K131895

5 510(k) Summary

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Date prepared	21 June 2013
Submitter	Fisher & Paykel Healthcare 15 Maurice Paykel Place East Tamaki Auckland New Zealand Tel: +64 9 574 0100 Fax +64 9 574 0158
Contact person	Brett Whiston Regulatory Affairs

OCT 24 2013

Trade or proprietary name	AIRVO 2 Series Humidifier
Common name	Respiratory Humidifier
Classification name	Humidifier, Respiratory Gas, (Direct Patient Interface) (21 CFR § 868.5450, product code BTT)

Predicate device	K121975, AIRVO Series Humidifier, Fisher & Paykel Healthcare Ltd K073706, MR850 Humidifier, Fisher & Paykel Healthcare Ltd

5.1 Device description

The AIRVO 2 Series Humidifier system is a heated humidifier with integrated flow source and a heated breathing tube to deliver conditioned respiratory gas flow to a patient. The AIRVO 2 Series comprises two similar devices; the AIRVO 2, is intended for use in hospitals and long term care facilities and myAIRVO 2, intended for home use and long term care facilities.

The AIRVO 2 Series Humidifier is comprised of two connected functional units. One is a motorised fan assembly that provides air flow. The fan speed is directly related to delivered flow, and is controlled by software with a flow sensor. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the AIRVO 2 Series Humidifier is a heated passover humidifier. The water is contained in a humidification chamber positioned on a heater plate at the front of the unit. The chamber connects directly to the blower assembly via a port at the back of the chamber. Software monitors ambient temperature and flow to optimise humidity delivery to the patient and minimise condensation.

The device interfaces with the patient via a nasal cannula, tracheostomy interface, or face mask.

The AIRVO 2 Series Humidifier is reusable and by using the high level disinfection kit it can be used on multiple patients. The interfaces, tubes and water chambers are disposable and are for single patient use only. The device may be operated by nurses, respiratory therapists, doctors or patients.

5.2 Intended use

The AIRVO 2 and myAIRVO 2 humidifiers are for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The AIRVO 2 is for patients in hospitals and long-term care facilities. The myAIRVO 2 is for patients in homes and long-term care facilities.

5.3 Substantial equivalence

The following information presents summary technological features in the determination of substantial equivalence comparison of the proposed Airvo 2 Series Humidifier to the identified predicate devices.

5.3.1 Comparison to MR850 predicate

The MR850 is used as a predicate for flow range. The flow range of the AIRVO 2 Series Humidifier is within the flow range of the predicate MR850 humidifier.

Feature	Proposed device AIRVO 2 Series Humidifier	Predicate device MR850 Humidifier
Flow range	2 – 60 L/min	< 60 L/min

5.3.2 Comparison to AIRVO Series Humidifier predicate

The Airvo 2 Series Humidifier is a modification of the Airvo Series Humidifier and is the main comparison of features.

- Summary of same technological characteristics.

Feature	Proposed device AIRVO 2 Series Humidifier	Predicate device AIRVO Series Humidifier
Design	Integrated blower and humidifier with chamber and heated breathing tube.	Integrated blower and humidifier with chamber and heated breathing tube.
Energy Source	Electrical from mains supply to power blower and heating.	Electrical from mains supply to power blower and heating.
Materials	Moulded plastics and metal heater plate	Moulded plastics and metal heater plate
Temperature setting	31 °C, 34 °C, 37 °C	31 °C, 34 °C, 37 °C
Operating principle	Delivery of entrained, humidified Air/O2 at constant flow to the patient	Delivery of entrained, humidified Air/O2 at constant flow to the patient
Patient Interfaces	Nasal cannula, tracheostomy direct connection, face mask.	Nasal cannula, tracheostomy direct connection, face mask.
Alarms	Audible and visual for Temperature, Flow and Oxygen Fraction.	Audible and visual for Temperature, Flow and Oxygen Fraction.
User interface	User set point adjustment via menu system on color display for temperature and flow.	User set point adjustment via menu system on color display for temperature and flow.
Display	LED display for Temperature, Flow, Oxygen Fraction.	LED display for Temperature, Flow, Oxygen Fraction.
Control	Software control using feedback sensors with hardware back ups	Software control using feedback sensors with hardware back ups

- Summary of different technological characteristics.

