August 27, 2026

Fisher and Paykel Healthcare Limited
Amelia Rosario
Regulatory Affairs Associate
15 Maurice Paykel Pl., E. Tamaki
Auckland, 2013
New Zealand

Re: K262268
Trade/Device Name: Optiflow Oxygen Kit (AA484J)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: July 28, 2026
Received: July 29, 2026

Dear Amelia Rosario:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assitant 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262268

Please provide the device trade name(s).

Optiflow Oxygen Kit (AA484J)

Please provide your Indications for Use below.

This product delivers respiratory gases to adult patients. It is intended for use with an F&P 820 humidifier at flows from 5 to 70 L/min.

This product can be used on multiple patients when used with a hydrophobic filter between the product and the patient interface for a maximum of 24 hours after setup.

This product is indicated for the delivery of nasal high flow (NHF) by appropriately qualified healthcare professionals under the direction of a physician anesthesiologist in a medical procedure or surgical room. Qualitative carbon dioxide sampling can be used at nasal interface flow rates from 5 to 50 L/min.

This product can be used for preoxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms under the direction of a physician anesthesiologist.

This product is not intended for apneic ventilation.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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	Amelia Rosario Regulatory Affairs Associate
Contact Person	Reena Daken Regulatory Affairs Manager – North America Telephone: +64 9 574 0100 Email: Reena.Daken@fphcare.co.nz
Date Prepared	18 June 2026

II. DEVICE

Name of Device	AA484J Optiflow Oxygen Kit
Common/Usual Name	Respiratory Gas Humidifier
Classification Name	21 CFR 868.5450
Regulatory Class	II
Product Code	BTT

III. PREDICATE DEVICE

Predicate Device: F&P Optiflow Oxygen Kit (AA403), K211096.

Reference device 1: F&P Optiflow Oxygen Kit Valve Coated (AA404), K234053

Reference device 2: AA451J Optiflow Oxygen Kit, K233821

Reference device 3: MR325 F&P 820 Chamber Manual Fill 500ml, K223684

IV. DEVICE DESCRIPTION

The AA484J Optiflow Oxygen Kit is a multiple-patient use breathing set.

The kit consists of a dry line, humidification chamber, inspiratory limb, tubing clips and date-change stickers.

The AA484J delivers humidified respiratory gases at flows from 5 to 70 L/min. When used with an FDA-cleared hydrophobic filter, the AA484J kit can be used on multiple patients. The kit is reprocessed between each patient. The kit can be exposed to a maximum of 30 reprocessing cycles and used for a maximum of 24 hours after setup.

When used with the appropriate accessories, the AA484J enables the delivery of nasal high flow (NHF) to adult patients by appropriately qualified healthcare professionals who perform anaesthesia care and airway management.

The AA484J is prescription only and provided in a non-sterile state.

V. INDICATIONS FOR USE

This product delivers respiratory gases to adult patients. It is intended for use with an F&P 820 humidifier at flows from 5 to 70 L/min.

This product can be used on multiple patients when used with a hydrophobic filter between the product and the patient interface for a maximum of 24 hours after setup.

This product is indicated for the delivery of nasal high flow (NHF) by appropriately qualified healthcare professionals under the direction of a physician anesthesiologist in a medical procedure or surgical room.

Qualitative carbon dioxide sampling can be used at nasal interface flow rates from 5 to 50 L/min.

This product can be used for preoxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms under the direction of a physician anesthesiologist.

This product is not intended for apneic ventilation.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

Design/technological characteristics	**Subject device** **AA484J Optiflow Oxygen Kit**	**Predicate device** **F&P Optiflow Oxygen Kit (AA403) (K211096)**	**Comments**
Indications for use and intended use			
Indications for Use	This product delivers respiratory gases to adult patients. It is intended for use with an F&P 820 humidifier at flows from 5 to 70 L/min. This product can be used on multiple patients when used with a hydrophobic filter between the product and the patient interface for a maximum of 24 hours after setup. This product is indicated for the delivery of nasal high flow (NHF) by appropriately qualified healthcare professionals under the direction of a physician anaesthesiologist in a medical procedure or surgical room. Qualitative carbon dioxide sampling can be used at nasal interface flow rates from 5 to 50 L/min. This product can be used for preoxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms under the direction of a physician anesthesiologist. This product is not intended for apneic ventilation.	This product delivers respiratory gases to adult patients. It is intended for use with an MR810 humidifier at flows from 5 to 70 L/min. This product can be used on multiple patients when used with a hydrophobic filter between the product and the patient interface for a maximum of 24 hours after setup. This product is indicated for the delivery of Nasal High Flow (NHF) by appropriately qualified healthcare professionals under the direction of a physician anesthesiologist in a medical procedure or surgical room. Qualitative carbon dioxide sampling can be used at nasal interface flow rates from 5 to 50 L/min. This product can be used for preoxygenation and short-term supplemental oxygenation (up to 10 minutes) during intubation in operating rooms under the direction of a physician anesthesiologist. This product is not intended for apneic ventilation.	Identical
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Patient Population	Adult patients	Adult patients	Identical

Design/technological characteristics	**Subject device** **AA484J Optiflow Oxygen Kit**	**Predicate device** **F&P Optiflow Oxygen Kit (AA403) (K211096)**	**Comments**
Intended Use Environment	Hospital Environment	Hospital Environment	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
System Specifications	**Flow Range**: 5 to 70 L/min	**Flow Range**: 5 to 70 L/min	Identical
Shelf Life	2 years	2 years	Identical
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
Reusability	Multi-patient use	Multi-patient use	Identical
Disposal	Dispose of product safely in accordance with standard hospital procedure.	Dispose of product safely in accordance with standard hospital procedure.	Identical
Components and Materials			
Inspiratory Tube	Included	Included	Identical
Water/Humidification Chamber	Included	Included	Similar
Clip	Included	Included	Identical
Dryline	Included	Included	Similar

VII. PERFORMANCE DATA

Summary of Biocompatibility Testing

Performance testing was completed using the same FDA recognized consensus standards as the predicate device and confirms the subject device does not raise new questions of safety and effectiveness. The testing demonstrates substantial equivalence of the subject device to the predicate device.

The subject device has been tested to the applicable requirements of the following standards:

- ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

VIII. CONCLUSION

The subject device 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 devices.