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

Re: K203449
Trade/Device Name: F&P Visairo NIV Mask Range
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: March 12, 2021
Received: March 15, 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,

Brandon Blakely, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203449

Device Name
F&P Visairo NIV Masks

Indications for Use *(Describe)*
The Fisher & Paykel Healthcare Visairo masks are single patient use masks intended for use as an accessory to ventilators to enable non-invasive positive pressure ventilation (NPPV) therapy (CPAP or bi-level) to be delivered to spontaneously breathing adult patients (> 30 kg) with respiratory insufficiency or respiratory failure who have been prescribed NPPV. The masks are to be fitted and therapy maintained by trained medical practitioners in a hospital/institutional environment with patient monitoring in place.

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 Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Market Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	12 April 2021

II. DEVICE

Name of Device	F&P Visairo™ NIV Masks
Common/Usual Name	Full Face Mask
Classification Name	Ventilator, Continuous, Facility Use
Regulatory Class	Class II (21 CFR §868.5895)
Product Code	CBK

III. PREDICATE DEVICE

- Predicate device:
  - F&P Nivairo™ RT046 Non-Vented Full Face Hospital Mask Standard Elbow Version, K173060
- Reference devices:
  - F&P Nivairo™ RT045 Non-Vented Full Face Hospital Mask Anti-Asphyxiation Valve Version, K170367
  - F&P Nivairo™ RT047 Vented Full Face Hospital Mask Standard Elbow Version, K191624
  - F&P Eson™ Nasal Mask, K121597
  - F&P Vitera™ Full Face Mask, K190713

IV. DEVICE DESCRIPTION

The F&P Visairo™ NIV Masks ("Visairo Masks") are oro-nasal full face masks that are intended for use as an accessory to deliver non-invasive positive pressure ventilation (NPPV) to a patient as part of a non-invasive ventilation system. The Visairo Masks are prescription only, provided in a non-sterile state.

A list of the subject device product codes can be found below:

Model	Product Code	Description
RT075	RT075A	Non-Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size A
	RT075B	Non-Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size B
	RT075C	Non-Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size C
RT076	RT076A	Non-Vented Hospital Under Nose Mask, Standard Elbow Version – Size A
	RT076B	Non-Vented Hospital Under Nose Mask, Standard Elbow Version – Size B
	RT076C	Non-Vented Hospital Under Nose Mask, Standard Elbow Version – Size C
RT077	RT077A	Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size A
	RT077B	Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size B
	RT077C	Vented Hospital Under Nose Mask, Anti-Asphyxiation Valve Version – Size C

V. INDICATIONS FOR USE

The Fisher & Paykel Healthcare Visairo masks are single patient use masks intended for use as an accessory to ventilators to enable non-invasive positive pressure ventilation (NPPV) therapy (CPAP or bi-level) to be delivered to spontaneously breathing adult patients (> 30 kg) with respiratory insufficiency or respiratory failure who have been prescribed NPPV. The masks are to be fitted and therapy maintained by trained medical practitioners in a hospital/institutional environment with patient monitoring in place.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

The comparison of features, performance data and intended use demonstrate that the F&P Visairo™ NIV Masks are substantially equivalent to the predicate device, F&P Nivairo™ RT046 Mask (K173060). Please see the table below.

Design / Technological Characteristic	Subject Device F&P Visairo Masks	Predicate Device F&P Nivairo RT046 Mask (K173060)	Comments
Classification			
Legal manufacturer	Fisher & Paykel Healthcare Ltd	Fisher & Paykel Healthcare Ltd	Identical
Regulation Number	21 CFR §868.5895	21 CFR §868.5895	
Product Code	CBK	CBK	
Classification Panel	Anaesthesiology	Anaesthesiology	
Intended Use / Indications for Use			
Indications for Use	The Fisher & Paykel Healthcare single patient use masks are intended for use as an accessory to ventilators to enable noninvasive positive pressure ventilation (NPPV) therapy (CPAP or bi-level) to be delivered to spontaneously breathing adult patients (>30 kg) with respiratory insufficiency or respiratory failure who have been prescribed NPPV. The masks are to be fitted and therapy maintained by trained medical practitioners in a hospital/institutional environment.	The Fisher & Paykel Healthcare single patient use masks are intended for use as an accessory to ventilators to enable noninvasive positive pressure ventilation (NPPV) therapy (CPAP or bi-level) to be delivered to spontaneously breathing adult patients (>30 kg) with respiratory insufficiency or respiratory failure who have been prescribed NPPV. The masks are to be fitted and therapy maintained by trained medical practitioners in a hospital/institutional environment.	Identical
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Identical
Patient Consciousness	Responsive and able to remove mask	Responsive and able to remove mask	Identical

