DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 20, 2016

Fisher&Paykel
Amelia Ortiz
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P O Box 14 348, Panmure
Auckland 2013, New Zealand

Re: K153505
Trade/Device Name: F&P Eson™ 2 Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: August 17, 2016
Received: August 22, 2016

Dear Ms. Ortiz:

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 801and Part 809); 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 and Part 809), 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,

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)*
K153505

Device Name
F&P Eson™ 2 Nasal Mask

Indications for Use *(Describe)*
The F&P Eson™ 2 Nasal 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 Eson™ 2 Nasal Mask is intended for single patient adult (≥ 66lb (30kg)) use in the home and for 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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510(k) Summary

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Date prepared	21 September 2016
Contact details	Address: 15 Maurice Paykel Place Paykel Building East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0158
Trade name	F&P Eson™ 2 Nasal Mask
Common name	Nasal Mask
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	Eson™ Nasal Mask (K121597)

Device Description

The F&P Eson™ 2 Nasal Mask is a non-invasive patient interface with a silicone seal which covers around the nose of a patient held in place by adjustable headgear straps.

The mask connects to a single breathing tube via 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 Eson™ 2 Nasal Mask is a prescription only device, provided in a non-sterile state.

An oxygen pressure port accessory is available to be used with the device for oxygen therapy and/or gas monitoring (previously covered by K121597 F&P Eson Nasal Mask).

Indications for Use

The F&P Eson™ 2 Nasal 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 Eson™ 2 Nasal Mask is intended for single patient adult (≥ 66lb (30kg)) use in the home and for multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

Technological Characteristics Comparison

The F&P Eson™ 2 Nasal Mask has the following similarities to the previously cleared predicate Eson™ Nasal Mask (K121597):

- 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 connector.
- Same RollFit™ seal mechanism where the silicone seal rolls back and forward on the bridge of the nose.
- Both new and the predicate device headgear are designed to attach at the same four points on the mask frame.

The key differences to the predicate device are that the F&P Eson™ 2 Nasal Mask:

- Has colour cues (VisiBlue™) added to swivel, frame, seal, and headgear components to aid in reassembly and orientation of the mask.
- Provide a simpler diffuser system whereby the diffuser mat and the cover have been integrated into a single component and is washable.
- Has a detachable elbow to aid in mask cleaning and disinfection.
- Has a headgear which allows over the head fitting of the mask.
- Has a notch mechanism for crown strap headgear adjustment, removing the need of a headgear buckle piece for adjustment.

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Classification Regulation	868.5905	868.5905	Identical
Product Code	BZD	BZD	Identical
Indications for Use	The F&P Eson 2 Nasal 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 Eson 2 Nasal Mask is intended for single patient adult (≥66lb (30kg)) use in the home and for 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 Eson Nasal Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Eson Nasal 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.	The indications for use between F&P Eson 2 Nasal Mask and Eson Nasal Mask are identical, with the addition of a weight specification for adult patients ≥66lb (30kg).
Patient Population	Adult	Adult	Identical
Operating Environment	Home, hospital or other clinical setting	Home, hospital or other clinical setting	Identical
Mask Availability	Prescription only	Prescription only	Identical
Breathing Circuit	Single inspiratory tube	Single inspiratory tube	Identical
Exhalation Vent (Exhaust holes)	Exhalation vent in the form of cluster of holes located on the elbow.	Exhalation vent in the form of cluster of holes located on the elbow.	Substantially equivalent

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Reusability between multiple patients	Reusable (Multi-Patient Use) – validated high-level thermal disinfection method available for cleaning between patient use	Reusable (Multi-Patient Use) – validated high-level thermal disinfection method available for cleaning between patient use	Identical
Face Coverage	Seal around the nose	Seal around the nose	Identical
Number of Seal Sizes	3 sizes – small, medium, and large.	3 sizes – small, medium, and large.	Identical
Accessories	Oxygen / Pressure Port Adaptor (900HC452)	Oxygen / Pressure Port Adaptor (900HC452)	Identical
Breathing Tube connection to Mask	22mm conical connector	22mm conical connector	Identical
Facial Seal Design	RollFit™ seal design which self-adjusts by rolling back and forward on the bridge of the nose.	RollFit™ seal design which self-adjusts by rolling back and forward on the bridge of the nose.	Identical
Diffuser	Washable one piece design with integrated diffuser mat and cover.	Two piece design consisting of diffuser cover and replacement only diffuser mat/filter.	Substantially equivalent. Function and mechanism of the diffuser component are identical. F&P Eson™ 2 Nasal Mask diffuser was modified to be washable and the number of components were reduced.
Elbow Design	Removable elbow	Permanently attached elbow	F&P Eson™ 2 Nasal Mask elbow modified to be removable for ease of cleaning.

