incorporating two separate sensors is required for independently controlling the chamber output temperature and the delivered gas temperature.

In the 880 System, the 900MR441 Adaptor combines the functions of the temperature probe and the heaterwire adaptor of the predicate system into a single assembly and incorporates an additional sensor for measuring ambient temperature. A proprietary algorithm has been developed in combination with a dedicated heated inspiratory tube which uses the ambient temperature in combination with the measured flow to control the power to the heated inspiratory tube, thus ensuring a consistent performance across the specified operating ambient temperature and flow range.

## 5.4 Non-clinical tests

Non-clinical testing of the 880 System has been carried out covering mechanical, electrical and thermal safety; electromagnetic compatibility, functional verification and performance.

The 880 System complies with requirements of IEC 60601-1-2 Electromagnetic Compatibility. The MR880 has been submitted for testing to IEC 60601-1 Medical electrical equipment - General requirements for safety.

## 5.5 Conclusion

Testing carried out on the 880 System indicates that they meet design and performance functional requirements. The proposed device meets the requirements of medical electrical equipment and respiratory humidifier standards for safety and performance. The 880 System is substantially equivalent to the predicate 850 System in terms of safety, effectiveness and purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Ivy Cheng
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New Zealand

MAY 2 8 2010

Re: K100554
Trade/Device Name: 880 Respiratory Humidification System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BBT
Dated: May 13, 2010
Received: May 19, 2010

Dear Mr. Cheng:

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,

for

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

# 4 Indications for Use Statement

510(k) Number

Device Name Fisher & Paykel Healthcare 880 Respiratory Humidification System

The Fisher & Paykel Healthcare 880 Respiratory Humidification System (880 System) is intended to be used to warm and humidify breathing gases delivered to spontaneously breathing patients requiring assisted breathing and / or mucosal humidification. The system is intended to be used in a hospital environment by trained healthcare providers.

The 880 System is designed for use with an air-oxygen mix, up to 100% oxygen, provided by an external flow source. The flow may be from 5 L/min to 45 L/min depending on the type of patient interface.

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)

L Schultheiss

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

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