January 27, 2023

Fisher & Paykel Healthcare
Reena Daken
Regulatory Affairs Manager
15 Maurice Paykel Place
Auckland, 2013
New Zealand

Re: K221338
Trade/Device Name: F&P Airvo 3
Regulation Number: 21 CFR 868.5454
Regulation Name: High Flow Humidified Oxygen Delivery Device
Regulatory Class: Class II
Product Code: QAV, BTT
Dated: December 28, 2022
Received: December 28, 2022

Dear Reena Daken:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

for James Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221338

Device Name
F&P Airvo 3

Indications for Use *(Describe)*
The Airvo 3 is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals and sub-acute facilities. It adds heat and moisture to the flow of air, or blended air/medical oxygen mixture, and assures the user of the air/oxygen mixture using an integrated oxygen analyzer and visual display. The flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals and sub-acute facilities.

The Airvo 3 provides high flow gases with simultaneous oxygen delivery through nasal cannula interfaces to augment the breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 is not intended to provide total ventilatory requirements and is not for use during field transport.

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.

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5 510(k) Summary

As required by 21 CFR 807.92

I. SUBMITTER

Company Name and Address	Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Prepared and Submitted by	Hannah Matthews Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: Reena.Daken@fphcare.co.nz
Date Prepared	27 January 2022

II. DEVICE

Name of Device	F&P Airvo 3
Common/Usual Name	High Flow Humidified Oxygen Delivery Device
Classification Name	High Flow/High Velocity Humidified Oxygen Delivery Device
Primary Regulatory Class	Class II (21 CFR §868.5454)
Primary Product Code	QAV
Secondary Regulatory Class	Class II (21 CFR §868.5450)
Secondary Product Code	BTT

III. PREDICATE DEVICES

- Primary Predicate Device

FDA Clearance Number	Device Name
DEN170001	Precision Flow® HVNI

- Secondary Predicate Device

FDA Clearance Number	Device Name
K131895	AIRVO 2 Humidifier

IV. DEVICE DESCRIPTION

The F&P Airvo 3 is a high-flow device comprised of heated humidifier with integrated flow source, intended to treat spontaneously breathing patients, pediatrics and adults, who would benefit from receiving high flow, warmed and humidified entrained air and oxygen (if required).

The F&P Airvo 3 can be reprocessed for use on multiple patients. The patient interfaces, heated breathing tube, and water chambers are disposable and are for single patient use only, however, the internal outlet elbow is high-level-disinfected for multi-patient use.

The F&P Airvo 3 is comprised of two main connected functional units: the blower and the humidifier.

The blower is a motorized fan assembly that provides air flow. The flow is adjustable, where a separate source of oxygen independently controlled can be input and mixed with the entrained air. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the F&P Airvo 3 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 gas is warmed and humidified in the chamber to the dew point set temperature, transported through the heated breathing tube and delivered to the patient through the selected interface.

V. INDICATIONS FOR USE

The Airvo 3 is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals and sub-acute facilities. It adds heat and moisture to the flow of air, or blended air/medical oxygen mixture, and assures the user of the air/oxygen mixture using an integrated oxygen analyzer and visual display. The flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals and sub-acute facilities.

The Airvo 3 provides high flow gases with simultaneous oxygen delivery through nasal cannula interfaces to augment the breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 is not intended to provide total ventilatory requirements and is not for use during field transport.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Table 1: Subject Device Comparison with the Primary Predicate Device

Feature/Characteristic for Comparison	**Subject Device F&P Airvo 3 Base Model**	**Primary Predicate Device Precision Flow Hi-VNI (DEN170001)**	**Similarity of Subject Device to Primary Predicate Device**
Device Image			**N/A**
Classification			
Legal manufacturer	Fisher & Paykel Healthcare Ltd	Vapotherm	**N/A**
Device Regulation	Class II, Regulation: 21 CFR §868.5454	Class II, Regulation: 21 CFR §868.5454	**Identical**
Product code	QAV	QAV	**Identical**
Classification name	High flow humidified oxygen delivery device	High flow humidified oxygen delivery device	**Identical**
Classification Panel	Anesthesiology	Anesthesiology	**Identical**
Intended Use/ Indications for Use			

