June 16, 2023

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

Re: K220703
Trade/Device Name: F&P 950 Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT, BZE
Dated: May 17, 2023
Received: May 17, 2023

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 J. Lee, Ph.D.
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)*
K220703

Device Name
F&P 950 Respiratory Humidifier

Indications for Use *(Describe)*

F&P 950 Respiratory Humidifier
The F&P 950 Respiratory Humidifier is intended to provide heat and humidity to respiratory gases delivered to patients. It is for use in a hospital or long-term care facility by a health professional.

F&P 950 Breathing Circuit Kits: 950A80J, 950A81J, 950A82J, 950A60J, 950A61J, 950A40J, AA451SU
The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.

F&P 950 Breathing Circuit Kits: 950P81J, 950P40J
The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant, child and adolescent patients, within the limits of its stated technical specifications.

F&P 950 Breathing Circuit Kits: 950N80J, 950N81J, 950N61J, 950N40J
The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients, within the limits of its stated technical specifications.

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	Nicholas Yap Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	15 June 2023

II. DEVICE

Name of Device	F&P 950 Respiratory Humidifier
Common/Usual Name	Respiratory Humidifier
Classification Name	Respiratory Gas Humidifier
Regulatory Class	Class II
Primary Classification Product Code	BTT (21 CFR §868.5450)
Secondary Product Code	BZE

III. PREDICATE DEVICE

- Primary Predicate device:

510(k) Number	Device Name
K110019	F&P MR850 Respiratory Humidifier

- Secondary Predicate devices:

510(k) Number	Device Name	Reason for secondary predicate
K122432	Adult Evaqua 2 (RT380/RT385)	Used as a predicate for the 950A80J, 950A81J, and 950A82J accessory breathing circuit kits.
K162553	F&P AirSpiral Heated Breathing Tube	Used as a predicate for the 950A40J, 950N40J, 950P40J, and AA451SU accessory breathing circuit kits.
K103767	F&P Infant Evaqua 2 (RT265/266)	Used as a predicate for the 950N80J, 950N81J, and 950P81J accessory breathing circuit kits.
K212031	F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (850A61)	Used as a predicate for the 950A60J, and 950A61J accessory breathing circuit kits.
K020332	Neonatal Breathing Circuits (RT130/RT131)	Used as a predicate for the 950N61J accessory breathing circuit kit.

- Reference device(s):

510(k) Number	Device Name	Reason for reference
K050927	F&P RT019 Inspiratory/Expiratory Filter	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to breathing circuit kit design – identical component(s) contained within subject device breathing circuit kit(s).
K173770	F&P OJR215 Pressure Relief Manifold NHF	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to breathing circuit kit design – identical component(s) contained within subject device breathing circuit kit(s).
K131895	F&P AIRVO 2	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to the adjustable temperature set points and flow rates for nasal high flow therapy in the subject device's Optiflow mode.
K211096	F&P Optiflow™ Oxygen Kit	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to the flow rates for nasal high flow therapy up to 70 L/min.

K982454	Philips Disposable Exhalation Port	Used to compare performance of DEP within F&P 950 accessory breathing circuit kits
K031745	Infant Flow SiPAP	Used to verify performance in accuracy of pressure delivery of the F&P 950 accessory breathing circuit kits.
K091111	Instrumentation Industries RTC 24-V Metered Dose Inhaler	Used to compare performance of MDI with the F&P 950 accessory breathing circuit kits
K133666	F&P RT016 Inspiratory Filter	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to breathing circuit kit design – identical component(s) contained within subject device breathing circuit kit(s).

IV. DEVICE DESCRIPTION

The F&P 950 Respiratory Humidifier is designed to warm and humidify air after it leaves a commercially available flow source and to maintain the air in a warmed and humidified condition to the point of delivery into the patient via heated tubing.

The F&P 950 Respiratory Humidifier is made up of a heaterbase, sensor cartridge and expiratory heater wire adapter with breathing circuit kits to support the use with adult, pediatric and neonatal patients. Breathing circuit kits enable the use of the F&P 950 Respiratory Humidifier with clinical procedures such as invasive ventilation and nasal high flow.

