August 9, 2024

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

Re: K233643
Trade/Device Name: F&P Airvo 3 NIV (PT311US)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: MNT
Dated: July 15, 2024
Received: July 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

John S. Bender -S

Digitally signed by John S. Bender -S
Date: 2024.08.09 15:10:16 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233643

Device Name
F&P Airvo 3 NIV (PT311US)

Indications for Use *(Describe)*
F&P Airvo 3 NIV (PT311US)

When used in NIV mode:
The Airvo 3 NIV provides non-invasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lb/30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.

When used in High Flow mode:
The Airvo 3 NIV is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals. 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 NIV provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals.

The Airvo 3 NIV 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 NIV is not intended to provide total ventilatory requirements and is not intended for use during field transport.

AirSpiral NIV tube and chamber kit (900PT573):
For use with noninvasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lbs./30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.

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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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 Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email:Reena.Daken@fphcare.co.nz
Date Prepared	9 August 2024

II. DEVICE

Name of Device	F&P Airvo 3 NIV AirSpiral NIV tube and chamber kit
Common/Usual Name	ventilator, continuous, minimal ventilatory support, facility use
Classification Name	Continuous Ventilator
Regulatory Class	Class II (21 CFR §868.5895)
Product Code	MNT

III. PREDICATE DEVICES

- Primary Predicate Device

FDA Clearance Number	Device Name
K090113	Breas Vivo 40 System

- Secondary Predicate Device

FDA Clearance Number	Device Name
K221338	F&P Airvo 3

- Reference Devices

FDA Clearance Number	Device Name	Reason for Reference
K082660	V60 VENTILATOR, MODEL V8000	Used to support claims of substantial equivalence with respect to User Adjustable Pressure Support Settings
K113640	STELLAR 150	Used to support claims of substantial equivalence with respect to User Adjustable Pressure Support Settings
K121623	BIPAP A 40 VENTILATORY SUPPORT SYSTEM	Used to support claims of substantial equivalence with respect to User Adjustable Pressure Support Settings
K103167	STELLAR 150	Used to support claims of substantial equivalence with respect to User Adjustable Pressure Support Settings
K162553	AirSpiral Heated Breathing Tube	Used to support claims of substantial equivalence with respect to the AirSpiral NIV Tube and Chamber Kit
K033008	AIR SAFETY HEPA AND NON-HEPA FILTERS	Used to support claims of substantial equivalence with respect to the patient inspiratory filter

IV. DEVICE DESCRIPTION

The subject device, F&P Airvo 3 NIV is a respiratory support device for the delivery of High Flow and NIV (Non-Invasive Ventilation) therapy intended to treat spontaneously breathing patients who would benefit from receiving High Flow or respiratory pressure support. The Airvo 3 NIV is NOT to be used for life-supporting or life-sustaining purposes.

The Airvo 3 NIV is a non-implantable, prescription-only device, provided in a non-sterile state, and intended to be used by healthcare professionals, namely respiratory therapists, doctors and nurses in hospitals. When used in High Flow mode, the Airvo 3 NIV delivers gas at flow rates of between 2-70 L/min. The Airvo 3 NIV also has three non-invasive ventilation therapy modes: CPAP, Bi-Level S/T and Bi-Level PCV.

The AirSpiral NIV Tube and Chamber Kit is a single limb circuit kit designed for use with the Airvo 3 NIV device, for non- ventilator dependent, spontaneously breathing adult patients with respiratory insufficiency.

V. INDICATIONS FOR USE

F&P Airvo 3 NIV (PT311US)

When used in NIV mode:

The Airvo 3 NIV provides non-invasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lb/30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.

When used in High Flow mode:

The Airvo 3 NIV is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals. 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 NIV provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals.

The Airvo 3 NIV 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 NIV is not intended to provide total ventilatory requirements and is not intended for use during field transport.

