December 19, 2025

Fisher & Paykel Healthcare Ltd
Jung Yun Lee
Regulatory Affairs Specialist
15 Maurice Paykel Place, East Tamaki
Auckland, 2013
New Zealand

Re: K253479
Trade/Device Name: Optiflow Switch+ Filtered Nasal Interface with CO2 Sampling (AA042J)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: October 13, 2025
Received: October 14, 2025

Dear Jung Yun Lee:

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

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.	K253479

Please provide the device trade name(s).

Optiflow Switch+ Filtered Nasal Interface with CO2 Sampling (AA042J)

Please provide your Indications for Use below.

This product is intended for delivery of respiratory gases to adult patients in hospitals.

This product is indicated for the delivery of nasal high flow (NHF) and low-flow oxygen by appropriately qualified healthcare professionals.

Qualitative carbon dioxide (CO2) sampling can be used at nasal cannula flow rates from 5 to 50 L/min in operating and procedure rooms.

This product can be used for pre-oxygenation, short-term supplemental oxygenation (up to 10 minutes) during intubation, and allows an anesthesia mask to be placed over the nasal interface to perform mask ventilation, by individuals who perform anesthesia care or airway management.

This product is not intended for apneic ventilation.

This product is not indicated for use during CPR.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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	Jung Yun Lee Regulatory Affairs Specialist Telephone: +64 9 574 0100 Email: JungYun.Lee@fphcare.co.nz
Date Prepared	3 December 2025

II. DEVICE

Name of Device	Optiflow™ Switch+ Filtered Nasal Interface with CO_2 Sampling
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 Filtered Nasal Interface with Anesthesia Mask Compatibility, K234058.

Reference Device: F&P Optiflow Nasal Oxygen Cannula with CO_2 sampling, K201723.

IV. DEVICE DESCRIPTION

The Optiflow™ Switch+ Filtered Nasal Interface with CO_2 Sampling interface is intended to deliver respiratory gases to the patient.

The subject device includes a CO_2 sampling tube that provides a sample of the patient's exhaled respiratory gases through the CO_2 sampling accessory to a CO_2 sampling line and CO_2 analyzer.

The subject device has been designed to allow for mask ventilation without the need to remove the nasal interface from the patient during therapy. To support this function, a Flow Diverter (K234053) is required.

The product is indicated for the delivery of nasal high flow (NHF) and low flow oxygen by appropriately qualified healthcare professionals.

This is a prescription-only device provided in a non-sterile state. It has a flow range of 5 to 70 L/min. The device will be offered in three sizes, small (S), medium (M), and large (L).

It is intended to be used in combination with a compatible respiratory humidifier, Optiflow Oxygen Kit and the Optiflow Flow Diverter (K234053).

V. INDICATIONS FOR USE

This product is intended for delivery of respiratory gases to adult patients in hospitals.

This product is indicated for the delivery of nasal high flow (NHF) and low-flow oxygen by appropriately qualified healthcare professionals.

Qualitative carbon dioxide (CO_2) sampling can be used at nasal cannula flow rates from 5 to 50 L/min in operating and procedure rooms.

This product can be used for pre-oxygenation, short-term supplemental oxygenation (up to 10 minutes) during intubation, and allows an anesthesia mask to be placed over the nasal interface to perform mask ventilation, by individuals who perform anesthesia care or airway management.

This product is not intended for apneic ventilation.

This product is not indicated for use during CPR.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