The device is a programmable electrical medical device that uses sensors throughout the system to humidify the gas. Gas travels through the chamber where it is humidified. The humidity is regulated through monitoring the gas temperature exiting the chamber to achieve the target humidity level. The gas is then transported to the patient through a heated delivery tube. The gas temperature exiting the heated delivery tube is monitored to minimize the formation of condensate.

V. INDICATIONS FOR USE STATEMENT

F&P 950 Respiratory Humidifier: The F&P 950 Respiratory Humidifier is intended to provide heat and humidity to respiratory gases delivered to patients. It is for use in a hospital or long-term care facility by a health professional.

F&P 950 Breathing Circuit Kits: 950A80J, 950A81J, 950A82J, 950A60J, 950A61J, 950A40J, AA451SU: The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.

F&P 950 Breathing Circuit Kits: 950P81J, 950P40J: The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant, child and adolescent patients, within the limits of its stated technical specifications.

F&P 950 Breathing Circuit Kits: 950N80J, 950N81J, 950N61J, 950N40J: The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients, within the limits of its stated technical specifications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: Subject Device and Primary Predicate Comparison Table

Design/technological characteristic for comparison	Subject Device F&P 950 Respiratory Humidifier	Primary Predicate Device F&P MR850 Respiratory Humidifier (K110019)	Comments
Intended use	To provide heat and humidity to respiratory gases	To provide heat and humidity to respiratory gases	***Identical***
Indications for use	The F&P 950 Respiratory Humidifier is intended to provide heat and humidity to respiratory gases delivered to patients. It is for use in a hospital or long-term care facility by a health professional.	The Fisher & Paykel Healthcare MR850 humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases.	***Equivalent*** The subject and primary predicate devices have equivalent indications for use. Both devices are indicated to provide heat and humidity to respiratory gases delivered to patients.
Patient population	Patients requiring respiratory gases	Patients requiring mechanical ventilation or positive pressure breathing assistance, via face non-invasive or invasive	***Identical*** The relevant patient populations are described in the relevant breathing circuit kits.
Intended use environment	Hospital or long-term care facility	Hospital	***Equivalent*** The intended use environments are equivalent.
Intended user group	Health professional	Hospital use by trained personnel	***Equivalent*** The intended user groups are equivalent.
Delivered humidity level	Bypassed airway: >33mg/L for flow < 60 L/min Non-bypassed airway: >12mg/L for flow < 120 L/min Breathing circuit kits have specified flow ranges based on patient population.	Bypassed airway: >33mg/L for flow < 60 L/min Non-bypassed airway: >10mg/L for flow < 120 L/min Breathing circuit kits have specified flow ranges based on patient population.	***Equivalent*** The subject device meets the humidity output requirements of ISO 80601-2-74:2017 while the primary predicate device meets the humidity output requirements of ISO 8185:2007.
Time to reach set temperature	<30min	<30 min	***Identical***
Operating principle	Gas travels through the chamber where it is humidified. The humidity is regulated through	Gas travels through the chamber where it is humidified. The humidity is regulated through	***Identical***

Design/technological characteristic for comparison	Subject Device F&P 950 Respiratory Humidifier	Primary Predicate Device F&P MR850 Respiratory Humidifier (K110019)	Comments
	monitoring the gas temperature exiting the chamber to achieve the target humidity level. The gas is then transported to the patient through a heated delivery tube. The gas temperature exiting the heated delivery tube is monitored to minimize the formation of condensate.	monitoring the gas temperature exiting the chamber to achieve the target humidity level. The gas is then transported to the patient through a heated delivery tube. The gas temperature exiting the heated delivery tube is monitored to minimize the formation of condensate.	
Ambient operating conditions	18-26˚C (Adult) 20-26˚C (Neonatal and Pediatric)	18-26˚C	***Equivalent*** The subject device falls within the primary predicate device operating conditions.
Device operating modes	Bypassed airway: • Invasive mode • Neonatal mode Non-bypassed airway: • Mask mode (adult and pediatric) • CPAP | NIV mode (neonatal) • Optiflow™ mode	Bypassed airway: • Invasive mode Non-bypassed airway: • Non-invasive (Mask) mode	***Equivalent*** The subject device includes five modes compared to the predicate device's modes. However, these modes are subsets of equivalent humidity levels and flow rates as described in rows above. The additional modes do not introduce new questions of safety or effectiveness as the specified flow ranges are tested in the performance testing and the humidity levels conform to the current recognized standards.
Alarms	Alarms exceed 45 dbA @1m Auditory alarm pause: 120 seconds Conforms to IEC 60601-1-8: 2006 + A1: 2012	Alarms exceed 50 dbA @1m Auditory alarm pause: 120 seconds Conforms to IEC 60601-1-8: 2003	***Equivalent*** The subject and primary predicate devices conform with applicable standards at the time of release.
Storage conditions (Hardware)	-20°C – 60°C	-10°C – 50°C	***Equivalent*** The subject device has broader storage conditions than the primary predicate device. This has been verified in the transport and storage testing included in performance testing.
Service life (Hardware)	7 years	7 years	***Identical***
IEC 60601-1 classification	Class II	Class I	***Equivalent***

