July 14, 2025

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

Re: K243917
Trade/Device Name: F&P Optiflow Air/Oxygen Flow Source
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: June 12, 2025
Received: June 12, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Bradley Q. Quinn -S

Bradley Quinn
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.

Submission Number *(if known)*

K243917

Device Name

F&P Optiflow Air/Oxygen Flow Source

Indications for Use *(Describe)*

This device is intended for the delivery of high flow respiratory gases (within the limits of its stated technical specifications) to patients in a hospital by appropriately qualified healthcare professionals.

This product is not intended to be used on patients with bypassed upper airways.

This product is not intended to be life-sustaining or life-supporting.

This product is not intended for apneic ventilation.

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.

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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	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	14 July 2025

II. DEVICE

Name of Device	F&P Optiflow™ Air/Oxygen Flow Source
Common/Usual Name	Breathing Gas Mixer
Classification	21 CFR §868.5330
Regulatory Class	II
Product Code	BZR

III. PREDICATE DEVICES

Primary Predicate Device: MaxBlend 2 and MaxBlend Lite, K161718

Secondary Predicate Device: Airvo 2 Humidifier and myAirvo 2 Humidifier, K131895

IV. DEVICE DESCRIPTION

The F&P Optiflow Air/Oxygen Flow Source is a respiratory high flow therapy device designed to generate a flow of air and/or oxygen. The device allows selectable flow rates up to 70L/min with selectable oxygen concentrations ranging from 21% to 100%.

The subject device is a multi-patient use prescription only device, provided in a non-sterile state. It operates at flow ranges between 0 to 70 L/min and is intended to be used by appropriately qualified healthcare professionals in hospitals.

V. INDICATIONS FOR USE

This device is intended for the delivery of high flow respiratory gases (within the limits of its stated technical specifications) to patients in a hospital by appropriately qualified healthcare professionals.

This product is not intended to be used on patients with bypassed upper airways.

This product is not intended to be life-sustaining or life-supporting.

This product in not intended for apneic ventilation.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design/technological characteristics	**Subject Device (F&P Optiflow Air/Oxygen Flow Source)**	**Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)**	**Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)**	**Comments**
Classification				
Device Classification	21 CFR 868.5330 Class II	21 CFR 868.5330 Class II	21 CFR 868.5450 Class II	Identical
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Identical
Product Code	BZR	BZR	BTT	Identical
Indications for use and intended use				
Indications for Use	This device is intended for the delivery of high flow respiratory gases (within the limits of its stated technical specifications) to patients in a hospital by appropriately qualified healthcare professionals. This product is not intended to be used on patients with bypassed upper airways. This product is not intended to be life-sustaining or life-supporting.	The MaxBlend 2 and MaxBlend Lite are designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and	The Airvo 2 Humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The Airvo 2 Humidifier is for patients in hospitals and long-term care facilities.	Equivalent

Design/technological characteristics	Subject Device (F&P Optiflow Air/Oxygen Flow Source)	Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)	Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)	Comments
	This product is not intended for apneic ventilation.	monitoring of air/oxygen mixtures is required. This is not intended as a life supporting device.		
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Intended Use Environment	Hospital	Professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities, where the delivery and monitoring of air/oxygen mixtures is required. Not for use in MRI environments	Hospitals and long-term care facilities	Equivalent
Users	Qualified healthcare professionals	Qualified trained personnel, under the direction of a physician	Healthcare professionals	Identical to secondary predicate.
Contraindications	No contraindications	No contraindications	No contraindications	Identical
Technological Characteristics				
Power/Energy Source	Mains power	Battery (4 x AA Alkaline batteries) – Power source for the oxygen monitor only.	Mains power	Identical to secondary predicate
Control & Monitoring	Electronic flow and FiO_2 control.	Mechanical flow and FiO_2 control. Monitoring FiO_2 output.	Electronic flow control.	Equivalent

