June 29, 2023

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

Re: K221436
Trade/Device Name: F&P 950 Bubble CPAP Breathing Circuit Kits
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 17, 2022
Received: May 17, 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant 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)*
K221436

Device Name
F&P 950 Bubble CPAP Breathing Circuit Kits

Indications for Use *(Describe)*

950N60J – Bubble CPAP Dual Heated Circuit Kit
The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), within the limits of its stated technical specifications.

950N62J – Bubble CPAP Dual Heated Circuit Kit (for Hudson interface)
The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), 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 Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	29 June 2023

II. DEVICE

Name of Device	F&P 950 Bubble CPAP Breathing Circuit Kits
Common/Usual Name	Bubble CPAP Breathing Circuit Kits
Classification Name	Ventilator, Non-Continuous, (Respirator)
Regulatory Class	Class II
Primary Classification Product Code	BZD (21 CFR §868.5905)

III. PREDICATE DEVICE

- Predicate device:

510(k) Number	Device Name
K100011	Bubble CPAP System (BC151/BC161)

- Reference Devices:

510(k) Number	Device Name	Reason for Reference Device
K212031	F&P 850 AirSpiral Adult NIV And NHF Circuit Kit (850A61)	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 – same AirSpiral™ inspiratory tube technology contained within the subject device.
K103767	F&P Infant Evaqua 2 (RT265/266)	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 the subject device.
K173770	OJR215 Pressure Relief Manifold	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 the subject device.

IV. DEVICE DESCRIPTION

The subject devices of this 510(k) are the F&P 950 Bubble CPAP Breathing Circuit Kits (950N60J and 950N62J).

The F&P 950 Bubble CPAP Breathing Circuit Kits are single patient use and designed for use with the F&P 950 Respiratory Humidifier.

The F&P 950 Bubble CPAP (continuous positive airway pressure) Breathing Circuit Kits provide breathing support to spontaneously breathing neonates and infants. The F&P 950 Bubble CPAP breathing circuit kits deliver heated and humidified respiratory gas through an inspiratory limb to the infant via a nasal interface. An expiratory limb connects to a Bubble CPAP generator to generate CPAP. The device is intended to be operated at input gas flows of 4 – 15 L/min with available CPAP levels of 3 – 10 cmH_2O.

V. INDICATIONS FOR USE STATEMENT

950N60J – Bubble CPAP Dual Heated Circuit Kit

The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), within the limits of its stated technical specifications.

950N62J – Bubble CPAP Dual Heated Circuit Kit (for Hudson interface)

The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), within the limits of its stated technical specifications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: 950N60J – Bubble CPAP Circuit Kit to Predicate Comparison Table

Characteristic for comparison	Subject Device 950N60J	Predicate Device F&P Bubble CPAP System BC161 Breathing Circuit Kit (K100011)	Comments
Classification Product Code	BZD	BZD	**Identical to Predicate**
Intended Use	Deliver heated and humidified respiratory gases to provide CPAP.	Deliver heated and humidified respiratory gases to provide CPAP.	**Identical to Predicate**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full-term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), within the limits of its stated technical specifications.	The Fisher & Paykel Healthcare Bubble CPAP System is intended to provide CPAP to spontaneously breathing neonates and infants who require breathing support due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired and is prescribed by a physician. The Bubble CPAP System is for use in the hospital clinical environment such as the NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit). The intended patient population is premature and full term neonates up to a weight of 10 kg.	**Equivalent to Predicate** The subject and predicate devices are both intended to provide CPAP to patients.
Operating Principle	Breathing circuit kit contains a humidification chamber, inspiratory limb, expiratory limb, pressure relief manifold and Bubble CPAP generator to allow for the generation and delivery of Bubble CPAP.	Breathing circuit kit contains a humidification chamber, inspiratory limb, expiratory limb, pressure relief manifold and Bubble CPAP generator to allow for the generation and delivery of Bubble CPAP.	**Identical to Predicate**
Patient Population	Neonatal and infant patients weighing <10 kg.	Neonatal and infant patients up to a weight of 10kg.	**Identical to Predicate**
Intended use environment	Hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit).	Hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit).	**Identical to Predicate**
Intended interface	Midline or lateral nasal CPAP interface with nasal prongs or a nasal mask	Midline or lateral nasal CPAP interface with nasal prongs or a nasal mask	**Identical to Predicate**

Characteristic for comparison	Subject Device 950N60J	Predicate Device F&P Bubble CPAP System BC161 Breathing Circuit Kit (K100011)	Comments
Interface Connections	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	**Identical to Predicate**
CPAP Range	3 – 10 cmH_2O	3 – 10 cmH_2O	**Identical to Predicate**
Specified Flow Range	4 – 15 L/min	4 – 15 L/min	**Identical to Predicate**
Over pressure protection for patient safety	Yes – 17 cmH_2O	Yes – 17 cmH_2O	**Identical to Predicate**
Ambient operating conditions	20˚C – 26˚C	20˚C – 26˚C	**Identical to Predicate**
Reusability	Single Use	Single Use	**Identical to Predicate**
Duration of Use	14 Days	7 days	**Different to Predicate** The subject device has been tested to 14 day duration of use.
Shelf Life	3 years	3 years	**Identical to Predicate**
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical to Predicate**
Bubble CPAP Generator	F&P 950 Bubble CPAP Generator	BC100 CPAP Generator	**Equivalent to Predicate** The same Bubble CPAP generator is included in both the subject and the predicate device.