Design/technological characteristic for comparison	Subject Device F&P 950 Respiratory Humidifier	Primary Predicate Device F&P MR850 Respiratory Humidifier (K110019)	Comments
			The subject device is double insulated with a functional earth, making it a Class II device.
IEC 62304 software classification	Class B	Class B	**Identical**

Table 2: 950A80J – Adult / Pediatric Ventilator Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A80J	Secondary Predicate Device F&P RT380 (K122432)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	The RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of adult patients, and to maintain the temperature of humidified inspired gas.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	Adult, adolescent and child patients with tidal volume above 200 mL.	Adult patients.	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	**Identical**

Specified Flow Range	Invasive mode: 5 – 60 L/min Mask mode: 5 – 120 L/min	Up to 60 L/min in Invasive mode as per the MR850 user instructions Up to 120 L/min in Noninvasive mode as per the MR850 user instructions	**Identical**
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-30°C – 50°C	**Equivalent** The subject device falls within the secondary predicate device storage condition range.

Table 3: 950A81J – Adult / Pediatric Ventilator Circuit Kit (with Filter) to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A81J	Secondary Predicate Device F&P RT380 (K122432)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	The RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of adult patients, and to maintain the temperature of humidified inspired gas.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	Adult, adolescent and child patients with tidal volume above 200 mL.	Adult patients.	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation:	Invasive ventilation:	**Identical**

Characteristic for comparison	Subject Device 950A81J	Secondary Predicate Device F&P RT380 (K122432)	Comments
	Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	
Specified Flow Range	Invasive mode: 5 – 60 L/min Mask mode: 5 – 120 L/min	Up to 60 L/min in Invasive mode as per the MR850 user instructions Up to 120 L/min in Noninvasive mode as per the MR850 user instructions	**Identical**
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-30°C – 50°C	**Equivalent** The subject device falls within the secondary predicate device storage condition range.
Filter	RT019 Inspiratory / Expiratory Filter	RT019 Inspiratory / Expiratory Filter	**Identical**

Table 4: 950A82J - Adult / Pediatric Ventilator Circuit Kit (with Filter and Pressure line) to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A82J	Secondary Predicate Device F&P RT385 (K122432)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	The RT380 and RT385 'Adult Evaqua 2' dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of adult patients, and to maintain the temperature of humidified inspired gas.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and	**Identical**

Characteristic for comparison	Subject Device 950A82J	Secondary Predicate Device F&P RT385 (K122432)	Comments
	expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	Adult, adolescent and child patients with tidal volume above 200 mL.	Adult patients.	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Non-vented mask with standard elbow	**Identical**
Specified Flow Range	Invasive mode: 5 – 60 L/min Mask mode: 5 – 120 L/min	Up to 60 L/min in Invasive mode as per the MR850 user instructions Up to 120 L/min in Noninvasive mode as per the MR850 user instructions	**Identical**
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-30°C – 50°C	**Equivalent** The subject device falls within the secondary predicate device storage condition range.
Filter	RT019 Inspiratory / Expiratory Filter	RT019 Inspiratory / Expiratory Filter	**Identical**
Pressure Line	498042178 Pressure Line with 693040748 Elbow	498042178 Pressure Line with 693040748 Elbow	**Identical**