Design/technological characteristics	**Subject device** **(Optiflow Switch+ Filtered Nasal Interface with CO_2 Sampling)**	**Predicate device** **(F&P Optiflow Filtered Nasal Interface with Anesthesia Mask Compatibility, K234058)**	**Reference device** **(F&P Optiflow Nasal Oxygen Cannula with CO_2 sampling, K201723)**	**Comments**
Indications for use and intended use				
Indications for Use	This product is intended for delivery of respiratory gases to adult patients in a hospital. This product is indicated for the delivery of nasal high flow (NHF) and low flow oxygen by appropriately qualified healthcare professionals. Qualitative carbon dioxide (CO_2) sampling can be used at nasal cannula flow rates from 5 to 50 L/min in operating and procedure rooms. This product can be used for pre-oxygenation, short-term supplemental oxygenation (up to 10 minutes) during intubation, and allows an anesthesia mask to be placed over the nasal interface to perform mask ventilation, by individuals who perform anesthesia care and airway management. This product is not intended for apneic ventilation.	This product is intended for delivery of respiratory gases to adult patients in a hospital. This product is indicated for the delivery of nasal high flow (NHF) and low flow oxygen by appropriately qualified healthcare professionals. This product can be used for pre-oxygenation, short-term supplemental oxygenation (up to 10 minutes) during intubation, and allows an anesthesia mask to be placed over the nasal interface to perform mask ventilation, by individuals who perform anesthesia care and airway management. This product is not intended for apneic ventilation. This product is not indicated for use during CPR.	This product is a single-patient-use device that delivers respiratory gases to adult patients in hospitals and long-term care facilities. This product is indicated for the delivery of Nasal High Flow (NHF) and Low Flow Oxygen to spontaneously breathing patients by appropriately qualified healthcare professionals. Qualitative carbon dioxide sampling can be used at nasal cannula flow rates from 5 to 50 L/min in operating and procedure rooms. This product can be used for pre-oxygenation 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.	Both devices have the same general intended use to deliver respiratory gases to adult patients in hospital environments. The difference between the predicate device and subject device is the inclusion of the carbon dioxide (CO_2) sampling tube feature. This identical feature has previously been cleared in Optiflow Nasal Oxygen Cannula with CO_2 Sampling K201723.

Design/technological characteristics	**Subject device** **(Optiflow Switch+ Filtered Nasal Interface with CO_2 Sampling)**	**Predicate device** **(F&P Optiflow Filtered Nasal Interface with Anesthesia Mask Compatibility, K234058)**	**Reference device** **(F&P Optiflow Nasal Oxygen Cannula with CO_2 sampling, K201723)**	**Comments**
	This product is not indicated for use during CPR			
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
Patient Population	Adult patients	Adult patients	Adult patients	Identical
Intended Use Environment	Hospital Environment	Hospital Environment	Hospitals and long term care facilities	Identical
Classification				
Device Classification	21 CFR 868.5450 Class II	21 CFR 868.5450 Class II	21 CFR 868.5450 Class II	Identical
Classification Panel	Anaesthesiology	Anaesthesiology	Anaesthesiology	Identical
Product Code	BTT	BTT	BTT	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)	18 to 26 °C (64.4 to 78.8°F)	Identical
System Specifications	**Flow Range**: 5 to 70 L/min **CO_2 Sampling Flow Range**: 5 to 50 L/min	**Flow Range**: 5 to 70 L/min **CO_2 Sampling Flow Range**: Not applicable	**Flow Range**: 5 to 70 L/min **CO_2 Sampling Flow Range**: 5 to 50 L/min	Identical to the reference device
Shelf Life	18 months	18 months	18 months	Identical

Design/technological characteristics	**Subject device** **(Optiflow Switch+ Filtered Nasal Interface with CO_2 Sampling)**	**Predicate device** **(F&P Optiflow Filtered Nasal Interface with Anesthesia Mask Compatibility, K234058)**	**Reference device** **(F&P Optiflow Nasal Oxygen Cannula with CO_2 sampling, K201723)**	**Comments**
Storage Temperature	10 °C to +50 °C (14 to 122 °F)	-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.	Device not provided sterile.	Identical
Reusability and Duration of Use	Single patient use only for a maximum period of 24 hours.	Single patient use only for a maximum period of 24 hours.	Single patient use only for a maximum period of 24 hours.	Identical
Sizes	AA042JS -Small AA042JM- Medium AA042JL- Large	AA041JS -Small AA041JM- Medium AA041JL- Large	AA030S - Small AA030M - Medium AA030L - Large	Identical
Disposal	Dispose of product safely in accordance with standard hospital procedure.	Dispose of product safely in accordance with standard hospital procedure.	Dispose of product safely in accordance with standard hospital procedure.	Identical
Nasal Interface Function and Design				
Connector	Included	Included	Included	Identical
Headgear attachment	Included	Included	Included	Identical
Headgear adjustment	Included	Included	Included	Identical
Interface Tubing	Included	Included	Included	Equivalent
Interface Collapsible Section	Included	Included	Not applicable	Identical
Nasal prongs	Included	Included	Included	Identical
CO_2 Sampling Tube	Included	Not included	Included	Identical to the reference device
CO_2 Clip	Included	Not included	Included	Identical to the reference device
Filter	Included	Included	Not applicable	Identical

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

Performance testing was completed 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 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
- IEC 62366-1:2015 + A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices

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 device.