January 25, 2018

Fisher and Paykel Healthcare Limited
Ashley Nguyen
Regulatory Affairs Specialist
15 Maurice Paykel Place
Auckland, 2013 NZ

Re: K173060
Trade/Device Name: F&P NivairoTM RT046 Non-Vented Hospital Full Face Mask, Standard Elbow Version
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: December 20, 2017
Received: December 22, 2017

Dear Ashley Nguyen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tara A. Ryan -S

Digitally signed by Tara A. Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara A. Ryan -S, 0.9.2342.19200300.100.1.1=1300030749
Date: 2018.01.25 14:24:33 -05'00'

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMS No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K173060

Device Name

F&P Nivairo™ RT046 Non-Vented Hospital Full Face Mask, Standard Elbow 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 (>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.

Type of Use (*Select one or both,* as *applicable)*

[X] 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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5 510(k) Summary

Contact person/submitter	Ashley Nguyen
Date prepared	January 25, 2018
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™ RT046 Non-Vented Hospital Full Face Mask, Standard Elbow Version
Common name	Full Face Mask
Classification name	Non Continuous Ventilator IPPB (accessory to) Class II, 21 CFR 868.5895 Product code CBK (Anesthesiology)
Predicate device	K083122 RT041 Hospital Full Face Mask Non-Vented
Reference devices:	K130328 F&P Simplus Full Face Mask K170367 F&P Nivairo™ RT045 Full Face Mask K023135 PerformaTrak SE (Image3 SE) Disposable Face Mask

5.1 Device Description

The Nivairo™ RT046 Non-Vented Hospital Full Face Mask, Standard Elbow Version (herein referred to as RT046) is a non-vented hospital full face mask with a standard elbow for use with dual limb circuits. The RT046 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 RT046 is an oronasal full face mask intended to be used in a hospital/institutional environment by trained medical staff with patient monitoring systems in place. It connects to a dual limb breathing circuit via a 22mm female swivel adaptor to receive pressurized breathing gases from an external flow source or ventilator (CPAP or Bi-Level).

The RT046 mask is a prescription only device, provided in a non-sterile state.

5.2 Intended 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

The RT046 (subject) contains the following key similarities to the previously cleared predicate RT041 Hospital Full Face Mask Non Vented (herein referred to as RT041):

- Substantially equivalent intended use with same patient population and operating environment.
- Same mode of operation whereby both masks deliver gases are oronasal.

The key differences between the RT046 are that the RT041:

- Headgear color is grey and light blue
- Has a new addition of a crown strap to the head gear
- Uses headgear clips instead of a push button clip
- Uses new headgear materials
- Facial Seal includes two new features – a rolling bridge (RollFit™) and two TubeFit™ zones
- Facial Seal sits under the lip, on the chin
- Does not include a silicone forehead padding
- Change in dead space volume
- Has a pressure range of 4–25 cmH_2O
- Is available in four sizes – extra small, small, medium and large

The RT046 (subject) contains the following key similarities to the reference devices:

- F&P Simplus Full Face Mask (K130328)
    - Headgear release design
    - Face coverage of seal
    - Seal (RollFit™)
    - Materials and components
- F&P Nivairo™ RT045 Full Face Mask (K170367)
    - Headgear color is grey and light blue
    - Has a new addition of a crown strap to the head gear
    - Uses headgear clips instead of a push button clip
    - Uses new headgear materials
    - Facial Seal includes two new features – a rolling bridge (RollFit™) and two TubeFit™ zones
    - Facial Seal sits under the lip, on the chin
    - Identical dead space volume
    - Has a pressure range of 4–25 cmH_2O
    - Is available in four sizes – extra small, small, medium and large
- Image3 SE Disposable Face Mask (K023135)
    - Similar dead space

5.4 Non-Clinical Performance Data

Performance testing of the RT046 (subject) was conducted and data were compared to the performance data for the RT041 (predicate) for performance. The data demonstrate substantial equivalence of the RT046 to the RT041. The results of the comparative bench testing do not raise any new questions regarding safety or effectiveness for the RT046.

Where applicable the RT046 has been evaluated to:

- ISO 5356-1:2004 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets.
- ISO 10993-1:2009 Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- Clauses 5.3 and 5.5 of ISO 17510-2:2007 Sleep Apnoea Breathing Therapy – Part 2: Masks and Application Accessories

The following biocompatibility testing was performed. The materials passed all parameters:

- Irritation
- Sensitization
- Cytotoxicity
- Genotoxicity
- Muscle Implantation
- Acute Systemic Toxicity
- Particulate Matter
- Chemical Characterization
- Volatile Organic Compounds

5.5 Clinical Performance Data

Clinical performance testing was not required to demonstrate substantial equivalence for the RT046.

5.6 Conclusions

The comparison of features, performance, technological characteristics, and intended use demonstrate that the RT046 (subject) is substantially equivalent to the RT041 (predicate).