Table 5: 950A40J – Optiflow™ Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A40J	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	Heated breathing tube for delivery of humidified respiratory gases. For use with AIRVO and AIRVO2 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** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a humidification chamber and inspiratory limb to create a single limb for the delivery of high flow therapy.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a single limb for delivery of high flow.
Patient Population	Adult, adolescent and child patients weighing above 10 kg.	Spontaneously breathing patient requiring flows between 2 –60 L/min.	**Different** The predicate is not indicated for a specific population but for a flow range. This includes both the adult and pediatric patient populations.
Intended Interface	High flow nasal cannula and tracheostomy high flow interface	High flow nasal cannula and tracheostomy high flow interface	**Identical**
Specified Flow Range	5 – 70 L/min	2 – 60 L/min on the F&P AIRVO 2 (K131895).	**Different** The subject device has the same specified flow range of 5 – 70 L/min as the AA403 Optiflow™ Oxygen Kit (K211096) reference device, also designed for use with high flow therapy.
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 6: 950N80J – Neonatal / Pediatric Ventilator Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950N80J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients, within the limits of its stated technical specifications.	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	For neonatal patients with tidal volume below 50 mL For infant and child patients with tidal volume 50 mL - 300 mL	Infant	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Midline or lateral CPAP interface with nasal prongs or a nasal mask	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Midline or lateral CPAP interface with nasal prongs or a nasal mask	**Identical**
Specified Flow Range	0.5 – 40 L/min	**RT266** 0.3 – 4 L/min **RT265** >4 L/min	**Equivalent** The subject device covers an equivalent flow range to the two secondary predicate devices. The AirSpiral™ technology in the F&P 950 inspiratory limb removes the need for separate low flow and high flow inspiratory limbs.
Duration of Use	14 Days	7 days	**Different** The subject device has the same duration of use as the RT380/RT385 secondary predicate device (K122432).

Characteristic for comparison	Subject Device 950N80J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 7: 950N81J – Neonatal / Pediatric Ventilator Circuit Kit (with Pressure line) to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950N81J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients, within the limits of its stated technical specifications.	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	For neonatal patients with tidal volume below 50 mL For infant and child patients with tidal volume 50 mL - 300 mL	Infant	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation:	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation:	**Identical**

Characteristic for comparison	Subject Device 950N81J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
	Midline or lateral CPAP interface with nasal prongs or a nasal mask	Midline or lateral CPAP interface with nasal prongs or a nasal mask	
Specified Flow Range	0.5 – 40 L/min	**RT266** 0.3 – 4 L/min **RT265** >4 L/min	**Equivalent** The subject device covers an equivalent flow range to the secondary predicate device. The AirSpiral™ technology in the F&P 950 inspiratory limb removes the need for separate low flow and high flow inspiratory limbs.
Duration of Use	14 Days	7 days	**Different** The subject device has the same duration of use as the RT380/RT385 secondary predicate device (K122432).
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**
Pressure Line	498042167 Pressure Line with 693040108 Elbow	498042167 Pressure Line with 693040108 Elbow	**Identical**

Table 8: 950N40J – Optiflow™ Junior Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950N40J	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients, within the limits of its stated technical	Heated breathing tube for delivery of humidified respiratory gases. For use with AIRVO and AIRVO2 Series humidifiers in hospitals and long-term care facilities.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.

Characteristic for comparison	Subject Device 950N40J	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
	specifications.	For use at flows from 2 to 60 L.min-1 depending on the patient interface.	
Operating Principle	Breathing circuit kit contains a humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a humidification chamber and inspiratory limb to create a single limb for the delivery of high flow therapy.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a single limb for delivery of high flow.
Patient Population	Neonatal, infant and child patients	Spontaneously breathing patient requiring flows between 2 –60 L/min.	**Different** The predicate is not indicated for a specific population but for a flow range. This includes pediatric patient populations.
Intended Interface	High flow nasal cannula and tracheostomy high flow interface	High flow nasal cannula and tracheostomy high flow interface	**Identical**
Specified Flow Range	0.5 – 36 L/min	2 – 60 L/min on the F&P AIRVO 2 (K131895).	**Different** The 950N40J flow range has been aligned directly with the specified flow range (0.5 – 36 L/min) of the previously cleared F&P OJR215 Pressure Relief Manifold NHF (K173770) that is contained within the kit.
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 9: 950P81J – Pediatric Ventilator Circuit Kit (with Pressure line) to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950P81J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
Classification Product Code	BZE	BZE	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**

