April 6, 2023

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

Re: K222197
Trade/Device Name: F&P Optiflow Junior 2/2+ Nasal Cannula Interface Range
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: July 22, 2022
Received: July 22, 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,

Ethan L. Nyberg -S

for James Lee
Division 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222197

Device Name
Optiflow Junior 2 / 2+ Nasal Cannula Interface Range

Indications for Use *(Describe)*

F&P Optiflow Junior 2:

The Fisher & Paykel Healthcare Optiflow Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in hospital environments and must be prescribed by a physician.

The intended pediatric subpopulations targeted for use of the F&P Optiflow Junior 2 Nasal Cannula range includes:

- Neonates, birth up to 1 month of age
- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2+

The Fisher & Paykel Healthcare Optiflow Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in hospital environments and must be prescribed by a physician.

The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2 HM Cannula

The Fisher & Paykel Healthcare Optiflow Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in long term care environments and must be prescribed by a physician.

The intended pediatric subpopulations targeted for use of the F&P Optiflow Junior 2 Nasal Cannula range includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2+ HM Cannula

The Fisher & Paykel Healthcare Optiflow™ Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in long term care environments and must be prescribed by a physician.

The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age.

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.

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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	Nicholas Yap Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager – North America Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	06 April 2023

II. DEVICE

Name of Device	F&P Optiflow™ Junior 2 / 2+ Nasal Cannula Interface Range
Common/Usual Name	Nasal Cannula
Classification Name	Respiratory gas humidifier 21 CFR §868.5450
Regulatory Class	II
Product Code	BTT

III. PREDICATE DEVICE

Predicate Device	F&P Optiflow Junior Nasal Cannula	K162553

IV. DEVICE DESCRIPTION

The F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range are single-use patient interfaces that are intended to deliver heated and humidified Nasal High Flow therapy to spontaneously breathing neonates, infants and children. It is intended to be prescription-only and provided in a non-sterile state.

The F&P Optiflow Junior 2 Product Codes are OJR410 (XS), OJR412 (S), OJR414 (M), OJR416 (L) OJR416HM (L), OJR418 (XL), and OJR418HM (XL).
The F&P Optiflow Junior 2+ Product Codes are OJR520 (XXL) and OJR520HM (XXL).

Optional Kits:

Ventilator Transition Kits

The F&P Optiflow Junior 2 and 2+ Ventilator Transition Kits allow the use of the F&P Optiflow Junior 2 and F&P Optiflow Junior 2+ cannula with approved Fisher & Paykel Healthcare breathing circuits when connected to a ventilator to deliver heated and humidified nasal high flow (NHF) therapy.

The intended population is identical to the F&P Optiflow Junior 2 and F&P Optiflow Junior 2+ models.

This kit contains the F&P Optiflow Junior 2 and 2+ cannula (subject device) and a 12F/15M Adaptor. The included 12F/15M Adaptor supplied allows for connection to approved Fisher & Paykel Healthcare infant breathing circuits.

The Ventilator Transition Kit Product Codes are OJR410VT (XS), OJR412VT (S), OJR414VT (M), OJR416VT (L), OJR418VT (XL) and OJR520VT (XXL).

Blender Transition Kits

The F&P Optiflow Junior 2 and 2+ Blender Transition Kits allow the use of F&P Optiflow Junior 2 and 2+ cannula with approved Fisher & Paykel Healthcare breathing circuits when connected to a blender to deliver heated and humidified nasal high flow (NHF) therapy to spontaneously breathing patients who require breathing support.

The intended patient population is identical to the F&P Optiflow Junior 2 and 2+ cannula models.

This kit contains F&P Optiflow Junior 2 and 2+ cannula (subject device), a 12F/15M Adaptor and a Pressure Relief Manifold (cleared in K173770). The included 12F/15M Adaptor supplied allows for connection to approved F&P infant breathing circuits. The included Pressure Relief Manifold allows for the relief of pressure in the event of occlusion downstream in the system.