Design/technological characteristics	**Subject Device (F&P Optiflow Air/Oxygen Flow Source)**	**Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)**	**Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)**	**Comments**
	Monitoring of flow and FiO_2 output.		Monitoring of flow and FiO_2 output.	
Device User Interface	Display with touch screen	Monitoring system has a display and push buttons for user input. Flow control is via rotary dial and a ball float for indicator	Display with push buttons	Different Similar to the primary and secondary predicates, the subject device has a display screen. Input and control for the subject device is via the touch screen, whereas both predicates utilise push buttons and a rotary dial (primary predicate only). The difference in device user interface does not raise new questions of safety and effectiveness.
Performance Specifications				
Flow Range	0 – 70 L/min	0 – 100 L/min	2 – 60 L/min	Equivalent
Flow Meter Accuracy	Accuracy of +/- 10%	Accuracy of +/- 10%	N/A	Identical
Operating Temperature Range	64°F to 79°F (18 °C to 26 °C)	59°F to 122°F (15°C to 50°C)	64°F to 79°F (18 °C to 26 °C)	Equivalent

Design/technological characteristics	**Subject Device (F&P Optiflow Air/Oxygen Flow Source)**	**Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)**	**Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)**	**Comments**
% Oxygen Control	21 – 100%	21 – 100%	21 – 100%	Identical
% Oxygen Control Accuracy	+/- 5%	+/- 3%	Not applicable	Different The subject device's % oxygen control accuracy limit is based on ISO 11195:2018, that specifies the requirements for the performance and safety of stand-alone gas mixers (blenders). The difference in oxygen control accuracy does not raise new questions of safety and effectiveness.
Alarms				
Alarm method	Visual and audible alarm system. Mute button	Visual and audible alarm system. Mute button	Visual and audible alarm system. Mute button	Identical
Oxygen Supply Alarm	Issues alarm if the oxygen supply pressure is < 40psi	Air/oxygen mixer feature: Pressure supply differential alarm – Air/oxygen pressure must be < 20 psi an alarm sounds	Not Applicable	Equivalent

Design/technological characteristics	**Subject Device (F&P Optiflow Air/Oxygen Flow Source)**	**Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)**	**Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)**	**Comments**
FiO_2 Alarm	Device alarms if it is unable to achieve set FiO_2 FiO_2: 21 - 100%	Oxygen monitor features: High alarm range – 16 – 100%	Issues alarm if oxygen fraction as measured by oxygen sensor is above or below user adjustable high/low limit.	Equivalent
Power-fail Alarm	Power out audible alarm for time, t > 2 minutes or until power is restored, or capacitor charge is depleted.	Unknown	Power out audible alarm for time, t > 2 minutes or until paused by user pushing alarm mute button, power is restored (non-latching alarm), or capacitor charge is depleted.	Equivalent
Disconnection	Disconnection alarm activated in < 5 seconds when no connection/disconnection has been detected	Unknown	'Check tube' and 'Check for leaks' alarms are activated in < 5 seconds if the breathing tube is not plugged in correctly	Identical to secondary predicate
Obstruction Detected/Flow Alarm	Obstruction alarm will be activated in < 5 seconds when an obstruction has been detected	Unknown	'Check for blockages' alarm in <10 seconds when the device has detected a blockage	Equivalent
General	General alarm warning is activated when internal faults, such as hardware, visual alarm, audio alarm and alarm systems has been detected.	Unknown	Fault alarm is activated when the unit has detected an internal fault and has shut itself down.	Equivalent

Design/technological characteristics	Subject Device (F&P Optiflow Air/Oxygen Flow Source)	Primary Predicate Device (MaxBlend 2 and MaxBlend Lite – K161718)	Secondary Predicate Device (Airvo 2 Humidifier and myAirvo 2 Humidifier – K131895)	Comments
Other				
Gas Supply Type & Pressure	Room air: Ambient pressure External oxygen source : 40 – 87 psi	Air/Oxygen: 30 – 75 psi	Room air: Ambient pressure External oxygen source (optional)	Equivalent
Materials in Gas Pathway	Externally communicating – tissue contact, permanent duration. No exposure to humidified gases. VOC and PM2.5	Externally communicating – tissue contact, permanent duration. No exposure to humidified gases. VOC and PM2.5	Indirect contact - External communicating - tissue, bone, dentin	Identical

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

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

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

- ANSI/AAMI ES 60601-1:2005/A2:2021 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance – Amendments 2
- IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 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 62304:2006 + A1:2015 Medical device software – Software life cycle processes
- IEC60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- 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
- IEC 62366-1:2015 + A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- AIM 7351731 Rev 3:2021 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- 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
- ISO 11195:2018 Gas mixers for medical use – Stand-alone gas mixers
- ANSI/AAMI ST98:2022 Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices.

VIII. CONCLUSION

The Flow Source is substantially equivalent to the predicates 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.