September 10, 2025

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

Re: K252173

Trade/Device Name: F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits - Size A (ONIV117A); F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits - Size B (ONIV117B); F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits - Size C (ONIV117C); F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size A (ONIV117A-F); F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size B (ONIV117B-F); F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size C (ONIV117C-F)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: July 11, 2025
Received: July 11, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
Respiratory, and Sleep 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252173

Please provide the device trade name(s).

F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits – Size A (ONIV117A);
F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits – Size B (ONIV117B);
F&P OptiNIV Hospital Vented Full Face Mask Compatible with Single-limb Circuits – Size C (ONIV117C);
F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size A (ONIV117A-F);
F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size B (ONIV117B-F);
F&P OptiNIV ONIV117-F Hospital Vented Full Face Mask with optional Expiratory Filter Compatible with Single-limb Circuits - Size C (ONIV117C-F)

Please provide your Indications for Use below.

The Fisher & Paykel Healthcare single-patient use masks are 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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 Jung Yun Lee
Regulatory Affairs Specialist

Contact Person Reena Daken
Regulatory Affairs Manager
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Email: reena.daken@fphcare.co.nz

Date Prepared 05 September 2025

II. DEVICE

Name of Device F&P OptiNIV Vented Full Face Mask

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 Visairo NIV Mask, K203449

Reference device: F&P Nivairo Mask, K191624

IV. DEVICE DESCRIPTION

The F&P OptiNIV Vented Full Face 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 OptiNIV Vented Full Face Masks are prescription-only, provided in a non-sterile state.

The F&P OptiNIV Vented Full Face Mask consists of a plastic shell with a seal to allow cushioning onto the patient's face, and straps to enable the mask to be secured over the head. The mask fits under the patient's nose and covers the nares of the nose and the mouth, with a soft seal to maintain pressure inside the mask whilst minimizing discomfort to the user.

The subject device is available in three sizes – A, B, and C to denote the seal sizes.

V. INDICATIONS FOR USE

The Fisher & Paykel Healthcare single-patient use masks are 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 CHARACTERISTICS WITH THE PREDICATE DEVICE

Design / Technological Characteristic	Subject Device F&P OptiNIV Vented Full Face Mask	Predicate Device F&P Visairo Mask (K203449) RT077 Model	Comments
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 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.	The Fisher & Paykel Healthcare single patient use masks are 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.	Equivalent
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Equivalent
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Equivalent
Operating Environment	Hospital/institutional environments	Hospital/institutional environments	Equivalent
Reusability	Single use	Single use	Equivalent
Technical Specifications and Features			
Operating Pressure Range	4 – 30 cmH_2O	4 – 40 cmH_2O	Equivalent
Compatibility with F&P Systems	F&P 850 (K110019) F&P 950 (K220703)	F&P 850™ (K110019) F&P 950™ (K220703)	Equivalent
Interface Connections	ISO 5356-1 Conical Connectors 22mm male ISO medical taper	ISO 5356-1 Conical Connectors 22mm male ISO medical taper	Equivalent

Design / Technological Characteristic	Subject Device F&P OptiNIV Vented Full Face Mask	Predicate Device F&P Visairo Mask (K203449) RT077 Model	Comments
Mask Dead Space	< 200 cm^3	< 200 cm^3	Equivalent
Anti-Asphyxiation Valve Operation	• Open to Atmospheric Pressure 0.41 cmH_2O • Closed to Atmospheric Pressure 0.92 cmH_2O	**(F&P Visairo Mask RT075 model)** • Open to Atmospheric Pressure 0.41 cmH_2O • Closed to Atmospheric Pressure 0.92 cmH_2O	Equivalent
Resistance to Flow through mask	• 0.23 cmH_2O @ 50 L/min • 0.61 cmH_2O @ 100 L/min	• 0.26 cmH_2O @ 50 L/min • 0.63 cmH_2O @ 100 L/min	Similar
Breathing Circuit	Single limb	Single limb	Equivalent
Sterility	Device not provided sterile	Device not provided sterile	Equivalent
Maximum duration of use	Mask 14 days Filter 48 hours	14 days	Similar
Shelf life	3 years	3 years	Equivalent
Sizes	Available in three sizes – A, B, and C	Available in three sizes – A, B, and C	Equivalent

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P OptiNIV Vented Full Face Mask range has been tested to applicable requirements and standards which have all passed:

- ISO 5356-1:2015 Anaesthetic and respiratory equipment — Conical connectors Part 1: Cones and sockets
- ISO 17510:2020 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
    - Pressure drop/resistance to flow testing
    - Mask deadspace testing
    - Pressure-flow curve testing
    - Anti-asphyxiation valve function testing
- ISTA 2A:2011 Procedure 2A: Packaged-products weighing 150 lb (68 kg) or less. Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration, and shock vibration
- IEC 62366-1:2015/AMD 1:2020 Medical devices – Part 1: Application of Usability Engineering to Medical Devices – Amendment 1 and FDA Guidance "*Applying Human Factors and Usability Engineering to Medical Devices*"
- ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particular matter
- ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic substances

Additional performance testing has also been completed to confirm the safety and effectiveness of the F&P OptiNIV Vented Full Face Mask range which have all passed:

- Shelf-life testing – all relevant functional testing was performed after simulated shelf-life of three years
- Venting leak testing to address CO2 rebreathing
- Pressure waveform testing
- Humidity delivery testing
- Product leak testing

VIII. CONCLUSIONS

The F&P OptiNIV Vented Full Face Mask range is substantially equivalent to the predicate device, F&P Visario NIV Masks (K203449), based on patient population, intended uses, comparison of the general technological characteristics, and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.