AirSpiral NIV tube and chamber kit (900PT573)

For use with noninvasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lbs./30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Table 1: Subject Device Comparison with Primary Predicate Device

Feature/Characteristic for Comparison	**Subject Device** **F&P Airvo 3 NIV**	**Primary Predicate Device** **Breas Vivo 40 System (K090113)**	**Similarity of Subject Device to Primary Predicate Device**
Classification			
Legal Manufacturer	Fisher & Paykel Healthcare Ltd.	Breas Medical AB	**N/A**
Device Regulation	Class II, Regulation: 21 CFR §868.5895	Class II, Regulation: 21 CFR §868.5895	**Identical**
Product Code	MNT	MNT	**Identical**
Classification Name	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	**Identical**
Classification Panel	Anesthesiology	Anesthesiology	**Identical**
Intended Use / Indications for Use			
Indications for Use	*When used in NIV mode:* The Airvo 3 NIV provides non-invasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lb/30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support. *When used in High Flow mode:* The Airvo 3 NIV is intended to provide high flow warmed and humidified respiratory gases for administration to spontaneously breathing infant, child, adolescent and adult patients in hospitals. 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	The Vivo 40 is an assist ventilator intended to augment the breathing of spontaneously breathing adult patients >66 lbs (>30 kg) suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea. The Vivo 40 is not intended to provide the total ventilatory requirements of the patient. The Vivo 40 is intended to be used for both invasive and non-invasive applications. The Vivo 40 is intended to be operated by qualified and trained personnel. The Vivo 40 is intended for use in clinical settings (e.g., hospitals, sleep	**Equivalent** Use of the subject device in high flow mode is equivalent to the secondary predicate device, Airvo 3 (K221338). The subject device is not intended to be used in Sub-Acute Care facilities.

