DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 18, 2017

Fisher & Paykel Healthcare Ltd.
Masar Mohammad
Regulatory Affairs Specialist
15 Maurice Paykel Place, East Tamaki
Auckland 2013
New Zealand

Re: K161412
Trade/Device Name: F&P Brevida™ Nasal Pillows Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 19, 2016
Received: December 22, 2016

Dear Masar Mohammad:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161412

Device Name
F&P Brevida Nasal Pillows Mask

Indications for Use *(Describe)*
The F&P Brevida™ Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Therapy. The F&P Brevida™ Nasal Pillows Mask is intended for single patient adult (≥ 66lbs (30kgs)) use in the home and multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

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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5. 510(k) Summary

Contact person/submitter	Masar Mohammad
Date prepared	17 Jan 2017
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 Brevida™ Nasal Pillows Mask
Common name	Nasal Pillows Mask
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	K120027 F&P Pilairo™ Nasal Pillows Mask

5.1. Device Description

The F&P Brevida™ Nasal Pillows Mask is a non-invasive patient interface with a silicone seal that encloses the nasal airway entrance. The mask is held on the face with a headgear.

The mask connects to a single breathing tube by a 22mm swivel adaptor to receive pressurized gases from a continuous airway pressure device (CPAP or Bi-Level). The exhaust holes on the elbow of the mask allow exhaled gases to be flushed out while the system is in operation.

The F&P Brevida™ Nasal Pillows Mask is a prescription only device, provided in a non-sterile state.

5.2. Intended Use

The F&P Brevida™ Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Therapy. The F&P Brevida™ Nasal Pillows Mask is intended for single patient adult (≥ 66lbs (30kgs)) use in the home and multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

5.3. Technological Characteristics Comparison

The F&P Brevida™ Nasal Pillows Mask has the following similarities to the previously cleared predicate Pilairo™ Nasal Pillows Mask (K120027).

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

- Same breathing tube connection mechanism via a 22mm male connector.
- Same silicone seal mechanism where mask seals on the entrance of the nostrils as well as around the nose.
- Both new and predicate device headgear are designed to attach at the same two point on the mask frame.

The key differences to the predicate device are that the F&P Brevida™ Nasal Pillows Mask:

- Has colour cues (VisiBlue™) added to swivel, frame, seal, and headgear components to aid the user in the reassembly and orientation of the mask.
- Provide a diffuser system in which the diffuser mat and the cover have been integrated into a single component. This component is washable.
- Has a detachable elbow to aid in mask cleaning and disinfection during multi-patient use.
- Has an adjustable headgear.

The below table provides a side-by-side comparison of the subject and predicate devices.

Table 1: Device Comparison Table

	F&P Brevida™ Nasal Pillows Mask	**F&P Pilairo™ Nasal Pillows Mask**	**Comments**
Indications for use and intended use			
Intended use	The F&P Brevida™ Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Therapy. The F&P Brevida™ Nasal Pillows Mask is intended for single patient adult (≥ 66lbs (30kgs)) use in the home and multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.	The F&P Pilairo™ Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator Therapy. The F&P Pilairo™ Nasal Pillows Mask is intended for single-patient adult use in the home and multiple-patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.	Identical intended use and patient population. The Intended Use of the F&P Brevida specifies the minimum weight of an adult patient. Specifying the weight of an adult patient was not found to introduce any new risks to the device and does not alter the intended use of the device.
Availability	Prescription use (Part 21 CFR 801 Subpart D)	Prescription use (Part 21 CFR 801 Subpart D)	Identical
Patient Population	Adult	Adult	Identical
Classification			
Product Code	BZD	BZD	Identical
Device classification	868.5905	868.5905	Identical

