April 22, 2022

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

Re: K212031
Trade/Device Name: F&P 850 AirSpiral Adult NIV and NHF Circuit Kit
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: March 22, 2022
Received: March 22, 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,

Brandon Blakely, Ph.D.
Respiratory Devices Team
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)*
K212031

Device Name
F&P 850 AirSpiral Adult NIV and NHF Circuit Kit

Indications for Use *(Describe)*
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.

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	22 April 2022

II. DEVICE

Device Name	F&P 850 AirSpiral Adult NIV and NHF Circuit Kit
Common/Usual Name	Heated Breathing Tube
Classification Name	Respiratory gas humidifier
Regulatory Class	Class II (21 CFR §868.5450)
Product Code	BTT

III. PREDICATE DEVICE

Predicate Device	F&P AirSpiral Heated Breathing Tube	K162553
Secondary Predicate Device	Bipap Vision Ventilatory Support	K982454
Reference Device(s)	F&P RT380 Adult Evaqua 2 Dual Heated Breathing Circuit • Used to support claims of substantial equivalence with respect to performance and system compatibility	K122432

DEVICE DESCRIPTION

The F&P 850 AirSpiral Adult NIV and NHF Circuit Kit (850A61) is designed to provide a gas conduit between respiratory support equipment and a patient interface such as a mask, nasal prongs or tracheostomy interface for a spontaneously breathing Adult patient.

The Inspiratory Limb is an extruded bubble tube design 1.6 metres in length, and is intended to connect the gas path from humidification chamber to the patient interface. Additionally, temperature sensor clips and a gown clip are included to aid in cable management and to affix the circuit to a gown or sheet. The subject device is single use, prescription only and is provided in a non-sterile state.

The Disposable Exhalation Port is an optional accessory for NIV applications. It features a perforated ventilation hole and a 22mm/15mm coaxial taper connector for connecting to patient interfaces and a 22mm tapered male connector for connecting to the patient end of the Inspiratory Limb. It also features a capped port for connecting to the Pressure Line.

IV. INDICATIONS FOR USE

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.

V. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

A comparison of intended use, features, and performance specifications demonstrate that the subject device is substantially equivalent to the predicate device.

Parameter	Subject Device F&P 850A61	Predicate Device F&P AirSpiral Heated Breathing Tube (K162553)	Comments
Classification			
Manufacturer	Fisher & Paykel Healthcare Ltd.	Fisher & Paykel Healthcare Ltd.	Identical
Device Regulation	Class II, Regulation: 21 CFR 868.5270	Class II, Regulation: 21 CFR 868.5270	
Product Code	BTT	BTT	
Classification Panel	Anesthesiology	Anesthesiology	
Intended Use and Indications for Use			
Intended Use	Heated breathing tube for delivery of humidified respiratory gases	Heated breathing tube for delivery of humidified respiratory gases	Identical
Indications for Use	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.	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 depending on the patient interface.	Equivalent
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Patient Population	Spontaneously breathing adult patients requiring flows between 10 – 120 L/min depending on the required therapy and patient interface.	Spontaneously breathing patient requiring flows between 2 – 60 L/min.	Equivalent

Parameter	Subject Device F&P 850A61	Predicate Device F&P AirSpiral Heated Breathing Tube (K162553)	Comments
Operating Environment	Hospital and long-term care environments	Hospital and long-term care facilities	Identical
Reusability	Single use	Single use	Identical
Sterility	Device not provided sterile	Device not provided sterile	Identical
Life Supporting or Life Sustaining	No	No	Identical
Operation and Safety Features			
Principle of Operation	Connects to a humidifier. Powered by the humidifier to maintain heat as a conduit for humidified heated respiratory gases. Connects the humidifier to the patient interface.	Connects to a humidifier. Powered by the humidifier to maintain heat as a conduit for humidified heated respiratory gases. Connects the humidifier to the patient interface.	Identical
Tube Dimensions	**Length**: 1.6 m **Internal Diameter**: 17 mm	**Length**: 1.8 m **Internal Diameter**: 13.1 mm	Equivalent
Design of the Tube Construction	Heated tube to transport humidified gas between the humidification chamber and the Patient End Two-spiral wall tubing design: • Insulating spiral made of Spiral-wound bubble tubing Heating spiral encapsulating heater wire	Heated tube to transport humidified gas between the Unit End and the Patient End Two-spiral wall tubing design: • Insulating spiral made of Spiral-wound bubble tubing Heating spiral encapsulating heater wire	Identical
Temperature Sensor	A removable temperature and flow sensor are used at the humidification chamber outlet port which is an accessory to the F&P MR850 humidifier.	An integrated temperature sensor at the patient end of the tube eliminates the need for external probes, cables or adaptors.	Similar

Parameter	Subject Device F&P 850A61	Predicate Device F&P AirSpiral Heated Breathing Tube (K162553)	Comments
	A removable temperature sensor is used at the patient end port which is an accessory to the F&P MR850 humidifier.		
Heater Wire Lumen Design	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 thermal insulation.	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 thermal insulation.	Identical
Clips	Allows the breathing tube to be attached to clothing or bedding and to position the tube to suit the clinician and patient	Allows the breathing tube to be attached to clothing or bedding and to position the tube to suit the clinician and patient	Identical
Humidifier Compatibility	F&P MR850 Respiratory Humidifier	F&P AIRVO / AIRVO2 Series Humidifier F&P myAIRVO / myAIRVO2 Series Humidifier	Similar
Water Chamber Compatibility	MR290V autofill chamber • Single patient use only	900PT290E auto fill chamber, • Single patient use only HC360 manual fill chamber, • Single patient reuse	Identical
Patient Interface Compatibility	**HF Indication:** • Interface with 22 mm male connector (ISO 5356) e.g. OPT944 Nasal Cannula (K162553) **NIV Indication:**	**HF Indication:** • OPT942, OPT944, OPT946 Nasal Cannula • OPT970 Tracheostomy Direct Connection • OPT980 Mask Interface Adapter	Equivalent