The Blender Transition Kit Product Codes are OJR410B (XS), OJR412B (S), OJR414B (M), OJR416B (L), OJR418B (XL), and OJR520B (XXL)

V. INDICATIONS FOR USE

F&P Optiflow Junior 2
The Fisher & Paykel Healthcare Optiflow Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in hospital environments and must be prescribed by a physician.
The intended pediatric subpopulations targeted for use of the F&P Optiflow Junior 2 Nasal Cannula range includes:

- Neonates, birth up to 1 month of age
- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2+
The Fisher & Paykel Healthcare Optiflow Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.
This product is designed for use in hospital environments and must be prescribed by a physician.
The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2 HM Cannula:

The Fisher & Paykel Healthcare Optiflow™ Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in long term care environments and must be prescribed by a physician.

The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2 Nasal Cannula includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

F&P Optiflow Junior 2+ HM Cannula:

The Fisher & Paykel Healthcare Optiflow™ Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.

This product is designed for use in long term care environments and must be prescribed by a physician.

The intended pediatric subpopulation targeted for use on the F&POptiflow Junior 2+ Nasal Cannula includes:

- Infants, 1 month up to 2 years of age
- Children, 2 years up to 12 years of age

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design/Technological Characteristic	Subject device F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range	Predicate device F&P Optiflow Junior (K162553)	Comments
Classification			
Manufacturer	Fisher & Paykel Healthcare Ltd.	Fisher & Paykel Healthcare Ltd.	Identical
Device Regulation	Class II, Regulation: 21 CFR 868.5450	Class II, Regulation: 21 CFR 868.5450	
Product Code	BTT	BTT	
Classification Panel	Anesthesiology	Anesthesiology	
Intended Use and Indications for Use			
Intended Use	Use with a nasal high flow therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.	Use with a nasal high flow therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.	Identical
Indications for Use	**F&P Optiflow™ Junior 2:** The Fisher & Paykel Healthcare Optiflow Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in hospital environments and must be prescribed by a physician. The intended pediatric subpopulations targeted for use of the F&P Optiflow Junior 2 Nasal Cannula range includes: • Neonates, birth up to 1 month of age • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow™ Junior 2+:** The Fisher & Paykel Healthcare Optiflow Junior 2+ nasal cannula is a single use nasal cannula	Single use nasal cannula intended for use with a nasal high flow therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients who require breathing support.	The Indications for Use statements for each of the subject device models are equivalent when compared to the predicate device.

Design/Technological Characteristic	Subject device F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range	Predicate device F&P Optiflow Junior (K162553)	Comments
	intended for use with a nasal high flow therapy (NHF) system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in hospital environments and must be prescribed by a physician. The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes: • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow Junior 2 HM Cannulas:** The Fisher & Paykel Healthcare Optiflow™ Junior 2 nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients. This product is designed for use in long term care environments and must be prescribed by a physician. The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2 Nasal Cannula includes: • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow Junior 2+ HM Cannulas:** The Fisher & Paykel Healthcare Optiflow™ Junior 2+ nasal cannula is a single use nasal cannula intended for use with a nasal high flow (NHF) therapy system to deliver heated and humidified nasal high flow therapy to spontaneously breathing patients.		

Design/Technological Characteristic	Subject device F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range	Predicate device F&P Optiflow Junior (K162553)	Comments
	This product is designed for use in long term care environments and must be prescribed by a physician. The intended pediatric subpopulation targeted for use on the F&P Optiflow Junior 2+ Nasal Cannula includes: • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age		
Patient Population	**F&P Optiflow Junior 2:** • Neonates, birth up to 1 month of age • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age **F&P Optiflow Junior 2+:** • Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age	• Infants, 1 month up to 2 years of age • Children, 2 years up to 12 years of age	Both subject and predicate devices are intended for use with pediatric populations. Both are intended for the pediatric subgroups 'infants' and 'children'. The subject device has additional sizes to accommodate for neonates, and infants and children.
Patient Acuity	Spontaneously breathing patients	Spontaneously breathing patients	Identical
Patient Monitoring	Appropriate patient monitoring	Appropriate patient monitoring	Identical
Operating Environment	The F&P Optiflow Junior 2 and 2+ are designed for use in hospital environments. F&P Optiflow Junior 2 HM and 2+ HM models are designed for use in long-term care environments.	Intended for use in both hospital and home environments.	The subject device is only intended for hospital and long term care environments.
Reusability	Single use	Single use	Identical
Duration	Seven days	Seven days	Identical