Characteristic for comparison	Subject Device 950P81J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant, child and adolescent patients, within the limits of its stated technical specifications.	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of infant patients, and to maintain the temperature of humidified inspired gas. The RT265 is used for flow rates greater than 4 L/min, and the RT266 is for flow rates between 0.3 and 4 L/min.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to create a closed circuit that allows for invasive or noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a closed circuit that allows for invasive or noninvasive ventilation.
Patient Population	For neonatal patients with tidal volume below 50 mL For infant, child and adolescent patients with tidal volume 50 mL - 300 mL	Infant	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Midline or lateral nasal CPAP interface, or non-vented mask with standard elbow	Invasive ventilation: Endotracheal tube (ETT) or tracheostomy interface Noninvasive ventilation: Midline or lateral nasal CPAP interface, or non-vented mask with standard elbow	**Identical**
Specified Flow Range	1 – 60 L/min	**RT266** 0.3 – 4 L/min **RT265** >4 L/min	**Equivalent** The subject device covers an equivalent flow range to the secondary predicate device. The AirSpiral™ technology in the F&P 950 inspiratory limb removes the need for separate low flow and high flow inspiratory limbs.
Duration of Use	14 Days	7 days	**Different** The subject device has the same duration of use as the RT380/RT385 secondary predicate device (K122432).
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent**

Characteristic for comparison	Subject Device 950P81J	Secondary Predicate Device F&P RT265 / RT266 (K103767)	Comments
			The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 10: 950P40J – Pediatric Optiflow™ Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950P40J	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant, child and adolescent patients, within the limits of its stated technical specifications.	Heated breathing tube for delivery of humidified respiratory gases. For use with AIRVO and AIRVO2 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** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a humidification chamber and inspiratory limb to create a single limb for the delivery of high flow therapy.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a single limb for delivery of high flow.
Patient Population	Neonatal, infant, child and adolescent patients	Spontaneously breathing patient requiring flows between 2 –60 L/min.	**Different** The predicate is not indicated for a specific population but for a flow range. This includes pediatric patient populations.
Intended Interface	High flow nasal cannula and tracheostomy high flow interface	High flow nasal cannula and tracheostomy high flow interface	**Identical**
Specified Flow Range	1 – 60 L/min	2 – 60 L/min on the F&P AIRVO 2 (K131895).	**Equivalent** The subject and secondary predicate devices have equivalent flow ranges.
Duration of Use	14 Days	14 Days	**Identical**

Characteristic for comparison	Subject Device 950P40J	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 11: AA451SU – Optiflow™ Oxygen Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device AA451SU	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	Heated breathing tube for delivery of humidified respiratory gases. For use with AIRVO and AIRVO2 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** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a humidification chamber and inspiratory limb to create a single limb for the delivery of high flow therapy.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to create a single limb for delivery of high flow.
Patient Population	Adult, adolescent and child patients weighing above 10 kg	Spontaneously breathing patient requiring flows between 2 –60 L/min.	**Different** The predicate is not indicated for a specific population but for a flow range. This includes both the adult and pediatric patient populations.
Interface Connections	Patient end connector is designed with Fisher & Paykel secure connector features	Patient end connector is designed with Fisher & Paykel secure connector features	**Equivalent**