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 NIV	Primary Predicate Device Breas Vivo 40 System (K090113)	Similarity of Subject Device to Primary Predicate Device
	flow may be from 2 to 70 L/min depending on the patient interface. The Airvo 3 NIV provides high flow gases with simultaneous oxygen delivery to spontaneously breathing patients with or without bypassed upper airways in hospitals. The Airvo 3 NIV 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 NIV is not intended to provide total ventilatory requirements and is not intended for use during field transport.	laboratories, sub-acute care institutions) and home environments. The Vivo 40 must always be prescribed by a licensed physician.	
Operation and Safety Features			
Availability	Prescription Only	Prescription Only	**Identical**
Patient Population	NIV mode – Adults > 30kg NHF mode – Infant to Adult	NIV Mode – Adults > 30kg NHF Mode – N/A	**Equivalent** The patient population of the device when used in NHF mode is Identical to the secondary predicate device, F&P Airvo 3 (K221338).
Intended User Group	Healthcare Professionals	Qualified and trained personnel	**Equivalent**
Patient Consciousness	Spontaneously Breathing Patients	Spontaneously Breathing Patients	**Identical**
Environment of Use	Hospital	Hospital Sleep Laboratories Sub-acute Care Settings	**Equivalent**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 NIV	Primary Predicate Device Breas Vivo 40 System (K090113)	Similarity of Subject Device to Primary Predicate Device
		Home	
Sterility	Not provided sterile	Not provided sterile	**Identical**
Life Supporting or Life Sustaining	No	No	**Identical**
Service Life	5 years	Not Specified	**Equivalent**
Technology			
Operating Principle	The Airvo 3 NIV design makes uses a centrifugal blower with a low inertia impeller to control the pressure based on the device setting as well as pressure and flow sensor measurements. The Airvo 3 NIV has three modes of NIV therapy: Bi-Level S/T, Bi-Level PCV and CPAP.	The Vivo 40 uses a centrifugal blower in combination with an electronically controlled valve to control the pressure delivered to the patient based on device settings and measurements from the pressure and flow sensors. The Breas Vivo 40 has three modes of operation: PSV (more commonly known as Bi-Level S/T), PCV, and CPAP.	**Equivalent** The service life of the Airvo 3 NIV is identical to the secondary predicate device, Airvo 3 (K221338)
Oxygen Input Sources	High-Pressure Oxygen (HPO) Inlet Port: Via DISS inlet from wall supply 200-600 kPa (41- 87 psi) When oxygen is delivered via the LPO port, the fraction of inspired oxygen is measured and displayed on the Airvo 3 NIV screen as FiO_2 (fraction of inspired oxygen). *And*	Low-Pressure Oxygen with a flow that does not exceed 15 l/min	**Equivalent**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 NIV	Primary Predicate Device Breas Vivo 40 System (K090113)	Similarity of Subject Device to Primary Predicate Device
	Low-Pressure Oxygen (LPO) Inlet Port: Via low-pressure connector (from rotameter) When oxygen is delivered via the HPO port, the device controls the FiO_2 to the user set value.		
Humidity Source	Heated Humidification Chamber	Optional use of an external humidifier	**Equivalent**
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	The use of SpO_2 Sensing with the subject device is identical to the secondary predicate device, Airvo 3 (K221338).
Performance Specifications			
Flow Range (High Flow)	2 – 70 L/min	No High Flow Mode	The high flow operation of the device is identical to the reference device, Airvo 3 (K221338)
Temperature Range (High Flow)	31 – 37 °C	No High Flow Mode	The high flow operation of the device is identical to the reference device, Airvo 3 (K221338)
Electrical System Characteristics			
Supply Frequency	50 – 60 Hz	50 – 60 Hz	**Identical**
Supply Voltage	100 – 115 VAC 220-240 VAC	100-240 VAC	**Identical**
Pressure Support Technological Characteristics			
Blower for creating pressure and maintaining pressure	Yes	Yes	**Identical**
Pressure and flow sensors for measurement	Yes	Yes	**Identical**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 NIV	Primary Predicate Device Breas Vivo 40 System (K090113)	Similarity of Subject Device to Primary Predicate Device
Microprocessors for control of pressure, user interface and other tasks.	Yes	Yes	**Identical**
Powered via mains power (100 to 240V).	Yes	Yes	**Identical**
Breathing tube to connect NIV interface to device.	Yes	Yes	**Identical**
Pressure Regulating Valve	The Airvo 3 NIV blower is designed such that a pressure regulating valve is not required.	The Breas device uses a blower in combination with a pressure regulating valve to control pressure	**Equivalent**
Non-Invasive Therapy Modes			
PCV (Pressure Control Ventilation)	Yes	Yes	**Identical**
CPAP	Yes	Yes	**Identical**
Bi-Level S/T	Yes	Yes Although Bi-Level S/T therapy is well understood there is no consistent naming convention for Bi-Level S/T therapy. As a result, Breas has labelled their implementation of Bi-Level S/T therapy as PSV (Pressure Support Ventilation)	**Identical**
High Flow Therapy	Yes	No	The high flow operation of the device is identical to the secondary predicate device, Airvo 3 (K221338)
User Adjustable Pressure Support Settings			
IPAP Range	4 – 30 cmH_2O	4 – 40 cmH_2O	**Equivalent**

Feature/Characteristic for Comparison	Subject Device F&P Airvo 3 NIV	Primary Predicate Device Breas Vivo 40 System (K090113)	Similarity of Subject Device to Primary Predicate Device
EPAP Range	4 – 25 cmH_2O	2 – 20 cmH_2O	**Equivalent**
CPAP Range	4 – 25 cmH_2O	4 – 20 cmH_2O	**Equivalent**
Alarms			
Alarm Method	Visual and audible alarm	Visual and audible alarm	**Identical**

1.1 900PT573 – AirSpiral NIV Tube and Chamber Kit

The table below provides a side-by-side comparison of the subject and reference device, AirSpiral Heated Breathing Tube.

Table 2: Subject Device Comparison with Reference Device, AirSpiral Heated Breathing Tube