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
Indications for use	The Airvo 3 is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals and sub-acute facilities. It adds heat and moisture to the flow of air, or blended air/medical oxygen mixture, and assures the user of the air/oxygen mixture using an integrated oxygen analyzer and visual display. The flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals and sub-acute facilities. The Airvo 3 provides high flow gases with simultaneous oxygen delivery through nasal cannula interfaces to augment the breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. The Airvo 3 is not intended to provide total ventilatory requirements and is not for use during field transport.	Precision Flow® Hi-VNI is intended for use to add warm moisture to breathing gases from an external source for administration to a neonate/infant, pediatric and adult patients in the hospital and subacute institutions settings. It adds heat and moisture to a blended medical air/ oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyzer. The flow rates may be from 1 to 40 liters per minute via nasal cannula. Precision Flow® Hi-VNI provides high velocity nasal insufflation (HVNI) with simultaneous oxygen delivery to augment breathing of spontaneously breathing patients suffering from respiratory distress and/or hypoxemia in the hospital setting. Precision Flow® Hi-VNI is not intended to provide total ventilatory requirements of the patient and not for use during field transport.	**Equivalent** Both the primary predicate and the subject device have the same overall intended use, of delivering high flow breathing gases (air/oxygen mixtures) with humidification for patients who are suffering from respiratory distress and/or hypoxemia. The subject device indications for use is a combination of the indications for use of the primary predicate and the secondary predicate device, AIRVO 2 Humidifier (K131895).
Operation and Safety Features			
Availability	Prescription use only (Part 21 CFR 801 Subpart D)	Prescription use only (Part 21 CFR 801 Subpart D)	**Identical**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
Patient Population	Infant, child, adolescent, and adult	Neonate/infant, pediatric and adult	**Equivalent** The subject device's patient population is a subset of the primary predicate devices patient population.
Intended User Group	Healthcare Professionals	Healthcare Professionals	**Identical**
Patient Consciousness	Spontaneously Breathing Patients	Spontaneously Breathing Patients	**Identical**
Environment of use	Hospital and subacute facilities	Hospital and subacute institutions settings	**Identical** Subacute facilities and subacute institutions have identical definitions and reflect an identical environment to each other. Additionally, the user group and patient population defined by these environments of use are identical.
Reusability	Multi-patient reusable when reprocessed between patients	Multi-patient reusable when cleaned and disinfected between patients.	**Identical**
Sterility	Device not provided sterile	Device not provided sterile	**Identical**
Life Supporting or Life Sustaining	No	No	**Identical**
Service Life	5 years	5 years	**Identical**
Physical Specifications			

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
Device dimensions	205 mm x 295 mm x 190 mm (8.0" x 11.7" x 6.6")	203.2 mm x 292.1 mm x 177.8 mm (8" x 11.5" x 7") (W x H x D)	**Equivalent** The subject device is larger than the primary predicate device by 1.8 mm x 2.9 mm x 12.2 mm (W x H x D)
Device weight (device only)	4.45 kg (9.8 lb.)	4.81 kg (10.6 lb.) without disposable patient	**Equivalent** The subject device is 0.36 kg lighter than the primary predicate device.
Technology			
Operating principle	Constant flow of warmed, humidified gas delivery via blower and humidifier	Constant flow of warmed, humidified gas delivery via blender and humidifier	The operating principle of the subject device is identical to the secondary predicate device (AIRVO 2 – K131895).
Oxygen input sources	High-Pressure Oxygen (HPO) Inlet Port: Via DISS inlet from wall supply 200-600 kPa (41-87 psi) *And* Low-Pressure Oxygen (LPO) Inlet Port: Via low-pressure connector (from rotameter)	Via DISS inlet from wall supply only, 28-586 kPa (4-85 psi)	The oxygen input via low-pressure oxygen (LPO) port connector is available in the previously- cleared secondary predicate device (AIRVO 2 – K131895). The rated flow range of the Low-Pressure Oxygen Port is identical between the Subject and secondary predicate device. The oxygen source of the subject device is a subset of the secondary predicate device.
High Pressure Oxygen Inlet (HPO Port) – Rated Pressure Range	280 kPa to 600 kPa (41 PSI to 87 PSI)	28 kPa to 586 kPa (4 PSI to 85 PSI)	**Similar** The maximum rated pressure of the subject device is approximately 2 % higher than the primary predicate device.