<table>
<tr><th>Design/Technological Characteristic</th><th>Subject device
F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range</th><th>Predicate device
F&P Optiflow Junior (K162553)</th><th>Comments</th></tr>
<tr><td>Range of cannula sizes</td><td>Available in six different sizes which are indicated by color:</td><td>Available in two sizes which are indicated by color:</td><td>The subject device contains the following additional cannula sizes:
Extra Small (XS)
Small (S)
Medium (M)
Extra Extra Large (XXL)</td></tr>
<tr><td colspan="4">Specifications</td></tr>
<tr><td>Ambient operating temperature</td><td>18 – 26 °C</td><td>18 – 26 °C</td><td>Identical</td></tr>
<tr><td>F&P AIRVO 2 system specifications</td><td>When the Airvo 2 system is set to Junior mode<table><tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr><tr><td>OJR416
OJR416HM</td><td>L</td><td>2 – 20</td></tr><tr><td>OJR418
OJR418HM</td><td>XL</td><td>2 – 25</td></tr></table>When the Airvo 2 system is set to Default mode:<table><tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr><tr><td>OJR520
OJR520HM</td><td>XXL</td><td>10 – 50</td></tr></table></td><td>Junior mode<table><tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr><tr><td>OPT316</td><td>L</td><td>2 – 20</td></tr><tr><td>OPT318</td><td>XL</td><td>2 – 25</td></tr></table></td><td>Only the L, XL and XXL sizes of the subject device are indicated for use on the AIRVO 2 system (K131895).</td></tr>
<tr><td>F&P MR850 system specifications</td><td>When the MR850 is set to Invasive mode*<table><tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr><tr><td>OJR410</td><td>XS</td><td>0.5 – 8</td></tr></table></td><td>Invasive mode<table><tr><th>Product Code</th><th>Size</th><th>Flow Rates (L/min)</th></tr><tr><td>OPT316</td><td>L</td><td>0.5 – 20</td></tr></table></td><td>The subject device is available in a larger range of sizes compared to the predicate.
The XS-XL sizes have flow rates which are equivalent to the predicate device.</td></tr>
</table>

Design/Technological Characteristic	Subject device F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range	Predicate device F&P Optiflow Junior (K162553)	Comments
	OJR412 S 0.5 – 9 **OJR414** M 0.5 – 10 **OJR416** L 0.5 – 23 **OJR418** XL 0.5 – 25 **OJR520** XXL 1 – 36	**OPT318** XL 0.5 – 25	The XXL size has an increased maximum flow rate. This is due to higher flow rates commonly prescribed to pediatric patients expected to fit the XXL size. *Setting the MR850 humidifier in invasive mode ensures adequate levels of humidity is being delivered. Setting the MR850 to invasive mode for the delivery of nasal high flow therapy is identical between the subject and predicate devices.
Shelf-Life	Three years	Three years	Identical
Sterility	Device not provided sterile	Device not provided sterile	Identical
Storage Temperature	-10°C to +50°C	-10°C to +50°C	Identical

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P Optiflow Junior 2 / 2+ Nasal Cannula Interface Range has been tested to applicable requirements to the following standards:

- ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
- ISTA 2A International Safe Transit Association Guidelines – Procedure 2A: Packaged Products weighing 150 lb (68 kg) or less.
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- IEC 62366-1:2015/AMD 1:2020 Medical devices – Part 1: Application of Usability Engineering to Medical Devices – Amendment 1

Additional performance testing has also been completed to confirm the safety and effectiveness of the Optiflow Junior 2 / 2+ Nasal Cannula Interface Range:

- Assembly Leak Testing
- Condensate Lavage Testing
- Retention System Testing
- Nasal Prong Stability Testing
- Tubing Testing
- Connector Testing
- Human Factors Testing
- Shelf Life Testing
- Transport Testing
- Accuracy of Delivered Flow Testing

VIII. CONCLUSIONS

The Optiflow Junior 2 / 2+ Nasal Cannula Interface Range are substantially equivalent to the predicate 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.