June 13, 2024

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

Re: K233821
Trade/Device Name: F&P Optiflow Oxygen Kit (AA451J)
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: May 29, 2024
Received: May 29, 2024

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.

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.
Assistant Director
DHT1C: Division of Sleep Disordered
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Anesthesia Devices
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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)*
K233821

Device Name
F&P Optiflow Oxygen Kit (AA451J)

Indications for Use *(Describe)*
This breathing set is an accessory to the F&P 950 Respiratory Humidifier to be used within the limits of its stated technical specifications.

It is intended for delivery of heated humidified high flow respiratory gases to adult patients in a hospital.

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 for use by appropriately qualified healthcare professionals who perform anesthesia care and airway management.

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.

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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	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	13 June 2024

II. DEVICE

Name of Device	F&P Optiflow™ Oxygen Kit (AA451J)
Common/Usual Name	Inspiratory tube
Classification Name	Respiratory gas humidifier
Regulatory Class	Class II (21 CFR §868.5450)
Product Code	BTT

III. PREDICATE DEVICE

- Primary Predicate Device: Optiflow™ Oxygen Kit, K211096
- Secondary Predicate: F&P 950 Respiratory Humidifier, K220703

IV. DEVICE DESCRIPTION

The Fisher & Paykel Healthcare (F&P) Optiflow™ Oxygen Kit is a multiple-patient use breathing tube kit. This F&P Optiflow™ Oxygen Kit is presented as the AA451J.

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

The flow source delivers gas through a dryline to a humidification chamber that sits on a humidifier. As the gas passes through the chamber, it is heated and humidified. The gas then flows through the inspiratory limb, through a hydrophobic filter and then through a patient interface into the patients' upper airway via the nose.

The AA451J kit delivers humidified respiratory gases at flows from 5 to 70 L/min. When used with an FDA-cleared hydrophobic filter, the AA451J 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.

The scope of this 510(k) submission is limited to the AA451J, F&P Optiflow™ Oxygen Kit. The flow source, humidifier, hydrophobic filter and interface are not in the scope of this submission.

V. INDICATIONS FOR USE

This breathing set is an accessory to the F&P 950 Respiratory Humidifier to be used within the limits of its stated technical specifications.

It is intended for delivery of heated humidified high flow respiratory gases to adult patients in a hospital.

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 for use by appropriately qualified healthcare professionals who perform anesthesia care and airway management.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

Design/Technological Characteristic	**Subject Device (AA451J – K233821)**	**Primary Predicate Device (AA403 – K211096)**	**Secondary Predicate Device (AA451SU – K220703)**	**Similarity of subject device to primary/secondary predicate device**
Indications for use	This breathing set is an accessory to the F&P 950 Respiratory Humidifier to be used within the limits of its stated technical specifications. It is intended for delivery of heated humidified high flow respiratory gases to adult patients in a hospital. 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 for use by appropriately qualified healthcare professionals who perform anesthesia care and airway management.	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.	The breathing set is an accessory to the F&P 950 Respiratory Humidifier. It is intended for delivery of heated humidified respiratory gases to adult, adolescent and child patients, within the limits of its stated technical specifications.	Equivalent. The subject device and the predicate devices are intended for use with humidifiers. The primary predicate is intended for use with the MR810 humidifier, whereas the subject device is intended for use with the F&P 950 humidifier. The subject device and secondary predicate are both intended for use with the F&P 950 humidifier.

Design/Technological Characteristic	Subject Device (AA451J – K233821)	Primary Predicate Device (AA403 – K211096)	Secondary Predicate Device (AA451SU – K220703)	Similarity of subject device to primary/secondary predicate device
Operation and safety features				
Patient Population	Adult patients	Adult patients	Adult, adolescent and child patients	Identical to primary predicate
Intended Use Environment	Hospitals	Hospitals	Hospital or long-term care facility	Identical to primary predicate
Availability	Prescription use	Prescription Use	Prescription use	Identical
Operating Principle	Breathing circuit kit contains a dryline, humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a dryline, humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Breathing circuit kit contains a dryline, humidification chamber, and inspiratory limb to create a single limb for the delivery of high flow therapy.	Identical
Reusability	Multi-patient use	Multi-patient use	Single Use	Identical to primary predicate
Duration of Use	< 24 hours	< 24 hours	14 Days	Identical to primary predicate
Specifications				
Specified Flow Range	5 – 70 L/min	5 to 70 L/min	5 – 70 L/min	Identical
Sterility	Device not provided sterile	Device not provided sterile	Device not provided sterile	Identical

Design/Technological Characteristic	Subject Device (AA451J – K233821)	Primary Predicate Device (AA403 – K211096)	Secondary Predicate Device (AA451SU – K220703)	Similarity of subject device to primary/secondary predicate device
Shelf Life	3 years	12 months	3 years	Identical to secondary predicate
Storage conditions	-10°C – 50°C	-10°C – 50°C	-10°C – 50°C	Identical
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: Fifth edition 2018-08 and ISO 18562-1: First Edition 2017-03	Testing performed according to ISO 10993-1: Fifth edition 2018-08 and ISO 18562-1: First Edition 2017-03	Identical
Components				
Humidification Chamber	Included	Included	Included	The humidification chamber of the subject device is identical to the secondary predicate.
Inspiratory Limb	Included	Included	Included	The inspiratory limb of the subject device is identical to the secondary predicate.

Design/Technological Characteristic	**Subject Device (AA451J – K233821)**	**Primary Predicate Device (AA403 – K211096)**	**Secondary Predicate Device (AA451SU – K220703)**	**Similarity of subject device to primary/secondary predicate device**
Dryline	Included	Included	Included	Identical
Circuit Clip	Included	Included	Included	Equivalent to primary predicate The tubing clip of the subject device is identical to the secondary predicate.

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

Performance testing of the F&P Optiflow™ Oxygen Kit was completed and confirms the subject device does not raise new questions of safety and effectiveness. The testing provided demonstrates that the reusability characteristic and environment of use of the subject device is substantially equivalent to the predicates.

The F&P Optiflow™ Oxygen Kit has been tested to the applicable requirements to the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 80601-2-74:2017 Part 2-74 Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- IEC 60601-1 Edition 3.2 (2020) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- ISO 5367:2014
- AAMI TIR12:2010
- AAMI ST98:2022

VIII. CONCLUSION

The F&P Optiflow™ Oxygen Kit is substantially equivalent to the predicates 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.