

K092846

SECTION 5. – 510K Summary

Fisher & Paykel
HEALTHCARE

JAN 27 2010

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Contact person	James Thompson
Date prepared	8 September 2009
Trade name	AIRVO Series Humidifier
Classification name	Humidifier, Respiratory Gas, (Direct Patient Interface) (21 CFR § 868.5450, product code BTT)
Predicate device	K073706 Fisher & Paykel Healthcare MR850 Humidifier K041900 Fisher & Paykel Healthcare HC604 CPAP Humidifier

5.1 Description

The AIRVO Series humidifier system is a heated humidifier with integrated flow source and a heated breathing tube. The AIRVO Series comprises two similar devices; the AIRVO which is intended for use in hospitals and myAIRVO which is intended for home use. The AIRVO Series humidifiers are intended to treat spontaneously breathing patients who would benefit from receiving high flow, warmed and humidified respiratory gases.

The AIRVO 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. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the AIRVO 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 or tracheostomy interface either in the hospital or home environment.

The AIRVO device 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 Series humidifiers are to treat spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have their upper airways bypassed. The AIRVO is for patients in hospitals, and the myAIRVO is for home patients.

5.3 Technological Characteristics Comparison

The fundamental technological characteristics of the AIRVO Series Humidifier are equivalent to the predicate devices listed above. Technological differences between the proposed device and listed predicates include;

- The AIRVO Series is the first Fisher & Paykel Healthcare Humidifier with an integrated flow source. It provides substantially equivalent humidification therapy to the predicate Fisher & Paykel Healthcare MR850 Humidifier though the MR850 requires connection to an external flow source. The integrated blower allows the AIRVO Series to be used in homes or hospital wards without flow sources. The flow rate can be adjusted between 15 and 45L/min in 5L/min steps.
- The AIRVO Series is based on the design of the predicate Fisher & Paykel Healthcare HC604 CPAP Humidifier and shares substantially equivalent fundamental technological characteristics and manufacturing processes. The blower module hardware which generates the air flow is identical to that used in the predicate Fisher & Paykel Healthcare HC604 CPAP Humidifier.
- The AIRVO Series allows for supplemental oxygen to be provided at the input air stream.

- The AIRVO Series heated breathing tube features an end of hose temperature sensor integrated into the tube design.

5.4 Non-Clinical Tests

Non-clinical testing of the AIRVO Series Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility, functional verification and performance. Copies of these test reports are included in Appendix E.

The AIRVO Humidifier complies with the requirements of IEC 60601-1 Electrical Safety and IEC 60601-1-2 EMC. Copies of these test reports are included in Appendix D.

5.5 Conclusion

Testing carried out on the AIRVO Series Humidifiers indicates that they meet design and performance functional requirements. The proposed device meets the requirements of medical electrical equipment and humidifier standards for safety and performance. The AIRVO Series Humidifiers are substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.



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. James Thompson
Regulatory Affairs Manager - OSA
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
Auckland 2013
NEW ZEALAND

JAN 27 2010

Re: K092846
Trade/Device Name: AIRVO Series Humidifiers
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: January 18, 2010
Received: January 22, 2010

Dear Mr. Thompson:

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.

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.

Page 2 - Mr. Thompson

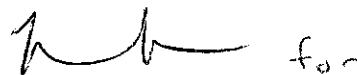
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

SECTION 4 – Indications for Use Statement

510(k) Number:

Device Name: AIRVO Series Humidifiers

Indications for Use:

The AIRVO and myAIRVO Humidifiers are to treat patients spontaneously breathing who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have upper airways bypassed.

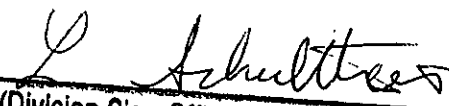
The AIRVO is for patients in hospitals. The myAIRVO is for home patients.

Prescription Use
(21 CFR 801 Subpart D)

AND/OR

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K092846