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

Re: K234053
Trade/Device Name: F&P Optiflow Flow Diverter
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing valve
Regulatory Class: Class II
Product Code: CBP
Dated: December 21, 2023
Received: December 22, 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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

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

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

Sincerely,

John S. Bender -S

Digitally signed by John S. Bender -S
Date: 2024.08.09 10:36:12 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234053

Device Name
F&P Optiflow Flow Diverter

Indications for Use *(Describe)*
This product is intended for use as an in-line pressure relief device, designed to limit the system pressure within the limits of its stated technical specifications.

This product is indicated for patients in a hospital for use by appropriately qualified healthcare professionals.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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	Danica Tung Regulatory Affairs Market Manager
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	8 July 2024

II. DEVICE

Name of Device	F&P Optiflow™ Flow Diverter
Common/Usual Name	Nonrebreathing Valve
Classification Name	Nonrebreathing Valve
Regulatory Class	Class II (21 CFR §868.5870)
Product Code	CBP

III. PREDICATE DEVICE

Predicate Device: OJR215 Pressure Relief Manifold, K173770

IV. DEVICE DESCRIPTION

The F&P Optiflow Flow Diverter is intended for use as an in-line pressure relief device, designed to limit the system pressure when used with the compatible F&P Optiflow Oxygen Kits and nasal interfaces.

The F&P Flow Diverter is placed between the flow meter and the dryline during use. It is a multi-patient use prescription-only device, provided in a non-sterile state. It operates at flow rates between 5 to 70 L/min and is intended to be used by appropriately qualified healthcare professionals in hospitals.

When an anesthesia mask is applied over the Optiflow Switch interface, the respiratory gas no longer has a pathway to flow through the nasal interface to the patient. This will trigger respiratory gas flow to be diverted into the atmosphere.

V. INDICATIONS FOR USE

This product is intended for use as an in-line pressure relief device, designed to limit the system pressure within the limits of its stated technical specifications.

This product is indicated for patients in a hospital for use by appropriately qualified healthcare professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

Design/Technological Characteristics	**Subject Device (F&P Optiflow™ Flow Diverter)**	**Predicate Device (OJR215 Pressure Relief Manifold – K173770)**	**Comments**
Indications for use and intended use			
Indications for Use	This product is intended for use as an in-line pressure relief device, designed to limit the system pressure within the limits of its stated technical specifications. This product is indicated for patients in a hospital for use by appropriately qualified healthcare professionals.	The OJR215 Pressure Relief Manifold is designed to protect neonates, infants and children from excessive inspiratory pressure in the event of a downstream occlusion occurring in continuous flow breathing gas delivery systems via nasal cannula. The device is intended for use with flow rates greater than 0.5 L/min up to, and including, 36 L/min. The OJR215 is fitted upstream of the patient. The OJR215 is single use only and is prescription only.	Equivalent
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Intended Use Environment	Hospital	Hospital/Institutional	Identical
Users	Qualified healthcare professionals	Qualified healthcare professionals	Identical
Operation and safety features			
Ambient Operating Temperature	18 to 26 °C (64.4 to 78.8°F)	18 to 26 °C (64.4 to 78.8°F)	Identical
Shelf Life	Up to 7 years	3 years	Different

Design/Technological Characteristics	**Subject Device (F&P Optiflow™ Flow Diverter)**	**Predicate Device (OJR215 Pressure Relief Manifold – K173770)**	**Comments**
Storage Temperature	-10°C to +50 °C (14 to 122 °F)	-10˚C to +50 °C (14 to 122 °F)	Identical
Sterility	Device not provided sterile.	Device not provided sterile.	Identical
Operating Pressure - Maximum Pressure	Maximum system pressure of 60cmH_2O at maximum rated flow rate of 70L/min	Maximum relief pressure is 75 cm H2O at maximum rated flow of 36 L/min.	Equivalent
Flow Range	5-70L/min	0.5-36 L/min	Equivalent
Application/Therapy	Nasal High Flow Therapy	Nasal High Flow Therapy	Identical
Function and Design			
Principles of Operation	During normal use, the valve seals against the valve body to create a seal, allowing gas to flow through the device to the patient. When the relief pressure is exceeded, the shaft is moved, allowing the seal to open and pressure is relieved, diverting flow from the gas path to atmosphere.	During normal use, the valve seals against the valve body to create a seal, allowing gas to flow through the device to the patient. When the relief pressure is exceeded, the shaft is moved, allowing the seal to open and pressure is relieved, diverting flow from the gas path to atmosphere.	Equivalent
Inlet Connection	DISS 1240	Inlet barb	Different
Outlet Connection	F&P female safety connection	22mm female taper connection as per ISO 5356-1	Different
Housing	The body and enclosure is moulded and includes the inlet and the outlet connection and is polycarbonate.	The manifold housing is ABS, and is moulded to include the gas inlet barb, the 22mm chamber inlet connection and the 15mm oxygen sensor port.	Equivalent

Design/Technological Characteristics	**Subject Device (F&P Optiflow™ Flow Diverter)**	**Predicate Device (OJR215 Pressure Relief Manifold – K173770)**	**Comments**
Shaft	The shaft connects to the 2-piece valve seal	The manifold plunger shaft is a 2-piece valve seal.	Equivalent
Plunger Seal	The valve seal rests on the valve body during normal use and then accurately relieves pressure by opening when the relief pressure is reached.	The seal on the manifold plunger seals the manifold valve during normal use and then accurately relieves pressure by opening when the relief pressure is reached.	
Spring Pressure Relief Valve	The shaft is moved by the valve seal that moves when the set pressure is exceeded.	The shaft is moved by a spring pressure relief valve that moves when the set pressure is exceeded.	
Manifold Shroud	The rear and front caps prevent any modification by the user to the pressure relief that has already been set during production.	The purpose of the manifold shroud is to prevent access to the pre-set operating pressures and tampering.	Equivalent
Accessories			
Breathing Circuit	F&P AA404 Optiflow Oxygen Kit Clearance status: a modified version of AA403 cleared under K211096	F&P RT330 Optiflow™ Junior Optiflow Tubing Kit Clearance status: cleared (K173770)	Equivalent
Patient Interface	Nasal cannula	Nasal cannula	Equivalent

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

Performance testing of the Flow Diverter was completed and confirms the subject device does not raise new questions of safety and effectiveness. The testing provided demonstrates substantial equivalence of the Flow Diverter to the predicate device.

The Flow Diverter has been tested to the applicable requirements of the following standards:

- ISO 80601-2-74:2017 Part 2-74 Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- CGA V-5: 2019 Standard for Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)
- IEC 60601-1 Edition 3.2 (2020) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- ISO 17664-2:2021 Processing of health care products – Information to be provided by medical device manufacturer for the processing of medical devices. Part 2: Non-critical medical devices
- ISO 80601-2-90:2021 Medical electrical equipment – Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
- IEC 62366-1:2015 + A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices

VIII. CONCLUSION

The Flow Diverter is substantially equivalent to the predicate based on intended use, 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.