Feature	Proposed device AIRVO 2 Series Humidifier	Predicate device AIRVO Series Humidifier
Flow range	2 – 60 L/min	5 – 50 L/min
Oxygen Input	< 60 L/min	< 30 L/min
Transport mode	Limits power to flow only	None

A wider flow range has been created to deliver flow from 2 L/min to 60 L/min to accommodate more patients with differing inspiratory demand. The AIRVO 2 Series Humidifier has also increased oxygen input up to 60 L/min to allow oxygen fraction to be set higher above 30 L/min than is possible in the predicate. The transport mode allows battery power to last longer by disabling heating to keep flow operating during transportation of the patient. The indications for use differ only by the flow range to the predicate.

5.4 Non clinical performance data

5.4.1 Summary of non clinical tests

Assessment of non clinical performance data is used in the determination of substantial equivalence. The AIRVO 2 Series Humidifier has undergone non-clinical testing and risk management that covers mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility, functional verification and performance.

Software and hardware is bench tested for the flow and temperature delivery, oxygen fraction measurement and accuracy, alarm conditions, over the stated flow and temperature ranges, in normal use and single fault situations. The testing examines the humidifier, water chamber, and breathing tube with patient interfaces, to test system performance. Patient contacting parts have been evaluated and tested for biocompatibility.

5.4.2 Standards applied

The device complies with the following applicable product standards:

ISO 8185: 2007	Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems
IEC 60601-1:1988	Medical Electrical Equipment, Part 1: General Requirements for Safety + A1:1991+A2:1995
IEC 60601-1-2:2007	General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2003	Tests for genotoxicity, carcinogenicity, and reproductive toxicity
ISO 10993-5:2009	Tests for in vitro cytotoxicity
ISO 10993-6:2007	Tests for local effects after implantation
ISO 10993-10:2010	Tests for irritation and skin sensitization

5.5 Conclusions on performance data

Testing carried out on the AIRVO 2 Series Humidifiers indicates that they meet design and performance functional requirements. The device complies with the standards for medical electrical equipment and respiratory humidifiers for safety and performance, and biocompatibility requirements.

The results obtained demonstrate that the AIRVO 2 Series Humidifier is substantially equivalent to the predicate AIRVO Series Humidifier, and has a similar operational flow range as the predicate MR850 Humidifier. It can be concluded that the AIRVO 2 Series Humidifier is substantially equivalent to the predicate AIRVO Series Humidifier and MR850 Humidifier.

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

October 24, 2013

Fisher & Paykel Healthcare Limited
Mr. Brett Whiston
Regulatory Affairs Specialist
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
AUCKLAND, NEW ZEALAND 2013

Re: K131895
Trade/Device Name: AIRVO 2 Series Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: September 25, 2013
Received: September 26, 2013

Dear Mr. Whiston:

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.

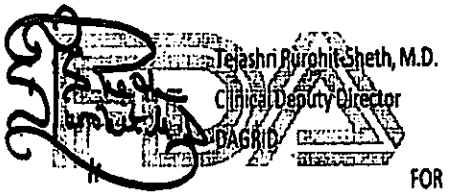
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Kwame Ulmer, 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

4 Indications for Use Statement

510(k) Number
(if known)

Device Name AIRVO 2 Series Humidifier

Indications for Use:

The AIRVO 2 and myAIRVO 2 humidifiers are for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface.

The AIRVO 2 is for patients in hospitals and long-term care facilities. The myAIRVO 2 is for patients in homes and long-term care facilities.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

K131895

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.10.24 11:03:19 -04'00'