# 5 510(k) Summary

K121975

Fisher & Paykel HEALTHCARE
Fisher & Paykel Healthcare Limited
Stewart Building
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

JAN 0 3 2013

| | |
|---|---|
| **Date prepared** | 2 July 2012 |
| **Contact person** | Brett Whiston |
| **Trade or proprietary name** | AIRVO Series Humidifier |
| **Common name** | Respiratory Humidifier |
| **Classification name** | Humidifier, Respiratory Gas, (Direct Patient Interface) (21 CFR § 868.5450, product code BTT) |
| **Predicate device** | K092846, AIRVO Series Humidifier, Fisher & Paykel Healthcare Ltd<br>K073706 MR850 Humidifier, Fisher & Paykel Healthcare Ltd |

## 5.1 Device description

The AIRVO 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 Series comprises two similar devices; the AIRVO which is intended for use in hospitals and long term care facilities and myAIRVO which is intended for home use and long term care facilities.

The AIRVO 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 Series Humidifier is a heated passover humidifier. The water is contained in a humidification chamber positioned on a heaterplate 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 either a nasal cannula, tracheostomy interface, or face mask.

The AIRVO 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 and myAIRVO 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 5 – 50 L/min depending on the patient interface. The AIRVO is for patients in hospitals and long-term care facilities. The myAIRVO is for patients in homes and long-term care facilities.

## 5.3 Technological characteristics comparison to predicate device

The modified AIRVO Series Humidifier has many of the same technological characteristics as its AIRVO Series predicate device. The design, generic materials, energy source, method of delivery, therapy, and application are unchanged. System add-on components, such as heated breathing tube, humidification chamber, and nasal cannula, are either unchanged or more sizes are available. The disinfection process is unchanged.

A wider flow range has been created with the introduction of a "Junior" operating mode able to deliver flow down to 5 L/min, whereas the predicate minimum was 15 L/min. An additional temperature setting can be made of 34 °C, besides the 31 °C and 37 °C which were only available in the predicate. In Junior mode the temperature setting is 34 °C. The limits to settings for flow, oxygen fraction, and temperature can be altered in the modified AIRVO Series Humidifier should the clinician want the device used in a narrower operating range.

The table summarises the AIRVO Series Humidifier technological differences to the Airvo Series predicate device:

| Different technological characteristic | Comparison to predicate |
|---|---|
| Addition of an internal oxygen sensor | The predicate has a look up table the user reads to determine the device flow setting and external oxygen source flow setting, for the desired input oxygen fraction (%). The user can now look at the display to see the value of the oxygen fraction for the AIRVO model. |
| Replaced monochrome LCD with high resolution color LED display | Previous LCD display limited the amount of information that could be displayed. |
| Addition of mains power out alarm | Should power be interrupted the device will now issue an alarm for 115 s or until power is restored within that time. |
| Higher efficiency entrainment port to allow up to 30 L/min supplemental oxygen input. | Predicate entrainment port limited maximum supplemental oxygen input to 15 L/min. Oxygen concentration limit increases to 90 %. |

## 5.4 Non clinical performance data

The modified AIRVO Series Humidifier has undergone non-clinical testing that covers mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility, functional verification and performance.

The AIRVO Series meets the requirements of the main standards applied:

| | |
|---|---|
| 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 |

## 5.5 Conclusions on performance data

Testing carried out on the modified AIRVO Series Humidifiers indicates that they meet design and performance functional requirements. The modified device meets the requirements of medical electrical equipment and humidifier standards for safety and performance. The modified AIRVO Series Humidifiers are substantially equivalent to the predicate device in terms of safety and effectiveness, and with the additional features performs as well as or better than the predicate device.

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

January 3, 2013

Mr. Brett Whiston
OSA Regulatory Affairs Engineer
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand 2013

Re: K121975
Trade/Device Name: AIRVO Series Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: December 20, 2012
Received: December 26, 2012

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 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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
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) K121975

Device Name AIRVO Series Humidifier

Indications for Use:

The AIRVO and myAIRVO 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 5 – 50 L/min depending on the patient interface.

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

Chan O. Lee -S
2013.01.03
11:37:10 -05'00'

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

510(k) Number: K121975