December 20, 2018

Fisher & Paykel Healthcare
Brett Whiston
Senior Regulatory Affairs Specialist
15 Maurice Paykel Place, East Tamaki
Auckland, 2013 NZ

Re: K162553
Trade/Device Name: AirSpiral Heated Breathing Tube
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: December 12, 2018
Received: December 14, 2018

Dear Brett 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection 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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162533

Device Name
AirSpiral Heated Breathing Tube

Indications for Use *(Describe)*

The 900PT561 heated breathing tube is for delivery of humidified respiratory gases. For use with AIRVO™ and AIRVO™ 2 Series humidifiers in hospitals and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.

The 900PT560 and 900PT560E heated breathing tube is for delivery of humidified respiratory gases. For use with myAIRVO™ and myAIRVO™ 2 Series humidifiers in homes and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.

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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

| | |
|---|---|
| Contact person/submitter | Brett Whiston |
| Date prepared | 20 December 2018 |
| Contact details | Address: 15 Maurice Paykel Place<br>East Tamaki<br>Auckland 2013, New Zealand<br>Telephone: +64 9 574 0100<br>Fax: +64 9 574 0158 |
| Trade name | AirSpiral Heated Breathing Tube |
| Common name | Humidifier |
| Classification name | Respiratory gas humidifier<br>Class II (21 CFR §868.5450), product code BTT |
| Predicate device | 900PT501 and 900PT531 Heated Breathing Tubes in K131895, AIRVO 2 Series Humidifier, Fisher & Paykel Healthcare Ltd |

## Device Description

### AirSpiral Heated Breathing Tube

The AirSpiral heated breathing tube is an accessory to the AIRVO 2 Series Humidifiers and comes in various packaging configurations with or without a humidification chamber, for hospital, long term care, or home use. The tube wall is made from air filled plastic spirally wound in a concentric manner to form the lumen. The trapped air in the plastic utilizes the thermal insulation properties of air. The heater wire is also wound into the wall of the tube to provide direct heating of the tube wall instead of being placed in the gas path. These features help reduce condensation inside the tube.

The AirSpiral heated breathing tube represents an alternative to the existing predicated heated breathing tube accessory in the predicate AIRVO 2 Series Humidifier K131895. It is provided in the same packaging configurations, can be used on AIRVO and AIRVO 2 Series humidifiers over the complete flow range, and uses similar patient interfaces, as the predicate breathing tube and patient interfaces. The patient interfaces consist of Nasal Cannula, Tracheostomy Direct Connection, and Mask Interface Adapter. Of the nasal cannula, spare part Wigglepads for Junior nasal cannula are available to replace those fitted on the cannula if needed. They provide adhesion to hold the cannula in place on the patient. Humidification chambers consist of an autofeed chamber with feedset, and a manual fill chamber, to contain water for humidification.

The Air Spiral models are as follows; (Note: the AirSpiral breathing tube is the same in all configurations)

| **Model** | **Configuration** | **Environment** |
|---|---|---|
| 900PT561 | Air Spiral Tube and Autofeed Chamber (10 pack) | Hospital and long term care facilities |
| 900PT560 | Air Spiral Tube (10 pack) | Home and long term care facilities |
| 900PT560E | Air Spiral Tube (single pack) | Home and long term care facilities |

### Indications For Use

The 900PT561 heated breathing tube is for delivery of humidified respiratory gases. For use with AIRVO™ and AIRVO™ 2 Series humidifiers in hospitals and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.

The 900PT560 and 900PT560E heated breathing tube is for delivery of humidified respiratory gases. For use with myAIRVO™ and myAIRVO™ 2 Series humidifiers in homes and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.

Compatible patient interfaces: nasal cannula, tracheostomy direct connection, mask adapter.

## Technological Characteristics Comparison

The AirSpiral Heated Breathing Tube is a new accessory device designed with a new tube wall and heater wire construction and patient interface connector compared to the existing predicate corrugated heated breathing tube accessory.

The predicate corrugated breathing tube and proposed AirSpiral breathing tube are accessories for use with the AIRVO/AIRVO 2 and myAIRVO/myAIRVO 2 Series Humidifiers. The proposed breathing tube provides better thermal insulation from ambient cooling effects when compared to the predicate corrugated tubing due to the spiral wound construction of the tube wall, having trapped air and placement of the heater wire in the plastic tube wall. The predicate tube in contrast has an extruded plastic tube wall and heater wire within the gas path.

