February 7, 2024

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

Re: K231956
Trade/Device Name: F&P Optiflow+ Duet Nasal Cannula
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: February 6, 2024
Received: January 8, 2024

Dear Reena Daken:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
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Center for Devices and Radiological Health

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)*
K231956

Device Name
F&P Optiflow+ Duet Nasal Cannula

Indications for Use *(Describe)*

OPT96X Model:

The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway.

This device is designed to be used in a hospital, sub-acute facility, or long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.

MYDUETXXX Model:

The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway.

This device is designed to be used in a long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.

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	Jung Yun Lee Regulatory Affairs Associate
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz

Date prepared	30 June 2023

II. DEVICE

Name of Device	F&P Optiflow+ Duet Nasal Cannula
Common/Usual Name	Nasal Cannula
Classification Name	Respiratory Gas Humidifier
Regulatory Class	Class II (21 CFR §868.5450)
Product Code	BTT

III. PREDICATE DEVICE

- Predicate device:
  - F&P Optiflow+ Nasal Cannula OPT94X, K162553

IV. DEVICE DESCRIPTION

The F&P Optiflow+ Duet Nasal Cannula is a nasal cannula interface for use with a respiratory gas humidifier and flow generator to deliver Nasal High Flow (NHF) therapy to spontaneously breathing patients.

The F&P Optiflow+ Duet Nasal Cannula is a prescription-only device, provided in a non-sterile state and intended to be used in a hospital, sub-acute facility, or long-term (managed) care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional. The device is single patient use only for up to 14 days in the hospital and up to 30 days in the home/long-term care facilities.

A list of the subject device product codes can be found below:

Model	Product Code	Product Description
OPT96X This device is designed to be used in a hospital, sub-acute facility or long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.	OPT962	Nasal Cannula – Small
	OPT964	Nasal Cannula – Medium
	OPT966	Nasal Cannula – Large
MYDUETXXX This device is designed to be used in a long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.	MYDUETSMALL	myAirvo Small Duet Nasal Cannula 2-pack
	MYDUETMEDIUM	myAirvo Medium Duet Nasal Cannula 2-pack
	MYDUETLARGE	myAirvo Large Duet Nasal Cannula 2-pack

V. INDICATIONS FOR USE

The indications for use for the OPT96X Model and the MYDUETXXX Model are below:

OPT96X Model:

The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway.

This device is designed to be used in a hospital, sub-acute facility, or long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.

MYDUETXXX Model:

The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway.

This device is designed to be used in a long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features, performance data, and intended use demonstrate that the F&P Solo Mask Range is substantially equivalent to the predicate device, F&P Nasal Cannula (K162553). Please see the table below.

Design/Technological Characteristic	Subject Device (F&P Optiflow+ Duet Nasal Cannula)	Predicate Device (K162553) (F&P Optiflow+ Nasal Cannula, OPT94X)	Comments
Classification			
Product Code	BTT	BTT	Identical
Device Classification	21 CFR §868.5450	21 CFR §868.5450	
Classification Panel	Anesthesiology	Anesthesiology	
Indications for use			
Indications for use	**OPT96X Model** The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway. This device is designed to be used in a hospital, sub-acute facility or long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.	Nasal cannula patient interface for delivery of humidified respiratory gases.	The Indications for Use statement for the subject device is more specific than the predicate device. Target population and operating environment have been defined for the subject devices, for clarity.

Design/Technological Characteristic	Subject Device (F&P Optiflow+ Duet Nasal Cannula)	Predicate Device (K162553) (F&P Optiflow+ Nasal Cannula, OPT94X)	Comments
	MYDUETXXX Model The F&P Optiflow+ Duet is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (10 years and up) and adult patients who would benefit from receiving high flow warmed and humidified respiratory gases to the upper airway. This device is designed to be used in a long-term care facility by appropriately qualified healthcare professionals, or in the home by lay users operating the device as prescribed by a healthcare professional.		
Availability	Prescription use. (Part 21 CFR 801 Subpart D)	Prescription use. (Part 21 CFR 801 Subpart D)	Identical
Patient Population	Pediatric (10 years and up) to adult.	Mainly Adult Patients.	Patient population for the subject device is more specific than the predicate device.
Patient Acuity	Spontaneously breathing patients.	Spontaneously breathing patients.	Identical
Patient Monitoring	Appropriate patient monitoring must be used at all times.	Appropriate patient monitoring must be used at all times.	Identical
Use Environment	**OPT96X Series:** Home and Hospital environment, sub-acute	Home and Hospital environment, long-term (managed) care facilities	Identical The addition of sub-acute facilities does not affect / change the user group and