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
			The minimum rated pressure of the subject device is a subset of the pressure range of the primary predicate device.
High Pressure Oxygen Inlet (HPO Port) – Source of High Pressure Oxygen	Medical Oxygen	Medical Oxygen	**Identical**
Humidity source	Heated humidification chamber.	Vapor Transfer Cartridge	The method of humidification used in the Airvo 3 is identical to the secondary predicate device, AIRVO 2, cleared in K131895.
SpO_2 Sensing	Ability to connect an external (non F&P) pulse oximeter to USB port, displays sensed SpO_2 and pulse rate on user interface	No SpO_2 Sensing	**New Feature** F&P has conducted testing that demonstrates that the SpO_2 and pulse rate values calculated by the pulse oximetry system are not corrupted during communication to the Airvo 3 and are displayed accurately on the user interface.
Performance Specifications			
Flow range	Infants: 2 – 25 L/min Children: 2 – 36 L/min Adolescents: 10 – 70 L/min Adults: 20 – 70 L/min The achievable flow range depends on the patient interface selected.	1 – 40 L/min	Flow rates of up to 60 L/min are available in the secondary predicate device, AIRVO 2 (K131895). The use of flow rates above 60 L/min is already common in the field using standalone air/oxygen blenders in combination with humidifiers.
Maximum O2 flowrate (Low Pressure Oxygen	60 L/min	60 L/min	**Identical**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
Inlet Port)			
Temperature range	31 – 37 °C	33 – 38 °C	The set temperature range of the subject device is identical to that of the secondary predicate device AIRVO 2 (K131895).
Ambient operating temperature range	18 – 28 °C	18 – 30 °C	**Equivalent** The subject device's ambient operating temperature range is a subset of the primary predicate devices ambient operating temperature range.
Alarms			
Alarm method	Visual and audible alarm system. Mute button.	Visual and audible alarm system. Mute button.	**Identical**
Electrical System Characteristics			
Supply Frequency	50-60 Hz	50/60 Hz	**Identical**
Supply Voltage	100 – 115 VAC 220-240 VAC	100-240 VAC	**Identical**
Accessories			
Patient interfaces	Nasal cannula And Unsealed tracheostomy connector And Unsealed mask adapter	Nasal cannula	Unsealed tracheostomy connector and unsealed mask adapters are available for use with the secondary predicate device, AIRVO 2 (K131895).

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 Base Model	Primary Predicate Device Precision Flow Hi-VNI (DEN170001)	Similarity of Subject Device to Primary Predicate Device
Heated Breathing tube	Heated breathing tube: single-lumen, spiral heater wires	Heated breathing tube: triple-lumen, water filled	This tube construction has been cleared for use with the secondary predicate device, AIRVO 2 (K162553).
Duration of Use – Heated Breathing Tube	14 Days single patient use	30 Days single patient use	**Equivalent** The duration of use of the subject device is shorter than that of the primary predicate device.

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P Airvo 3 has been tested to the applicable requirements of the following standards:

Standards and Designation Number	Standards Title
ISO 5367: 2014	Anaesthetic and respiratory equipment. Breathing sets and connectors
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
IEC 62304:2015 Consolidated Version	Medical device software – software lifecycle processes
AIM Standard 7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers – An AIM Standard
IEC 62366-1:2015 + AMD:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 18562-2: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
ISO 18562-3: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 1-: General requirements for basic safety and essential performance – Collateral standard: Usability
ANSI AAMI IEC 60601-1-8:2006 and A1:2012	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

ISO 80601-2-61:2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements
ISO 17664: 2017	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
ISTA 2A	Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or less. Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration, and shock vibration
AAMI TIR30:2011	A Compendium of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in healthcare facilities

Biocompatibility Testing

The biocompatibility evaluation for the Airvo 3 device was conducted in accordance with the International Standards ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," and "ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process" as recognized by FDA. Testing of the Airvo 3 System demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety, Electromagnetic Compatibility (EMC), and Alarms

Electrical safety, thermal safety, mechanical safety, EMC and radiofrequency identification testing were conducted on the Airvo 3 system. The system complies with ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-2:2014 and AIM Standard 7351731 Rev. 2.00 2017-02-23. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device. Alarms testing was performed in accordance with ANSI AAMI IEC 60601-1-8:2006 and A1:2012.

Software Verification and Validation Testing

Software verification, validation and hazard analysis was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Cleaning/Reprocessing

As per the FDA Guidance: "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", the Outlet Elbow is classified as a semi-critical device and was therefore subject to cleaning followed by high-level disinfection. The acceptance criteria and endpoints used are based on the following standard:

- AAMI TIR30:2011 A compendium of Processes, Materials, Test Methods, And Acceptance Criteria for Cleaning Reusable Medical Devices

Bench / Performance Testing

Comparative performance testing was performed to demonstrate substantial equivalence and to meet the Special Controls requirements of 21 CFR 868.5454 High flow humidified oxygen delivery device, and included:

- Blending accuracy
- Flow rate accuracy
- Continuous use thermal stability
- Humidification output

VIII. CONCLUSIONS

The F&P Airvo 3 is substantially equivalent to the predicate devices based on patient population, intended uses, comparison of the technological characteristics and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate devices.