The intended use of the new device is identical to the intended use of the predicate Heated Breathing Tubes cleared by K131895 [AIRVO 2 Series Humidifier]. The following table summarizes the comparison between the new and predicate breathing tube accessories.

**Substantial Equivalence Comparison Summary**

### Similarities

| Design/technological characteristic | New device (AirSpiral Breathing Tube) | Predicate device (Corrugated Breathing Tube) |
|---|---|---|
| **Indications For Use** | The 900PT561 heated breathing tube is for delivery of humidified respiratory gases. For use with AIRVO™ and AIRVO™ 2 Series humidifiers in hospitals and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.<br><br>The 900PT560 and 900PT560E heated breathing tube is for delivery of humidified respiratory gases. For use with myAIRVO™ and myAIRVO™ 2 Series humidifiers in homes and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.<br><br>Compatible patient interfaces: nasal cannula, tracheostomy direct connection, mask adapter. | 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. |
| **Principle of Operation** | Connected to the AIRVO or AIRVO 2 Series humidifiers. Powered by the humidifier to maintain heat as a conduit for humidified heated respiratory gases. | Connected to the AIRVO or AIRVO 2 Series humidifiers. Powered by the humidifier to maintain heat as a conduit for humidified heated respiratory gases. |

| Design/technological characteristic | New device (AirSpiral Breathing Tube) | Predicate device (Corrugated Breathing Tube) |
|---|---|---|
| | Connects the humidifier to the patient interface. | Connects the humidifier to the patient interface. |
| **Target population** | As per AIRVO/AIRVO 2 Series humidifiers, patients requiring flows between 2 – 60 L/min. | As per AIRVO/AIRVO 2 Series humidifiers, patients requiring flows between 2 – 60 L/min. |
| **Useful life** | Single patient use.<br>14 days in Hospital / Long-term care facilities environments.<br>60 days in Home care environments. | Single patient use.<br>14 days in Hospital / Long-term care facilities environments.<br>60 days in Home care environments. |
| **Temperature sensor** | An integrated temperature sensor at the patient end of the tube eliminates the need for external probes, cables or adaptors. | An integrated temperature sensor at the patient end of the tube eliminates the need for external probes, cables or adaptors. |
| **Flow range** | (2 to 60) L/min delivered.<br>Default mode: 10 to 60 L/min<br>Junior mode: 2 to 25 L/min | (2 to 60) L/min delivered.<br>Default mode: 10 to 60 L/min<br>Junior mode: 2 to 25 L/min |
| **Breathing tube heater wire resistance** | 20.5 Ω to 23.5 Ω | 20.5 Ω to 23.5 Ω |
| **Chambers** | HC360 manual fill chamber, single patient reuse<br>900PT290E auto fill chamber, single patient use only | HC360 manual fill chamber, single patient reuse<br>900PT290E auto fill chamber, single patient use only |

## Differences

| Design/technological characteristic | New device (AirSpiral Breathing Tube) | Predicate device (Corrugated Breathing Tube) |
|---|---|---|
| **Length and diameter** | 1.8 m, 13 mm Ø | 1.8 m, 22 mm Ø |
| **Tube wall** | Air filled sealed plastic strip wound in a spiral to form lumen wall. | Solid corrugated extruded plastic to form lumen wall. |
| **Heater wire** | Consists of an insulated filament conductor.<br>Double helix wound moulded into bead of tube wall. Heater wire is not directly in the gas path. | Consists of an insulated filament conductor.<br>Double helix wound sitting inside tube in the gas path. Heater wire is in the gas path. |
| **Patient end connector** | Multi connector to connect to all OPT nasal cannula for Default mode and Junior mode.<br>Also connects to OPT tracheostomy and face mask interface extensions. | Requires breathing tube with connector for Default mode nasal cannula, and a breathing tube with connector for Junior mode nasal cannula, to be able to connect to all OPT nasal cannula.<br>Also connects to OPT tracheostomy and face mask interface extensions. |