Characteristic for comparison	Subject Device AA451SU	Secondary Predicate Device F&P AirSpiral™ Heated Breathing Circuit (K162553)	Comments
Specified Flow Range	5 – 70 L/min	10 – 60 L/min on the F&P AIRVO 2 (K131895).	**Different** The subject device has the same specified flow range of 5 – 70 L/min as the AA403 Optiflow™ Oxygen Kit (K211096) reference device, also designed for use with high flow therapy.
Duration of Use	14 Days	14 Days	**Identical**
Reusability	Single Use	Single Use	**Identical**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 12: 950A60J – Bi-Level / CPAP Single Limb Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A60J	Secondary Predicate Device F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (K212031)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases	Heated breathing tube for delivery of humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	For the delivery of heated, humidified breathing gases to spontaneously breathing adult patients. This breathing set is suitable for use with Fisher & Paykel Healthcare MR850 Humidifiers in hospital and long-term care environments.	**Equivalent** Both the subject and secondary predicate device are indicated to deliver heated and humidified respiratory gases to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and disposable exhalation port to create a single limb with intentional leak for delivery of noninvasive ventilation.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and disposable exhalation port to create a single limb with intentional leak for delivery of noninvasive ventilation.	**Identical** Both the subject device and the secondary predicate device contain the components that connect together to allow for noninvasive ventilation.
Patient Population	Adult, adolescent and child patients weighing above 10 kg.	Spontaneously breathing adult patients requiring flows between 10 – 120 L/min	**Different**

Characteristic for comparison	Subject Device 950A60J	Secondary Predicate Device F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (K212031)	Comments
		depending on the required therapy and patient interface.	The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Non-vented mask (used with DEP) and vented mask	Non-vented mask (used with DEP) and vented mask	**Identical**
Specified Flow Range	5 – 120 L/min	10 – 120 L/min	**Equivalent**
Ambient operating conditions	18˚C – 26˚C	20˚C – 26˚C	**Equivalent**
Reusability	Single Use	Single Use	**Identical**
Duration of Use	14 Days	14 days	**Identical**
Shelf Life	3 years	2 years	**Equivalent** The subject device meets a 3 year shelf life.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

Table 13: 950A61J – Bi-Level / CPAP Single Limb Circuit Kit (with filter) to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950A61J	Secondary Predicate Device F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (K212031)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Heated breathing tube for delivery of humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	For the delivery of heated, humidified breathing gases to spontaneously breathing adult patients. This breathing set is suitable for use with Fisher & Paykel Healthcare MR850 Humidifiers in hospital and long-term care environments.	**Equivalent** Both the subject and secondary predicate device are indicated to deliver heated and humidified respiratory gases to patients.
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and disposable exhalation port to create a single	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and disposable exhalation port to create a single	**Equivalent**

Characteristic for comparison	Subject Device 950A61J	Secondary Predicate Device F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (K212031)	Comments
	limb with intentional leak for delivery of noninvasive ventilation.	limb with intentional leak for delivery of noninvasive ventilation.	Both the subject device and the secondary predicate device contain the components that connect together to allow for noninvasive ventilation
Patient Population	Adult, adolescent and child patients weighing above 10 kg.	Spontaneously breathing adult patients requiring flows between 10 – 120 L/min depending on the required therapy and patient interface.	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Non-vented mask (used with DEP) and vented mask	Non-vented mask (used with DEP) and vented mask	**Identical**
Specified Flow Range	5 – 120 L/min	10 – 120 L/min	**Equivalent**
Ambient operating conditions	18˚C – 26˚C	20˚C – 26˚C	**Equivalent**
Reusability	Single Use	Single Use	**Identical**
Duration of Use	14 Days	14 days	**Identical**
Shelf Life	3 years	2 years	**Equivalent** The subject device meets a 3 year shelf life.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**
Filter	RT016 Inspiratory Filter	RT016 Inspiratory Filter	**Identical**

Table 14: 950N61J – Nasal CPAP Flow Driver Circuit Kit to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device 950N61J	Secondary Predicate Device F&P RT130 / RT131 (K020332)	Comments
Classification Product Code	BTT	BTT	**Identical**
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases for mechanical ventilation or support.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to neonatal, infant and child patients,	The heated-wire breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas, to reduce condensation. They are accessories	**Equivalent** Both the subject and secondary predicate device are indicated to deliver heated and humidified respiratory gases to patients.

