June 25, 2025

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

Re: K251611
Trade/Device Name: Optiflow+ Nasal Cannula - Small (OPT942); Optiflow+ Nasal Cannula - Medium (OPT944); Optiflow+ Nasal Cannula - Large (OPT946); Optiflow+ Nasal Cannula Small (MYOPT9SMALL); Optiflow+ Nasal Cannula Medium (MYOPT9MEDIUM); Optiflow+ Nasal Cannula Large (MYOPT9LARGE)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: May 26, 2025
Received: May 27, 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,

John S. Bender -S
2025.06.25 19:04:59 -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)*
K251611

Device Name
Optiflow+ Nasal Cannula Range

Indications for Use *(Describe)*

OPT94X Model:

The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to 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.

MYOPT9X Model:

The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to 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.

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	Jung Yun Lee Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date prepared	**23 June 2025**

II. DEVICE

Name of Device	F&P Optiflow+ Nasal Cannula Range
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 range, K162553

IV. DEVICE DESCRIPTION

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

The F&P Optiflow+ Nasal Cannula range 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.

Indications for Use:

The modification in scope of this 510(k) submission is to change the labeling of the subject device only, specifically to the Indications for Use statement.

The subject device's technological characteristics, material composition, and intended use remain identical to those of the predicate device. The device's part numbers also remain the same.

Refer to the table below for the revised Indications for Use of the OPT94x model, and the myOPT9x model:

Model	Indications for Use
OPT942 OPT944 OPT946	The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to 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.
MYOPT9SMALL MYOPT9MEDIUM MYOPT9LARGE	The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to 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.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison table shows the comparison between the modified device and the previously cleared device.

Features comparison	Subject device F&P Optiflow+ Nasal Cannula (K251611)	Predicate device F&P Optiflow Nasal Cannula (K162553)	Comments
Classification			
Legal Manufacturer	Fisher & Paykel Healthcare Ltd	Fisher & Paykel Healthcare Ltd	Equivalent.
Product Code	BTT	BTT	
Regulation Number	21 CFR §868.5450	21 CFR §868.5450	
Classification Name	Humidifier, Respiratory Gas, (Direct Patient Interface)	Humidifier, Respiratory Gas, (Direct Patient Interface)	
Classification Panel	Anesthesiology	Anesthesiology	
Intended Use/Indications for Use			
Intended Use	Nasal cannula patient interface for delivery of humidified respiratory gases.	Nasal cannula patient interface for delivery of humidified respiratory gases.	Equivalent.
Indications for Use	**OPT94X Model:** The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to 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. **MYOPT9X Model:** The F&P Optiflow+ is a nasal cannula patient interface for use with specified respiratory gas humidifiers to treat spontaneously breathing pediatric (3 years and older) to adult patients who would benefit from receiving high flow warmed	Nasal cannula patient interface for delivery of humidified respiratory gases.	The Indications for Use statement for the subject device is more defined than the predicate device. IFU statement now specifies patient population and operating environment based on state-of-the-art labelling requirements.

	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)	Equivalent.
Patient Population	Pediatric (3 years and older) to adult	Mainly adult patients	The patient population is more clearly defined.
Patient Acuity	Spontaneously breathing patients	Spontaneously breathing patients	Equivalent.
Patient Monitoring	Appropriate patient monitoring must be used at all times.	Appropriate patient monitoring must be used at all times.	Equivalent.
Use Environment	Hospital, sub-acute facility, or long-term care facility and home environment	Home and Hospital environment, long-term (managed) care facilities	Equivalent.
Reusability	Single patient-use only, < 14 days in hospital 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	Equivalent.
Compatibility with other devices			
Humidifier Compatibility	Airvo 2 and myAirvo 2 (K131895) MR850 humidifier (K110019) Airvo 3 (K221338) myAirvo 3 (K222292) Airvo 3 NIV (K233643) F&P 950 Respiratory Humidifier (K220703) F&P 820 System (K223684)	Airvo 2 and myAirvo 2 (K131895) MR850 humidifier (K110019) Airvo 3 (K221338) myAirvo 3 (K222292) Airvo 3 NIV (K233643) F&P 950 Respiratory Humidifier (K220703) F&P 820 System (K223684)	Equivalent.

VI. Non-Clinical Performance Evaluation

The subject device is identical to the predicate device except for a more specific Indications for Use statement in the device labelling.

No new performance or biocompatibility testing was conducted on the subject device since the device design is identical to the predicate device.

VII. CONCLUSION

The subject device is identical to the predicate device except for the device labeling. Based on the comparison of the intended use and the technological characteristics between the subject and predicate devices, the F&P Optiflow+ Nasal Cannula is substantially equivalent to the predicate device.