Design / Technological Characteristic	Subject Device F&P Visairo Masks	Predicate Device F&P Nivairo RT046 Mask (K173060)	Comments
Patient Monitoring	Appropriate patient monitoring	Appropriate patient monitoring	Identical
Operating Environment	Hospital/institutional environments	Hospital/institutional environments	Identical
Application	CPAP or Bi-level positive pressure ventilation	CPAP or Bi-level positive pressure ventilation	Identical
Reusability	Single use	Single use	Identical
Technical Specifications and Features			
Operating Pressure Range	4 – 40 cmH_2O	4 – 25 cmH_2O	The subject device was designed to achieve a seal and deliver therapy at higher operating pressures. This is consistent with other under the nose NIV masks on the market.
Compatibility with F&P Systems	F&P 850™	F&P 850™	Identical
Interface Connections	ISO 5356-1 Conical Connectors • **RT075** and **RT076**: 22mm female ISO medical taper • **RT077**: 22mm male ISO medical taper	ISO 5356-1 Conical Connectors • RT045 and RT046: 22mm female ISO medical taper • RT047: 22mm male ISO medical taper	Identical The **RT075** and **RT076** are identical to the RT046 predicate device (K173060). The **RT077** is identical to the RT047 reference device (K191624).
Mask Dead Space	All models: < 200 cm^3	< 325 cm^3	All Visairo Mask models were calculated to have a dead space of 191cm^3 or less. This is consistent with other NIV masks with an under the nose seal on the market.
Anti-Asphyxiation Valve Operation	**RT075** • Open to Atmospheric Pressure 0.41 cmH_2O	RT045 • Open to Atmospheric Pressure 0.41 cmH_2O	Identical The **RT075** is identical to the RT045 reference device (K170367)

Design / Technological Characteristic	Subject Device F&P Visairo Masks	Predicate Device F&P Nivairo RT046 Mask (K173060)	Comments
	• Closed to Atmospheric Pressure 0.92 cmH_2O **RT076** • N/A (No Anti-Asphyxiation Valve) **RT077** • Open to Atmospheric Pressure 0.24 cmH_2O • Closed to Atmospheric Pressure 0.80 cmH_2O	• Closed to Atmospheric Pressure 0.92 cmH_2O RT046 • N/A (No Anti-Asphyxiation Valve) RT047 • Open to Atmospheric Pressure: 0.24 cmH_2O • Closed to Atmospheric Pressure: 0.80 cmH_2O	The **RT076** is identical to the RT046 predicate device (K173060) The **RT077** is identical to the RT047 reference device (K191624)
Resistance to Flow through mask	**RT075** • 0.23 cmH_2O @ 50 L/min • 0.51 cmH_2O @ 100 L/min **RT076** • 0.07 cmH_2O @ 50 L/min • 0.33 cmH_2O @ 100 L/min **RT077** • 0.26 cmH_2O @ 50 L/min • 0.63 cmH_2O @ 100 L/min	RT045 • 0.23 cmH_2O @ 50 L/min • 0.51 cmH_2O @ 100 L/min RT046 • 0.07 cmH_2O @ 50 L/min • 0.33 cmH_2O @ 100 L/min RT047 • 0.26 cmH_2O @ 50 L/min • 0.63 cmH_2O @ 100 L/min	Identical The **RT075** is identical to the RT045 reference device (K170367) The **RT076** is identical to the RT046 predicate device (K173060) The **RT077** is identical to the RT047 reference device (K191624)
Breathing Circuit	• **RT075** – Single limb with an exhalation port	• RT045 – Single limb with an exhalation port	Identical

Design / Technological Characteristic	Subject Device F&P Visairo Masks	Predicate Device F&P Nivairo RT046 Mask (K173060)	Comments
	• **RT076** – Dual limb • **RT077** – Single limb, exhalation port optional	• RT046 – Dual limb • RT047 – Single limb, exhalation port optional	The **RT075** is identical to the RT045 reference device (K170367) The **RT076** is identical to the RT046 predicate device (K173060) The **RT077** is identical to the RT047 reference device (K191624)
Sterility	Device not provided sterile	Device not provided sterile	Identical
Maximum number of days in use	14-day usage	14-day usage	Identical
Shelf life	3-year shelf life	3-year shelf life	Identical
Sizes	Available in three sizes – A, B, and C	Available in four sizes – XS, S, M, L	The naming convention has been changed due to the Seal fit. The subject device patient population is identical to that of the predicate device.

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P Visairo NIV Masks have been tested to applicable requirements to the following standards:

- ISO 17510:2020 Sleep apnoea breathing therapy – Masks and application accessories
- 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

VIII. CONCLUSIONS

The F&P Visairo NIV Masks 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.