Characteristic for comparison	Subject Device 950N61J	Secondary Predicate Device F&P RT130 / RT131 (K020332)	Comments
	within the limits of its stated technical specifications.	for the Fisher & Paykel Healthcare MR850 Respiratory Gas Humidifier. The RT130 is used for flow rates between 0.3 and 4 L/min, and the RT131 is for flow rates greater than 4 L/min, for neonatal patients.	
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and adapters to allow for delivery of Nasal CPAP.	Breathing circuit kit contains a dryline, humidification chamber, inspiratory limb, and expiratory limb to allow for the delivery of Nasal CPAP.	**Equivalent** Both the subject device and the secondary predicate device contain the components that connect together to allow for Nasal CPAP.
Patient Population	Neonatal, infant and child patients.	Infant patients.	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	CPAP Generator assembly with nasal interface (prongs or mask)	Nasal CPAP interface with nasal prongs or nasal mask	**Equivalent**
Specified Flow Range	0.5 – 40 L/min	**RT130** 0.3 – 4 L/min **RT131** >4 L/min	**Equivalent** The subject device covers an equivalent flow range to the two secondary predicate devices. The AirSpiral™ technology in the F&P 950 inspiratory limb removes the need for separate low flow and high flow inspiratory limbs.
Ambient operating conditions	20˚C – 26˚C	20˚C – 26˚C	**Identical**
Reusability	Single Use	Single Use	**Identical**
Duration of Use	14 Days	7 Days	**Different** The subject device has a different duration of use to the RT130/RT131 secondary predicate (K020332). However, the duration of use is the same as the RT380/RT385 (K122432).
Shelf Life	3 years	5 years	**Equivalent**
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P 950 Respiratory Humidifier has been tested to the applicable requirements of the following standards:

Standards	Title
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 18562-1:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 1: Evaluation and Testing Within a Risk Management Process
IEC 62304:2015 Consolidated Version	Medical device software – software lifecycle processes
IEC 60601-1-2:2014 + AMD1:2020 Ed 4.1	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
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
ISO 5367:2014	Anaesthetic and respiratory equipment – Breathing sets and connectors
ISO 5356-1:2004	Anaesthetic and Respiratory Equipment – Conical Connectors – Part 1: Cones and Sockets.
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (edition 3.1).
ISO 80601-2-74: 2017	Medical Electrical Equipment- Part 2-74: Particular Requirements For Basic Safety and Essential Performance Of Respiratory Humidifying Equipment
IEC 60601-1-6:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8:2012	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.
IEC 62366-1:2015 + AMD:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISTA 3A	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

Biocompatibility Testing:

The biocompatibility evaluation for the F&P 950 Respiratory Humidifier and accessory breathing circuit kits was conducted in accordance with the International Standards ISO 10993-1:2018 “Biological Evaluation of Medical Devices − Part 1: Evaluation and testing within a risk management process,” and ISO 18562-1:2017 “Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a

risk management process" as recognized by the FDA. Testing of the F&P 950 Respiratory Humidifier and accessory breathing circuit kits demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety, Electromagnetic Compatibility (EMC), and Alarms:
Electrical safety and EMC testing were conducted on the F&P 950 Respiratory Humidifier and accessory breathing circuit kits. The system complies with ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-2:2014 + AMD1:2020 Ed 4.1 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 IEC 60601-1-8:2006 and A1:2012.

Software Verification and Validation Testing:
Software verification and validation 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."

Human Factors Testing:
A Human Factors and Usability Engineering validation study was conducted on the F&P 950 Respiratory Humidifier and accessory breathing circuit kits, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices". The validation study demonstrates that the device has been found to be safe and effective for the intended users, uses, and use environments.

Bench / Performance Testing:
Performance testing was conducted to demonstrate substantial equivalence including:

- Humidification output, thermal overshoot, surface temperature of applied parts in line with ISO 80601-2-74:2017
- Resistance to flow, compliance, and gas leak testing in line with ISO 5367:2014
- Comparative ME systems testing in line with ISO 80601-2-12:2020
- Comparative Disposable Exhalation Port leak rate
- Comparative testing of MDI port performance

VIII. CONCLUSION

The F&P 950 Respiratory Humidifier and accessory breathing circuit kits are substantially equivalent to the predicate devices based on intended uses, comparison of the technological characteristics and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the devices are substantially equivalent to the legally marketed predicate devices.