March 9, 2020

Fisher & Paykel Healthcare Limited
Nicholas Yap
Regulatory Affairs Associate
15 Maurice Paykel Place
Auckland, 2013 NZ

Re: K191624
Trade/Device Name: F&P Nivairo™ RT047 Vented Hospital Full Face Mask, Anti-Asphyxiation Valve Version
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNT
Dated: February 3, 2020
Received: February 7, 2020

Dear Nicholas Yap:

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)*
K191624

Device Name
Nivairo™ RT047 vented Hospital Full Face Mask, Anti-Asphyxiation Valve Version

Indications for Use *(Describe)*
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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5 510(k) Summary

Official Contact	Reena Daken
Submitter	Nicholas Yap
Date prepared	March 09, 2020
Contact details	Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0158
Trade name	F&P Nivairo™ RT047 Vented Hospital Full Face Mask, Anti-Asphyxiation Valve Version
Common name	Full Face Mask
Classification name	Continuous Ventilator (accessory to) Class II, 21 CFR 868.5895 Product code MNT (Anesthesiology)
Predicate device	K170367 RT045 Non-Vented Hospital Full Face Mask, Anti-Asphyxiation Valve
Reference devices:	K130328 F&P Simplus Full Face Mask K173060 F&P Nivairo™ RT046 Non-Vented Full Face Mask, Standard Elbow Version K060044 F&P RT040 Acute Care Face Mask

5.1 Device Description

The Nivairo™ RT047 Vented Hospital Full Face Mask, Anti-Asphyxiation Valve Version (referred as RT047) is a vented hospital full face mask with an anti-asphyxiation valve for use with single limb circuits. The RT047 is a single use device intended for use as an accessory to deliver non-invasive positive pressure ventilation (NPPV) to a patient as part of a passively vented non-invasive ventilation system.

The RT047 is a prescription only device, provided in a non-sterile state.

5.2 Intended Use / Indications for Use

The Fisher & Paykel Healthcare single 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 (>30kg) 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.

5.3 Technological Characteristics Comparison

5.3.1 Similarities between the subject and predicate devices

The RT047 has the following key similarities to the previously cleared predicate Nivairo™ RT045 Hospital Full Face Mask Non-Vented, Anti-Asphyxiation Version (referred as RT045):

- Identical intended use with same patient population and operating environment
- Same mode of operation – both masks deliver gases oro-nasally
- Same Headgear

5.3.2 Differences between the subject and predicate devices

The key differences between the RT047 and the RT045 are:

- RT047 Elbow is vented. RT045 elbow is not vented.
- RT047 Swivel is a 22mm male ISO taper. RT045 Swivel is a 22mm female ISO taper.
- RT047 Swivel has a Pressure Port with a Pressure Port Cap. RT045 Swivel does not have a Pressure Port and thus, no Pressure Port Cap.
- Elbow color: RT047 is orange while RT045 is clear/colourless.

5.4 Non-Clinical Performance Data

The RT047 has been tested to applicable clauses of the following standards:

- ISO 17510:2015 Sleep apnoea breathing therapy – Masks and application accessories
- ISO 5356-1:2015 Anesthetic 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 10993-2:2006 Biological evaluation of medical devices – Part 2: Animal welfare requirements
- 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)

Performance testing of the RT047 was completed to determine that device design changes, compared to the predicate do not raise new questions of safety or effectiveness. The following tests demonstrate substantial equivalence of the RT047 to the predicate device.

- Dead Space Testing
- Pressure Drop and Resistance to Flow Testing
- CO2 Testing
- Non-rebreathing valve (NRV) Flap Operation and Leak Testing
- Venting Leak Rate and Product Leak Testing
- Pressure Port Testing
- Humidity Delivery Performance
- Simulated Transport, Storage Testing in accordance with ASTM-D4169-16
- Condensate Testing for Biocompatibility Assessment
- Exhaustive Extractables Testing
- Biocompatibility testing as per ISO 10993 and ISO 18562 standards listed above

5.5 Clinical Performance Data

Clinical performance testing was not required to demonstrate substantial equivalence for the RT047.

5.6 Conclusions

The comparison of features, performance, technological characteristics, and intended use demonstrate that the RT047 is substantially equivalent to the predicate RT045 (K170367).