Design/Technological Characteristic	Subject Device (F&P Optiflow+ Duet Nasal Cannula)	Predicate Device (K162553) (F&P Optiflow+ Nasal Cannula, OPT94X)	Comments
	facilities, long-term (managed) care facilities **MYDUET Series:** Home and long-term (managed) care facilities		patient population compared to the predicate.
Reusability	Single patient-use only, < 14 days in hospital, including sub-acute facilities Single patient-use only, < 30 days in home, and long-term care facilities	Single patient-use only, < 14 days in hospital Single patient-use only, < 30 days in home and long-term care facilities	Identical
Number of Cannula Sizes	Both Hospital and Home models are available in: Small Medium Large	Both Hospital and Home models are available in: Small Medium Large	Identical
Compatibility with other devices			
Humidifier Compatibility	Airvo 2 and myAirvo 2 (K131895) Airvo 3 (K221338) MR850 humidifier (K110019) F&P 950 Respiratory Humidifier (K220703)	Airvo 2 and myAirvo 2 (K131895) MR850 humidifier (K110019)	The predicate was not cleared for use with the Airvo 3 or the F&P 950 System.

Design/Technological Characteristic	Subject Device (F&P Optiflow+ Duet Nasal Cannula)	Predicate Device (K162553) (F&P Optiflow+ Nasal Cannula, OPT94X)	Comments
Nasal Cannula Design			
Overall Cannula Construction	The F&P Optiflow+ Duet Nasal Cannula is made up of two sub-assemblies that connect to the Nasal Prong component. The two sub-assemblies are: • Tubing sub-assembly • Headgear sub-assembly	The F&P Optiflow+ Nasal Cannula is made up of two sub-assemblies that connect to the Nasal Prong component. The two sub-assemblies are: • Tubing sub-assembly • Headgear sub-assembly	Identical
Headgear Adjustment	The headgear size adjustment (i.e. headstrap length and tightness adjustment) method comprises of the Headstrap component looping through (and being retained by) two slots on the Headstrap Buckle component.	The headgear size adjustment (i.e. headstrap length and tightness adjustment) method comprises of the Headstrap component looping through (and being retained by) two slots on the Headstrap Buckle component.	Identical
Size Identification Color Coding	Size Small: Orange Size Medium: Blue Size Large: Green	Size Small: Orange Size Medium: Blue Size Large: Green	Identical
Performance Specifications			
F&P Airvo 2 System Flow Range	OPT962 (Small) 10 – 50 L/min OPT964 (Medium) 10 – 60 L/min OPT966 (Large) 10 – 60 L/min	OPT942 (Small) 10 – 50 L/min OPT944 (Medium) 10 – 60 L/min OPT946 (Large) 10 – 60 L/min	Identical
F&P Airvo 3 System Flow Range	OPT962 (Small) 10 – 60 L/min OPT964 (Medium) 10 – 70 L/min OPT966 (Large) 10 – 70 L/min	OPT942 (Small) 10 – 60 L/min OPT944 (Medium) 10 – 70 L/min OPT946 (Large) 10 – 70 L/min	Identical

Design/Technological Characteristic	Subject Device (F&P Optiflow+ Duet Nasal Cannula)	Predicate Device (K162553) (F&P Optiflow+ Nasal Cannula, OPT94X)	Comments
MR850 System Flow Range	OPT962 (Small) 5 - 60 L/min OPT964 (Medium) 5 - 60 L/min OPT966 (Large) 5 - 60 L/min	OPT942 (Small) 5 - 60 L/min OPT944 (Medium) 5 - 60 L/min OPT946 (Large) 5 - 60 L/min	Identical
F&P 950 System Flow Range	OPT962 (Small) 5 - 70 L/min OPT964 (Medium) 5 - 70 L/min OPT966 (Large) 5 - 70 L/min	N/A	The predicate was not cleared for use with the F&P 950 System.
F&P myAirvo System Flow Range	MYDUETSMALL 10 – 50 L/min MYDUETMEDIUM 10 – 60 L/min MYDUETLARGE 10 – 60 L/min	OPT942E (Small) 10 – 50 L/min OPT944E (Medium) 10 – 60 L/min OPT946E (Large) 10 – 60 L/min	Identical
Shelf life	3 years	Shelf life not claimed on labeling	The subject device claims a 3-year shelf life.
Transport and Storage Temperature range	-10 °C to + 50 °C	-10 °C to + 50 °C	Identical
Sterility	Device not provided sterile	Device not provided sterile	Identical

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

The F&P Optiflow+ Duet Nasal Cannula has been tested to applicable requirements to the following standards:

- 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
- ISO 5356-1:2015 Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- IEC 62366-1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices
- ISTA 2A:2011 International Safety Transit Association Guidelines - Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or less

VIII. CONCLUSIONS

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