March 16, 2021

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

Re: K201723
Trade/Device Name: F&P Optiflow Nasal Oxygen Cannula with CO2 Sampling
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: February 12, 2021
Received: February 16, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201723

Device Name
F&P Optiflow Nasal Oxygen Cannula with CO2 Sampling

Indications for Use *(Describe)*

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.

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.

510(k) Summary

As Required by 21 CFR 807.92(c)

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 Ortiz Rios Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Market Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	16 March 2021

II. DEVICE

Name of Device	F&P Optiflow™ Nasal Oxygen Cannula with CO2 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:
  - K162553 F&P Optiflow™+ Nasal Cannula
- Reference device:
  - K162343 Westmed Gas Sampling Cannula with O2 Delivery

IV. DEVICE DESCRIPTION

The F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling is a medical device intended to deliver respiratory gases to the patient and provide a sample of the patient's exhaled respiratory gases through the CO2 sampling accessory to a CO2 sampling line and CO2 analyzer.
The device is offered in three sizes being small (S), medium (M) and large (L). The F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling is a prescription only device, provided in a non-sterile state.

Principle of Operation

The subject device is an interface which delivers respiratory gases to the patient from a humidification system or a flow meter. The internal diameter of the tube and the geometry of the manifold, gas path connector and nasal prongs have been designed to reduce turbulent flow, allowing it to deliver respiratory gas at both low and high flows.

The F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling may be connected to breathing circuits and a humidifier or it may also be used with a flow meter, such as, the Compensated Thorpe Tube Flowmeter. the Nasal Oxygen Cannula may be connected to breathing circuits through a male medical taper connector as per ISO 5356-1:2015 'Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets'.

The nasal cannula delivers respiratory gases from the inspiratory tube to the patient. The nasal cannula is fitted onto the patient and attached to the inspiratory tube using the above connector. The CO2 sampling component connects to a commercially available carbon dioxide sampling line (not included with this product) and is fitted on the patient to sample exhaled gas from either the nares, or mouth.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design/technological characteristic for comparison	Subject device F& P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling	Predicate device F&P Optiflow™+ Nasal Cannula	Rationale for Substantial Equivalence
Indications for Use	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.	Nasal cannula patient interface for delivery of humidified respiratory gases.	Equivalent The intended uses are equivalent. The subject and predicate devices are both intended to deliver high flow humidified respiratory gases. The subject device has a carbon dioxide sampling functionality which is supported through performance testing as per the reference device, K162343.
Availability	Prescription use. (Part 21 CFR 801 Subpart D)	Prescription use. (Part 21 CFR 801 Subpart D)	Identical.
Patient Population	Adult patients.	Mainly adult patients.	Equivalent. Patient population for the subject device is a subset of the patient population of the predicate device.
Operating Environment	Hospitals and long term care facilities.	Hospitals and long term care facilities.	Identical.

Reusability and Duration of Use	Single patient use only for a maximum period of 24 hours.	Single patient use only, < 14 days hospital Single patient reusable, < 30 days home	Equivalent.
Sizes	AA030S AA030M AA030L	OPT942 Small OPT944 Medium OPT946 Large	Identical.
Specifications			
Ambient Operating Temperature	18 – 26 °C	18 – 28 °C	Equivalent The operating temperature range is within that of the predicate device.
System Specifications	When assembled with 22 mm heated inspiratory tube and chamber and a compatible F&P humidifier: Flow Range: AA030S(Small) 5-70L/min AA030M(Medium) 5-70L/min AA030L(Large) 5-70L/min	MR850 Humidifier in invasive mode, RT series kit with 22 mm heated inspiratory tube and chamber. Flow Range: OPT942 (Small) 10 - 60L/min OPT944 (Medium) 10 - 60 L/min OPT946 (Large) 10 - 60 L/min	Equivalent The subject device is intended for use with a larger flow range.
Shelf Life	18 months	Shelf-life not claimed on labelling	The subject device claims an 18-month shelf life.
Storage Temperature	-10˚C to +50˚C	-10°C to +50°C	Identical
Sterility	Device not provided sterile	Device not provided sterile	Identical
Disposal	Dispose of product safely in accordance with standard hospital procedure.	Disposal not defined.	Disposal information defined for subject device in the User Instruction.
Nasal Cannula Function and Design			
22 mm Male ISO Taper Connector	Included.	Included.	Identical.
Proprietary F&P Connector	Included.	Included.	Identical.
CO2 Sampling tube's Luer connection	Included	Not Included	CO2 Sampling feature is only present in the subject device and not available in the predicate device. The sampling functionality is equivalent to that of the reference device, K162343.

VII. PERFORMANCE DATA

Non-Clinical Performance Data

Performance testing of the F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling was completed to determine that the differences between the subject device and the predicate device do not raise new questions of safety or effectiveness. These tests demonstrate substantial equivalence of the F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling to the predicate device.

- Shelf life testing was performed following accelerated aging conditioning as per ASTM F1980-16 to demonstrate product requirements continue to be met after 18 months of storage.
- Transportation testing was performed following transportation simulation to ISTA 2A:2011 Packaged-Products 150 lbs (68 kgs) or Less.
- The following additional performance testing has also been completed to confirm the safety and effectiveness of the Optiflow™ Nasal Oxygen Cannula with CO2 Sampling:
    - Nasal Cannula Leak Test
    - CO2 Sampling Tube Leak Test
    - Resistance to flow of the CO2 Sampling Tube
    - Resistance to flow during compression of the CO2 Sampling Tube
    - Testing was performed to ensure functional requirements were met after transport, storage, and simulated use conditioning.
    - Strength testing of CO2 Sampling Tube's permanent connections after transport, storage, and simulated use conditioning.
    - Testing to validate the device's CO2 Sampling functionality

Usability testing conducted on the use of the CO2 Sampling feature and the warnings and directions for use related to the CO2 Sampling feature only.

The Optiflow™ Nasal Oxygen Cannula with CO2 Sampling has been tested to applicable requirements of the following standards:

- ISO 594-2, "Conical fitting with 6% (Luer) taper for syringes, needles and certain other medical equipment- Part 2: Lock fittings".
- ISO 5356-1:2004 "Anesthetic and Respiratory Equipment- Conical Connectors- Part 1: Cones and Sockets".
- ISO 5361:2012 "Anesthetic and Respiratory Equipment-Tracheal tubes and connectors"
- ISO 10993-1 Fifth Edition 2018-08 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process".
- ISO 18562-1 First Edition 2017-03, "Biocompatibility evaluation of breathing gas pathways in healthcare applications- Part 1: Evaluation and testing within a risk management process".

Clinical Performance Data

Clinical performance data has not been relied upon in this marketing submission to demonstrate substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The comparison of features, performance data and intended use demonstrate that the F&P Optiflow™ Nasal Oxygen Cannula with CO2 Sampling is substantially equivalent to the predicate, Optiflow™ + Nasal Cannula, (K162553).