January 28, 2022

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

Re: K211096
Trade/Device Name: Optiflow Oxygen Kit
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: January 26, 2022
Received: January 28, 2022

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,

Brandon Blakely
Assistant Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211096

Device Name
Optiflow™ Oxygen Kit

Indications for Use *(Describe)*
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 set-up.

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 cannula flow rates from 5 to 50 L/min.

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.

5 510(k) Summary

As Required by 21 CFR 807.92

I. SUBMITTER

Date prepared	26 Jan 2022
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	Carolina Zatarain Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz

II. DEVICE

Name of Device	F&P Optiflow™ Oxygen Kit
Common/Usual Name	Inspiratory tube
Classification Name	Respiratory gas humidifier, 21 CFR §868.5450
Regulatory Class	II
Product Code	BTT

III. PREDICATE DEVICE

- **Predicate Device:**
  - AirSpiral Heated Breathing tube (K162553)

- **Reference Device:**
  - RT380 and RT385 Adult Evaqua 2 Dual Heated Breathing Circuits (K122432)

IV. DEVICE DESCRIPTION

The Fisher & Paykel (F&P) Optiflow™ Oxygen Kit consists of a dry line, humidification chamber inspiratory tube, and tubing clips. The figure below shows the Optiflow™ Oxygen Kit, as it would be legally marketed in the USA.

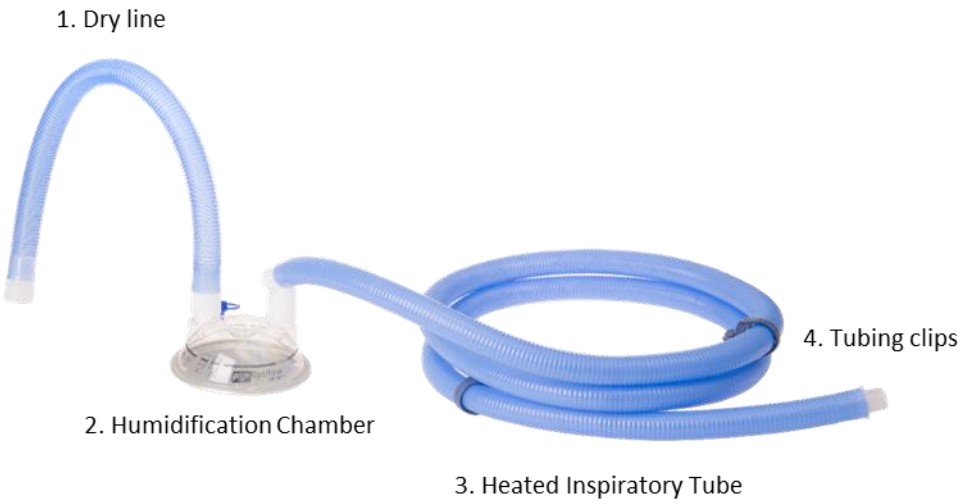

Figure 5-1 Optiflow™ Oxygen Kit

The dryline (1) transfers the respiratory gases from a flow source to the humidification chamber. The humidification chamber (2) provides a reservoir filled to an indicated maximum level with sterile water. As the humidifier heats the water in the chamber, water vapor is formed, which heats and humidifies the respiratory gases delivered from the dryline. The respiratory gas is then transferred to the inspiratory tube. The inspiratory tube (3) (also known as inspiratory limb) electrically heats the respiratory gas utilizing a heater wire to maintain the temperature of the gas. The inspiratory tube delivers the gas through an FDA-cleared filter and interface. The filter and the patient interface are not in the scope of this submission. The tubing clips (4) are attached to the inspiratory tube. They are used to connect the tube to the hospital bed sheet or pillow.

The device delivers gas at flow rates between 5 and 70 L/min. The device is to be used by medical professionals on multiple patients over a 24-hour period.

Only the Optiflow™ Oxygen Kit is part of this 510(k) submission. The flow source, humidifier, filter and interface are not in the scope of this submission.

V. INDICATIONS FOR USE

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 set-up.

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 cannula flow rates from 5 to 50 L/min.

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

Table 5-1 compares technological characteristics of the subject device compared to the predicate device.

Table 5-1 Comparison of technological Characteristics with Predicate

Design/technological characteristic for comparison	**Subject device** Optiflow™ Oxygen Kit	**Predicate device** AirSpiral Heated Breathing tube (K162553)	**Comments**
Indications for use	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 set-up. 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 cannula flow rates from 5 to 50 L/min. This product can be used for pre-oxygenation and short-term supplemental oxygenation (up to 10 minutes) during	The 900PT561 inspiratory tube is for the delivery of humidified respiratory gases. For use with AIRVO™ and AIRVO™ 2 Series humidifiers in hospitals and long-term care facilities. For use at flows from 2 to 60 L/min depending on the patient interface.	***Equivalent*** Subject and predicate devices have the same intended use to deliver humidified respiratory gases. The indications for the use of the subject device include multi-patient use when used with an FDA-cleared filter and interface for each patient.

