March 19, 2020

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

Re: K191818
Trade/Device Name: F&P Optiflow 3S Nasal Cannula
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: February 14, 2020
Received: February18 , 2020

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,

James J. Lee Ph.D.
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)*
K191818

Device Name
F&P Optiflow 3S Nasal Cannula

Indications for Use *(Describe)*
The F&P Optiflow™ 3S nasal cannula is a 14 day single use nasal cannula interface for use with specified respiratory gas humidifiers to deliver Nasal High Flow (NHF) therapy to spontaneously breathing adult patients. This product is designed to be used by appropriately qualified healthcare professionals in a hospital / institutional environment.

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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# 510(k) Summary

| | |
|---|---|
| **Date prepared** | 18 March 2020 |
| **Company Name and Address** | Fisher and Paykel Healthcare<br>15 Maurice Paykel Place, East Tamaki,<br>Auckland 2013,<br>New Zealand |
| **Submitter** | Masar Mohammad |
| **Contact Person** | Reena Daken<br>Senior Regulatory Affairs Specialist<br>Telephone: +64 9 574 0100<br>Fax: +64 9 574 0158<br>Reena.Daken@fphcare.co.nz |
| **Trade name** | F&P Optiflow™ 3S Nasal Cannula |
| **Common name** | Nasal Cannula |
| **Classification name** | Respiratory Gas Humidifier (accessory to)<br>Class II (21 CFR §868.5450<br>Product Code BTT (Anaesthesiology) |
| **Predicate Device** | F&P Optiflow+ Nasal Cannula – K162553 |

## Device Description

The F&P Optiflow™ 3S Nasal Cannula is intended to be used in a hospital / institutional environment. A dual 22 mm male ISO taper and AIRVO™ specific connector allows connection to breathing circuits to receive humidified breathing gases from F&P 850™ and AIRVO™ systems. The F&P Optiflow™ 3S Nasal Cannula is offered in three sizes being small (S), medium (M) and large (L). The F&P Optiflow™ 3S Nasal Cannula is a prescription only device, provided in a non-sterile state.

## Indications for Use Statement

The F&P Optiflow™ 3S nasal cannula is a 14 day single use nasal cannula interface for use with specified respiratory gas humidifiers to deliver Nasal High Flow (NHF) therapy to spontaneously breathing adult patients. This product is designed to be used by appropriately qualified healthcare professionals in a hospital / institutional environment.

## Non-Clinical Performance Data

### Performance Testing

Performance testing of the F&P Optiflow™ 3S Nasal Cannula was completed to demonstrate substantial equivalence of the F&P Optiflow™ 3S Nasal Cannula to the predicate device.

- Shelf life simulation was based on ASTM F1980-07, ISO 11607-1:2006/A1 2014 and ISO 291:2008(E).
- Transportation simulation was based on ISTA 2A Packaged-Products weighing 150lb (68kg) or less.
- Relevant Humidification Output and Thermal Overshoot testing.
- Gas path and headgear joint and connection strength testing following selected pre-conditioning intended to simulate worst case life scenarios.
- Gas path leak testing following selected pre-conditioning intended to simulate worst case life scenarios.
- 24-hour maximum accumulated and emitted condensation testing intended to simulate worst case.

The F&P Optiflow™ 3S Nasal Cannula has been tested to applicable requirements of the following standards:

- ISO 5356-1:2015 Anaesthetic and respiratory equipment- Conical connectors: Part 1: Cones and sockets

### Biocompatibility

- ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and reproductive toxicity.

  ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic Toxicity
- ISO 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference material

- ISO 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005, Biological evaluation of medical devices – Part 18: chemical characterization of materials
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 3: Tests for emissions of volatile organic compounds (VOCs)

## Technological Characteristics Comparison

A comparison of the F&P Optiflow™ 3S Nasal Cannula and the predicate device is provided in table below.

**Comparison of Technological Characteristics with the Predicate Device**

| | Subject Device | Predicate Device | Comments |
|---|---|---|---|
| | **F&P Optiflow 3S Nasal Cannula** | **F&P Optiflow+ Nasal Cannula** | |
| **Intended use / Indications for use** | | | |
| **Intended Use / Indications for Use** | The F&P Optiflow™ 3S nasal cannula is a 14 day single use nasal cannula interface for use with specified respiratory gas humidifiers to deliver Nasal High Flow (NHF) therapy to spontaneously breathing adult patients. This product is designed to be used by appropriately qualified healthcare professionals in a hospital / institutional environment. | Nasal cannula patient interface for delivery of humidified respiratory gases. | The Intended Use / Indications for Use statement for the subject device is more specific than the predicate device. |
| **Availability** | Prescription use.<br>(Part 21 CFR 801 Subpart D) | Prescription use.<br>(Part 21 CFR 801 Subpart D) | Identical. |
| **Patient Population** | Adult patients. | Adult patients. | Identical. |
| **Operating Environment** | Hospital environment. | Home or hospital environment. | Similar.<br>The Operating Environment for the subject device is a subset of the predicate device |
| **Reusability** | Single patient use only,<br>< 14 days hospital | Single patient use only,<br>< 14 days hospital | Identical. |
| **Specifications** | | | |
| **Ambient Operating Temperature** | 18 – 28 °C | 18 – 28 °C | Identical. |
| **AIRVO System Specifications** | AIRVO / AIRVO 2 Humidifier with 900PT56x-series tube; or tube and chamber kit (e.g. 900PT561)<br><br>Flow Range:<br>OPT1042 (Small) 10 - 50L/min<br>OPT1044 (Medium) 10 - 60 L/min<br>OPT1046 (Large) 10 - 60 L/min | AIRVO / AIRVO 2 Humidifier with 900PT56x-series tube; or tube and chamber kit (e.g. 900PT561)<br><br>Flow Range:<br>OPT942 (Small) 10 - 50L/min<br>OPT944 (Medium) 10 - 60 L/min<br>OPT946 (Large) 10 - 60 L/min | Identical. |

**Comparison of Technological Characteristics with the Predicate Device**

| | Subject Device | Predicate Device | Comments |
|---|---|---|---|
| | **F&P Optiflow 3S Nasal Cannula** | **F&P Optiflow+ Nasal Cannula** | |
| **F&P 850 System Specifications** | MR850 Humidifier in invasive mode, RT series kit with 22 mm heated inspiratory tube and chamber.<br><br>Flow Range:<br>OPT1042 (Small) 10 - 60L/min<br>OPT1044 (Medium) 10 - 60 L/min<br>OPT1046 (Large) 10 - 60 L/min | MR850 Humidifier in invasive mode, RT series kit with 22 mm heated inspiratory tube and chamber.<br><br>Flow Range:<br>OPT942 (Small) 10 - 60L/min<br>OPT944 (Medium) 10 - 60 L/min<br>OPT946 (Large) 10 - 60 L/min | Identical. |
| **Shelf-Life** | 3 years. | Shelf-life not claimed on labelling | The subject device claims a 3 year 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 according to hospital protocol. | Not defined. | Disposal information added in the User Instruction. |
| **Cannula Function & Design** | | | |
| **Headgear Release Mechanism** | Included. | Not present. | New feature. |
| **User Side Swapping functionality** | Included. | Not present. | New feature. |
| **22 mm Male ISO Taper Connector** | Included. | Included. | Identical. |
| **AIRVO Specific Connector** | Included. | Included. | Identical. |

## Conclusion

The comparison of features, performance, and intended use demonstrate that the F&P Optiflow™ 3S Nasal Cannula is substantially equivalent to the predicate F&P Optiflow+ Nasal Cannula (K162553).