	F&P Brevida™ Nasal Pillows Mask	F&P Pilairo™ Nasal Pillows Mask	Comments
Classification panel	Anaesthesiology	Anaesthesiology	Identical
Operation and safety features			
Operating Environment	Home, hospital or other clinical setting	Home, hospital or other clinical setting	Identical
Breathing Circuit	Single Inspiratory Tube	Single Inspiratory Tube	Identical
Exhalation Vent	Numerous tiny vent holes in Elbow	Numerous tiny vent holes in Elbow	Identical
Breathing Tube connection to mask	22mm ISO Taper	22mm ISO Taper	Identical
Fixation	Headgear with 2 attachment points	Headgear with 2 attachment points	Identical
Headgear Release	One hook connection per side to the mask frame	One hook connection per side to the mask frame	Identical
Face Coverage	Direct Nasal	Direct Nasal	Identical
Dead Space	Dynamic 29.27cc (XS-S) 33.14cc (M-L)	Dynamic 32cc (Single size)	The dead space of the small seal is less than that of the predicate, while the larger seal has more dead space. Both seal sizes are in conformance with ISO 17510-2 (2007) and this difference does not introduce any additional risk to the user. For additional information please refer to Test Report TR-27521 Attached in Appendix I.
Patient Consciousness	Responsive and able to remove mask	Responsive and able to remove mask	Identical
Pressure Range	4 to 25 cm H20	4 to 25 cm H20	Identical
Components and materials			
Sterility	Device not provided sterile	Device not provided sterile	Identical
Reusability	Reusable – Multi Patient Use	Reusable – Multi Patient Use	Identical
High Level Disinfection Methods	Thermal Disinfection (80°C for 10 mins and 75°C for 30 mins)	Sterrad 100S, Cidex OPA, Thermal Disinfection	The parameters used for the thermal disinfection are identical. Please see Section 14 for testing of both sets of parameters.
Facial Seal	Soft pliable seal between mask base and nares	Soft pliable seal between mask base and nares	Identical
Seal sizes	Available in two different sizes (XS-S, and M-L)	1 size	The subject device has two seal sizes, the additional seal size has

	F&P Brevida™ Nasal Pillows Mask	F&P Pilairo™ Nasal Pillows Mask	Comments
			not been found to introduce any additional risk to the patient. Both seal sizes have undergone product verification and meet all product requirements. Please see Section 18 for details on performance testing.
Mask Frame	Two piece coloured/clear polycarbonate with connection for elbow, silicone seal, and headgear	Two piece coloured / clear polycarbonate with connection for silicone seal, and headgear	The components and structure of the mask frame is identical, however, there have been some changes in the materials used. The new materials have been assessed for biocompatibility and no additional risk to the patient was found to have been introduced due to the new materials. Please refer to Section 15 for Biocompatibility assessment.
Mask Elbow Design	Removable	Non-removable	The F&P Brevida™ Nasal Pillows Mask has a removable elbow to aid the user in the cleaning and disinfection of the mask during multi-patient reuse.
Headgear	Adjustable headgear made up of one strap, elastic.	Non-adjustable headgear. Headgear is elastic.	The design of the subject device headgear consists of two parts. At the back of the headgear, two straps form a halo which is then connected to a single strap on either side. This is different to the single strap of the predicate device. Additionally, the headgear used in the predicate would stretch to fit the patient, while the subject device's headgear is adjustable. These differences are intended to better fit a larger percentage of the patient population and have not been found to introduce any new risk to the patient.
Accessories			
Oxygen/Pressure Port (900HC452)	Available as a separate part, not provided with device.	Available as a separate part, not provided with device.	Identical - The Oxygen/Pressure port is the same accessory used with the predicate device. This accessory was cleared under K023559 and has not been modified.

5.4. Non-Clinical Performance Data

Testing of the Brevida™ Nasal Pillows Mask was compared to the predicate K120027 F&P Pilairo™ Nasal Pillows Mask for performance. These tests demonstrate substantial equivalence of the Brevida™ Nasal Pillows Mask to the predicate device. The results of the comparative bench testing do not raise any new questions of safety or effectiveness for the F&P Brevida™ Nasal Pillows Mask.

The Brevida™ Nasal Pillows Mask has been tested to the following standards:

- ISO 17510-2:2007, Sleep Apnoea Breathing Therapy- Part 2: Masks and Application Accessories
- 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.
- 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 10993-6:2007, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation.
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2006, 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.

5.5. Clinical Performance Data

Substantial equivalence was not based on an assessment of clinical performance data

5.6. Conclusions

The comparison of features, performance, and intended use demonstrate that the Brevida™ Nasal Pillows Mask is substantially equivalent to the predicate K120027 F&P Pilairo™ Nasal Pillows Mask.