Parameter	Subject Device F&P 850A61	Predicate Device F&P AirSpiral Heated Breathing Tube (K162553)	Comments
	• Non-vented mask with 22 mm male connector (ISO 5356) and exhalation port e.g. RT045 Mask (K170367) • Vented mask with 22 mm female connector (ISO 5366) e.g. RT047 Mask (K191624) All are single patient use only	• OPT316, OPT318 Junior Nasal Cannula All are single patient use only	
Performance			
Flow Range	10 – 120 L/min **HF (MR850 Invasive Mode):** • 10 – 60 L/min **NIV (MR850 Mask Mode):** • 10 – 120 L/min	2 – 60 L/min **Default Mode**: • 10 – 60 L/min **Junior Mode**: • 2 – 5 L/min	The expanded flow rate range of the subject device is supported by the reference device (K122432), which is also indicated for use up to 120 L/min when used with MR850.
Shelf Life	2 Years	5 Years	Both devices were preconditioned using equivalent methods to simulate shelf life and performance was verified thereafter.
Useful Life	Single patient use – 14 days in Hospital / Long-term care facilities	Single patient use – 14 days in Hospital / Long-term care facilities	Identical
Humidity Delivery	Noninvasive Mode: > 12 mg/L Invasive Mode: > 33 mg/L	Noninvasive indications: >12 mg/L • Default and Junior modes Invasive indications: > 33 mg/L • Default and Junior modes	Identical

Technical Characteristic	Secondary Predicate Device Philips Disposable Exhalation Port (K982454)	Subject Device F&P Disposable Exhalation Port	Comments
Indications for Use	This item is supplied as a component in a complete breathing system and supports the respective indications for use.	This item is supplied as a component in the circuit kit and supports the respective indications for use.	Identical
Availability	Prescription only	Prescription only	
Patient Population	Adult	Adult	
Patient State	Spontaneously breathing	Spontaneously breathing	
Patient Monitoring	Appropriate patient monitoring	Appropriate patient monitoring	
Operating Environment	Hospital and long-term care	Hospital and long-term care	
User Group	Respiratory therapists, sleep lab technicians or nurses under the supervision or direction of a physician	Under the supervision of trained medical personnel	
Reusability	Single Patient Use	Single Patient Use	
Useful Life	-	14 days	
Technical Specifications and Features			
Connection to interface	ISO 5356-1 Conical connectors (22mm male and 15mm female)	ISO 5356-1 Conical connectors (22mm male and 15mm female)	Identical
Connection to circuit	ISO 5356-1 Conical connectors (22mm male)	ISO 5356-1 Conical connectors (22mm male)	
Connection to pressure port	Compatible with 1/8” pressure line and port cap	Compatible with 1/8” pressure line and port cap	
Inhalation Path Diameter (min)	15.2 mm	15.2 mm	
Exhalation Port functional performance	>15 L/min @ 4 cmH2O	>15 L/min @ 4 cmH2O	Equivalent
Pressure port functional performance	3 mL air volume	3.5 mL air volume	Equivalent
Inhalation Path functional performance	17% Tidal volume discrepancy	13% Tidal volume discrepancy	Equivalent
Materials			
Materials	Polycarbonate	Polycarbonate	Identical

VI. PERFORMANCE DATA

Summary of non-clinical tests

The F&P 850A61 has been tested to applicable requirements of the following standards:

Standards and Designation Number	Standards Title
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
IEC 60601-1:2005+AMD1:2012	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
AIM 7351731 Rev 2.0:2017	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
ISO 5356-1:2015	Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
ISO 5367:2014	Anaesthetic and respiratory equipment – Breathing sets and connectors
IEC 60601-1-6 ed 3.1:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 62366-1:2015	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 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials 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
ISTA 3A	Packaged Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

In addition to the standards listed above, the following testing has been completed to demonstrate substantial equivalence:

Exhalation Port Equivalence:

A comparison of the flow rates through the exhalation port for the subject and predicate DEP was tested. Testing showed there is minimal difference in flow rate between the predicate and subject DEP at any of the pressures tested.

Pressure Port Equivalence:

A comparison of the inspired volume required for the inspiration of a breath was performed using the subject and predicate DEP.
The comparative testing showed the tidal volumes of the subject DEP within 1 mL of the predicate DEP and can be considered to have an equivalent sensitivity to a breath being taken by the patient.

Inhalation Path Equivalence:

A comparison of the tidal volumes delivered to the patient in relation to the volumes set on the ventilator showed the configurations using the subject DEP have a smaller tidal volume difference than those using the predicate DEP, and hence allow equivalent accuracy of delivery of therapy to the patient.

Human Factors Evaluation

A Human Factors and Usability Engineering validation study was conducted, and documentation was provided as per FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Medical Devices".
Validation study participants included 15 experienced, US Licensed Respiratory Therapists, and the report demonstrates that the critical tasks of the 850A61 breathing set can be completed by experienced respiratory therapists.

VII. CONCLUSIONS

The F&P 850A61 is substantially equivalent to the predicate device based on intended use, patient population, comparison of the technological characteristics and performance specifications. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate device.