| Design/technological characteristic | New device (AirSpiral Breathing Tube) | Predicate device (Corrugated Breathing Tube) |
|---|---|---|
| **Model variants (single patient use)** | 900PT561:<br>AirSpiral tube and 900PT290V chamber (10 pack) (Hospital) (Default and Junior mode)<br>900PT560:<br>AirSpiral tube no chamber (10 pack) (Home) (Default and Junior mode)<br>900PT560E:<br>AirSpiral tube no chamber (single) (Home) (Default and Junior mode)<br>The 900PT56x tubes can be used with both AIRVO 2 modes "Default" and "Junior", depending upon the patient interface, due to the patient end multi connector | 900PT501:<br>Corrugated tube and 900PT290V chamber (10 pack) (Hospital) (Default mode)<br>900PT500:<br>Corrugated tube no chamber (10 pack) (Home) (Default mode)<br>900PT500E:<br>Corrugated tube no chamber (single) (Home) (Default mode)<br>900PT531:<br>Corrugated tube and 900PT290V chamber (10 pack) (Hospital) (Junior mode)<br>The 900PT50x tubes are intended to be used with AIRVO 2 "Default" mode, while 900PT531 is intended to be used with AIRVO 2 "Junior Mode". |
| **Patient Interfaces** | OPT316, OPT318 Junior Nasal Cannula (AIRVO 2 Series only)<br>OPT012 Wigglepads spare part<br>All are single patient use only<br>OPT942, OPT944, OPT946 Nasal Cannula (and "E' models)<br>OPT970 Tracheostomy Direct Connection (and "E' models)<br>OPT980 Mask Interface Adapter (and "E' models)<br>All are single patient use only | OPT316, OPT318 Junior Nasal Cannula (AIRVO 2 Series only)<br>OPT012 Wigglepads spare part<br>All are single patient use<br>OPT842, OPT844, OPT846 Nasal Cannula (and "E' models)<br>OPT870 Tracheostomy Direct Connection (and "E' models)<br>RT013 Mask Interface Adapter (and "E' models)<br>All are single patient use only |

## Non-Clinical Performance Data

Assessment of non-clinical performance data is used in the determination of substantial equivalence. The AirSpiral Heated Breathing Tube has undergone non-clinical testing and risk management that covers pneumatic, electrical and thermal safety, environmental conditions, functional verification and performance testing.

The following were tested to support the substantial equivalence decision:

- Condensation testing, to show an improvement in condensate accumulation over the predicate line of tubes.
- Pressure loss with bending
- Leak testing with and without an interface
- Connection forces for each connector
- Tensile strength of the tube

- Useful life, to show that tubes will last at least 2 weeks in the hospital or long term care facility environment and 60 days in the home and long term care environments and pass leak test, electrical test and pull test.
- Compatibility of tube parts and components with oxygen under normal conditions and single-fault conditions.
- Device to function normally after storage, transportation and drop testing using ISTA 2A

Results showed that the proposed AirSpiral Heated Breathing Tubes passed the acceptance criteria for all tests.

The AirSpiral Heated Breathing Tubes were also assessed in conjunction with the AIRVO 2 Series Humidifiers to test system performance to ISO 8185: 2007.

Results showed that ISO 8185 limits were met for key attributes:

- Maximum accessible surface temperature of the delivery tube with 25 cm of patient connection port: Surface temperature < 44 °C.
- Maximum delivered gas temperature in normal use: Delivered temperature < 43 °C.
- Heating is interrupted to the heater-plate and breathing tube heater wire in single fault condition: Heating stopped when delivered gas temperature > 43 °C.
- Maximum thermal overshoot enthalpy at patient connection port: Overshoot specific enthalpy < 194 $kJ.kg^{-1}$.
- Minimum humidity output for invasive and non-invasive patient interfaces: Humidity output > 33 $mg.L^{-1}$ for invasive and > 10 $mg.L^{-1}$ for non-invasive patient interfaces.

**Biocompatibility**

Biocompatibility evaluation of Cytotoxicity, Sensitization, Irritation, Muscle Implantation, Genotoxicity and Extractables/Leachables for the 900PT561 AirSpiral Heated Breathing Tube and patient interfaces was conducted in accordance with FDA guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process’” (June 2016).

Extractables and leachables testing for chemical characterization was conducted on the AirSpiral Heated Breathing Tube and patient interfaces using worst-case volume of condensate measured. A toxicological risk assessment based on the chemical characterization testing was performed for each chemical observed following recommendations outlined in ISO 10993-17:2002: Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances, with margin of safety calculated for each chemical characterized.

**Standards**

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 |

## Clinical Performance Data

No Clinical Performance Data was used to support substantial equivalence.

## Conclusions

Testing carried out on the AirSpiral Heated Breathing Tubes indicates that they meet design, performance, and biocompatibility requirements. The AIRVO 2 Series Humidifier System, when used with the AirSpiral Heated Breathing Tubes, complies with the standards for medical electrical equipment and respiratory humidifiers for safety and performance.

The results obtained demonstrate that the AirSpiral Heated Breathing Tubes are substantially equivalent to the predicate.