Table 2: 950N62J – Bubble CPAP Circuit Kit (for Hudson interface) to Predicate Comparison Table

Characteristic for comparison	Subject Device 950N62J	Predicate Device F&P Bubble CPAP System BC151 Breathing Circuit Kit (K100011)	Comments
Classification Product Code	BZD	BZD	**Identical to Predicate**
Intended Use	Deliver heated and humidified respiratory gases to provide CPAP.	Deliver heated and humidified respiratory gases to provide CPAP.	**Identical to Predicate**
Indications for Use	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended to provide heated and humidified CPAP to spontaneously breathing premature and full-term neonates and infant patients (up to a weight of 10 kg) who require breathing support, due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired. It	The Fisher & Paykel Healthcare Bubble CPAP System is intended to provide CPAP to spontaneously breathing neonates and infants who require breathing support due to conditions associated with prematurity (such as Respiratory Distress Syndrome) or other conditions where CPAP is required or desired and is prescribed by a physician.	**Equivalent to Predicate** The subject and predicate devices are both intended to provide CPAP to patients.

Characteristic for comparison	Subject Device 950N62J	Predicate Device F&P Bubble CPAP System BC151 Breathing Circuit Kit (K100011)	Comments
	is intended for use within a hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit), within the limits of its stated technical specifications.	The Bubble CPAP System is for use in the hospital clinical environment such as the NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit). The intended patient population is premature and full term neonates up to a weight of 10 kg.	
Operating Principle	Breathing circuit kit contains a humidification chamber, inspiratory limb, expiratory limb, pressure relief manifold, Bubble CPAP generator, and Hudson extensions to allow for the generation and delivery of Bubble CPAP.	Breathing circuit kit contains a humidification chamber, inspiratory limb, expiratory limb, pressure relief manifold, Bubble CPAP generator, and unheated extension to allow for the generation and delivery of Bubble CPAP.	**Identical to Predicate**
Patient Population	Neonatal and infant patients weighing <10 kg.	Neonatal and infant patients weighing <10kg.	**Identical to Predicate**
Intended use environment	Hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit).	Hospital clinical environment such as a NICU (Neonatal Intensive Care Unit) and PICU (Pediatric Intensive Care Unit).	**Identical to Predicate**
Intended interface	Nasal CPAP interface with nasal prongs with 8 mm tapers	Nasal CPAP interface with nasal prongs with 8 mm tapers	**Identical to Predicate**
Interface Connections	ISO 5356-1 Conical Connectors	ISO 5356-1 Conical Connectors	**Identical to Predicate**
CPAP Range	3 – 10 cmH_2O	3 – 10 cmH_2O	**Identical to Predicate**
Specified Flow Range	4 – 15 L/min	4 – 15 L/min	**Identical to Predicate**
Over pressure protection for patient safety	Yes – 17 cmH_2O	Yes – 17 cmH_2O	**Identical to Predicate**
Ambient operating conditions	20˚C – 26˚C	20˚C – 26˚C	**Identical to Predicate**
Reusability	Single Use	Single Use	**Identical to Predicate**
Duration of Use	14 Days	7 days	**Different to Predicate** The subject device has been tested to 14 day duration of use.
Shelf Life	3 years	3 years	**Identical to Predicate**
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical to Predicate**
Bubble CPAP Generator	F&P 950 Bubbler CPAP Generator	BC100 CPAP Generator	**Equivalent to Predicate** The same Bubble CPAP generator is included in both the subject and the predicate device.

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P 950 Bubble CPAP Breathing Circuit Kits 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 10993-5:2009	Biological evaluation of medical devices – Part 5: Test for in-vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Test for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
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 materials
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 18562-1:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 1: Evaluation and Testing Within a Risk Management Process
ISO 18562-2:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
ISO 18562-3:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
ISO 18562-4:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
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.
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 62366-1:2015 + AMD:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISTA 3A:2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less

Biocompatibility Testing:
The nature of body contact of materials used in the design of the F&P 950 Bubble CPAP breathing kits were classified as being external communicating gas pathway (both dry and humidified) with permanent (> 30 days) duration of contact. The biocompatibility evaluation for the F&P 950 Bubble CPAP 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” and associated standards as recognized by the FDA. Testing of the F&P 950 Bubble CPAP breathing circuit kits demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety and Electromagnetic Compatibility (EMC):
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.

Human Factors Testing:
A Human Factors and Usability Engineering validation study was conducted on the F&P 950 Bubble CPAP 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 system level pneumatic performance testing

VIII. CONCLUSION

The F&P 950 Bubble CPAP Breathing Circuit Kits are 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 devices are substantially equivalent to the legally marketed predicate devices.