Feature/Characteristic for Comparison	**Subject Device** **AirSpiral NIV Tube and Chamber Kit**	**Reference Device** **AirSpiral Heated Breathing Tube (K162553)**	**Similarity of Subject Device to Reference Device**
Heated Breathing Tube for NIV Therapy			
Indications for Use	For use with noninvasive ventilator support for non-ventilator dependent, spontaneously breathing adult patients (66 lbs./30 kg and above) with respiratory insufficiency. It is intended to be used in hospitals. It is not intended for life support.	Heated breathing tube 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-1 depending on the patient interface.	**Equivalent**
Principle of Operation	Used as part of the Airvo 3 NIV system, the single limb AirSpiral NIV heated breathing tube provides a conduit for humidified heated respiratory gases that connects the humidifier to the patient interface. The heater wires maintain the gas temperature for delivery and are controlled by the humidifier. The tubing provides insulation from the ambient air.	Used as part of the Airvo or Airvo 2 Series humidifier system, the single limb AirSpiral heated breathing tube provides a conduit for humidified heated respiratory gases that connects the humidifier to the patient interface. The heater wires maintain the gas temperature for delivery and are controlled by the humidifier. The tubing provides insulation from the ambient air.	**Identical**
Inspiratory Limb	**Tubing** 18.25 mm diameter, 1.8 m heated tube to transport humidified gas between the Unit End and Patient End. Two-spiral wall tubing design:	**Tubing** 13.1 mm diameter, 1.8 m heated tube to transport humidified gas between the Unit End and Patient End. Two-spiral wall tubing design:	**Equivalent**

Feature/Characteristic for Comparison	Subject Device AirSpiral NIV Tube and Chamber Kit	Reference Device AirSpiral Heated Breathing Tube (K162553)	Similarity of Subject Device to Reference Device
	• Insulating spiral made of Spiral-wound bubble tubing • Heated spiral encapsulating heater wire The resistance to flow of the inspiratory limb is between 2.72 and 4.72 cmH_2O at 60 l/min. **Heater wire** Consists of filament conductor Position in tube: Double helix wound moulded into bead of tube wall. Filament insulation: Filament is moulded into the bead. The bead provides the insulation. **Unit End Connector** Assembled connector for connection with Airvo 3 NIV device; with retention clips and boot providing a secure connection. **Patient End Connector** Assembled connector for connection with a Patient Inspiratory Filter designed with Fisher & Paykel secure connection features.	• Insulating spiral made of Spiral-wound bubble tubing • Heated spiral encapsulating heater wire The resistance to flow of the inspiratory limb is < 6 cmH_2O at 60 l/min. **Heater wire** Consists of filament conductor Position in tube: Double helix wound moulded into bead of tube wall. Filament insulation: Filament is moulded into the bead. The bead provides the insulation. **Unit End Connector** Assembled connector for connection with the Airvo device; with a locking, Sliding Collar providing a secure connection. **Patient End Connector** Assembled connector for connection with a Patient Interface designed with Fisher & Paykel secure connection features.	

Feature/Characteristic for Comparison	Subject Device AirSpiral NIV Tube and Chamber Kit	Reference Device AirSpiral Heated Breathing Tube (K162553)	Similarity of Subject Device to Reference Device
		An integrated temperature sensor at the patient end eliminates the need for external probes, cables or adaptors	
Tubing Clip	Yes	Yes	**Identical**
Humidification Chamber	900PT290E Source of water vapor for humidifying respiratory gases	900PT290E Source of water vapor for humidifying respiratory gases	**Identical**
Exhalation Port	Yes	No	Exhalation Port is an optional accessory for NIV applications.
Patient Inspiratory Filter	Yes	No	Patient Inspiratory Filter is an optional accessory for NIV applications.
Heater wire Resistance	33.5 Ω	22.0 Ω	**Equivalent**
Useful Life	14 days	14 days	**Identical**
Shelf Life	3 Years	5 Years	**Equivalent**
Therapy Mode Operation	NIV Therapy	High Flow	The reference device, AirSpiral Heated Breathing Tube, is not cleared for NIV Therapy. The larger diameter tube results in a lower resistance to flow for delivery of NIV therapy.
Intended Patient Interface	For use with F&P non-vented masks with anti-asphyxiation valve or F&P vented masks with anti-asphyxiation valve.	Nasal Cannula or Tracheostomy Interface or Face Masks	**Equivalent**

VII. PERFORMANCE DATA

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. 3.00 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 Device Software Functions."

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 included:

- Blending accuracy
- Flow rate accuracy
- Continuous use thermal stability
- Pressure waveform analysis
- Humidification output

VIII. CONCLUSIONS

The F&P Airvo 3 NIV 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.