Design/technological characteristic for comparison	**Subject device** Optiflow™ Oxygen Kit	**Predicate device** AirSpiral Heated Breathing tube (K162553)	**Comments**
	intubation in operating rooms under the direction of a physician anesthesiologist. This product is not intended for apneic ventilation.		
Operation and safety features			
Reusability	Multi-patient use	Single patient use	Indications for use include multi-patient use. This difference was addressed using the FDA Guidance document, "Reprocessing Medical Devices in Healthcare Care Settings: Validation Methods and Labeling." Cleaning and reprocessing instructions were validated. Testing per the guidance document demonstrates that this difference does not raise new questions of safety and effectiveness
Use Duration	< 24 hours	< 14 days (hospital)	Subject device duration of use is within the duration of use of the predicate device. Decreasing the duration of use does not raise new questions of safety and effectiveness
Availability	Prescription use	Prescription use	***Identical***

Design/technological characteristic for comparison	**Subject device** Optiflow™ Oxygen Kit	**Predicate device** AirSpiral Heated Breathing tube (K162553)	**Comments**
	(Part 21 CFR 301 Subpart D)	(Part 21 CFR 301 Subpart D)	
Patient Population	Adult patients	Adult and Pediatric patients	Subject device patient population is a subset of the predicate device patient population. Limiting the patient population just to adults does not raise new questions of safety and effectiveness.
Intended Use Environment	Hospitals	Hospitals and long-term care facilities	***Equivalent*** Both the subject and predicate devices are intended to be used in the hospital. Subject device is not intended to be used in long-term care facilities.
Principle of Operation	The Optiflow™ Oxygen Kit transports respiratory gases from a flow source via a humidifier to the patient interface.	AirSpiral Heated Breathing tube transport respiratory gases from a flow source via a humidifier to the patient interface.	***Equivalent*** Both the subject and predicate devices transport respiratory gases from a flow source via a humidifier to the patient interface.
Specifications			
Flow Range	5 to 70 L min^{-1}	2 to 60 L min^{-1}	***Equivalent*** The subject device is intended to be used with higher flow rates. Performance testing to demonstrate that the device performs as

Design/technological characteristic for comparison	**Subject device** Optiflow™ Oxygen Kit	**Predicate device** AirSpiral Heated Breathing tube (K162553)	**Comments**
			intended at the higher flow rate has been provided. The increased flow rate does not raise new questions of safety and effectiveness.
Sterility	Device not provided sterile	Device not provided sterile	***Identical***
Shelf Life	12 months	Five years shelf-life	Difference in shelf life does not raise new questions of safety and effectiveness.
Storage Temperature	-10°C to +50°C	-10°C to +50°C	***Identical***
Disposal	Dispose of product safely in accordance with standard hospital procedure.	None	Disposal instructions were not provided for the predicate device. The addition of disposal instructions for the subject device does not raise new questions of safety and effectiveness.
Biocompatibility and Materials			
Assessment	Testing performed according to ISO 10993-1: Fifth edition 2018-08 and ISO 18562-1: First Edition 2017-03	Testing performed according to ISO 10993-1:2009	***Equivalent*** The subject device complies with the latest standards.
Components and materials			
Inspiratory breathing tube	Included.	Included.	***Equivalent*** Similar design.

Design/technological characteristic for comparison	**Subject device** Optiflow™ Oxygen Kit	**Predicate device** AirSpiral Heated Breathing tube (K162553)	**Comments**
Inspiratory breathing tube heater wire	Included.	Included.	***Equivalent*** Similar design.
Humidification Chamber	Included.	Included.	***Equivalent*** Similar design.
Clip	Included.	Included.	***Identical***
Dryline	Included.	Not Included.	The addition of this component to the Optiflow™ Oxygen Kit does not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA

- **Summary of non-clinical tests**

Performance testing of the Fisher & Paykel Optiflow™ Oxygen kit was completed to determine that the differences between the subject device and the predicate device do not raise new questions of safety and effectiveness. These tests demonstrate substantial equivalence of the Fisher & Paykel Optiflow™ Oxygen kit to the predicate device.

The following preconditioning was carried out as applicable for each test:

- Shelf-life testing was performed following accelerated aging conditioning as per ASTM F1980-16 to demonstrate product requirements continue to be met after 12 months of storage.
- Transportation testing was performed following transport and storage simulation as per ISTA 2A:2011.
- Mechanical strength testing was performed following push, impact, drop, and mold stress relief conditioning as per IEC 60601-1 15.3.2, 15.3.3, 15.3.4, and 15.3.5
- Cleaning and low-level disinfection as per the indications for use.

The following additional performance testing has also been completed to confirm the safety and effectiveness of the Optiflow™ Oxygen Kit:

- Permanent connections test
- Removable connections test
- Gas delivery test
- Resistance to flow test

The Optiflow™ Oxygen Kit has been tested to applicable requirements of the following standards:

- ISO 80601-2-74:2017(E) “Medical electrical equipment, Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment”.
- IEC 60601-1-2 4th 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62366-1:2015 Usability Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 5356-1:2004 “Anesthetic and Respiratory Equipment- Conical Connectors- Part 1: Cones and Sockets”.

- **Summary of Biocompatibility testing.**

The biocompatibility evaluation of the Fisher & Paykel Optiflow™ Oxygen Kit was conducted in accordance with the use of international standard ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process; and ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within risk management process.

VIII. CONCLUSIONS

The Optiflow™ Oxygen kit device is substantially equivalent to the predicate based on patient population, intended use, comparison of the technological characteristics, and performance. In addition, the conclusions drawn from the nonclinical tests demonstrate that the differences between the predicate and subject devices do not raise new questions of safety and effectiveness, and the subject device is substantially equivalent to the legally marketed predicate device.