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Headgear Design	▪ Six headgear straps. ▪ Four attachment points on the mask frame. ▪ Notch mechanism for crown headgear strap adjustment.	▪ Six headgear straps. ▪ Four attachment points on mask frame. ▪ Buckle adjustment mechanism for crown headgear straps.	Different in design - crown headgear strap modified to eliminate the need of a buckle piece for adjustment. The modification has not significantly altered the way in which the headgear interacts with the patient or the connection points on the mask. The adjustment points on the headgear for the patient remain the same as the predicate.
Mask Fitting	▪ Using headgear clips located on the bottom headgear strap. ▪ By loosening of bottom headgear straps. ▪ Over the head	▪ Using headgear clips located on the bottom headgear strap. ▪ By loosening of bottom headgear straps.	F&P Eson™ 2 Nasal Mask provides an additional method of fitting the mask to the predicate – over the head.
Mask Elbow Design (ball elbow)	Removable	Non-removable	F&P Eson™ 2 Nasal Mask elbow modified to be removable to aid in cleaning and disinfection of the mask.

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Resistance to Flow	With diffuser: ▪ Pressure drop through mask @ 50L/min: 0.19 ± 0.1cmH_2O ▪ Pressure drop through mask @ 100L/min: 0.80 ± 0.1cmH_2O Without diffuser: ▪ Pressure drop through mask @ 50L/min: 0.17 ± 0.1cmH_2O ▪ Pressure drop through mask @ 100L/min: 0.73 ± 0.1cmH_2O	With diffuser: ▪ Pressure drop through mask @ 50L/min: 0.14 ± 0.1cmH_2O ▪ Pressure drop through mask @ 100L/min: 0.65 ± 0.1cmH_2O Without diffuser: ▪ Pressure drop through mask @ 100L/min: 0.15 ± 0.1cmH_2O ▪ Pressure drop through mask @ 100L/min: 0.62 ± 0.1cmH_2O	F&P Eson™ 2 Nasal Mask has a higher pressure drop and is in conformance with ISO 17510-2.
Dead Space	Small: 69 cc Medium: 86 cc Large: 98 cc	Small: 61 cc Medium: 67 cc Large: 79 cc	F&P Eson™ 2 Nasal Mask has more dead space and is in conformance with ISO 17510-2
Pressure Range	4 to 30 cmH_2O	4 to 25cmH_2O	F&P Eson 2 has a higher allowable pressure rating

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Sound	With diffuser: ▪ Sound power level: 21.3 dBA with uncertainty 2.5 dBA. ▪ Sound pressure level: 13.3 dBA with uncertainty 2.5 dBA. Without diffuser: ▪ Sound power level: 31.4 dBA with uncertainty 2.5 dBA. ▪ Sound pressure level: 23.4 dBA with uncertainty 2.5 dBA.	With diffuser: ▪ Sound power level: 30 dBA with uncertainty 2.5 dBA. ▪ Sound pressure level: 22 dBA with uncertainty 2.5 dBA. Without diffuser: ▪ Sound power level: 32 dBA with uncertainty 2.5 dBA. ▪ Sound pressure level: 24 dBA with uncertainty 2.5 dBA.	F&P Eson™ 2 Nasal Mask is quieter than the predicate.

Feature	F&P Eson™ 2 Nasal Mask	Predicate Device: Eson™ Nasal Mask (K121597)	Comment
Materials of Construction	▪ Swivel: polycarbonate, ink pad print. ▪ Elbow: polycarbonate. ▪ Diffuser assembly: polycarbonate, polyethylene phthalate with pigment. ▪ Frame assembly: polycarbonate, ink pad print, blue colorant. ▪ Seal assembly: polycarbonate, silicone, ink pad print. ▪ Headgear: nylon/spandex, polyurethane foam, nylon, grey and blue colorant. ▪ Headgear clips: acetal.	▪ Swivel: polycarbonate, grey colourant. ▪ Elbow: polycarbonate. ▪ Diffuser assembly: polycarbonate, polyester fibre. ▪ Frame: Polycarbonate. ▪ Seal assembly: polycarbonate, silicone. ▪ Headgear: nylon/spandex, polyurethane foam. ▪ Headgear clips: acetal. ▪ Headgear buckle: nylon, grey colorant.	F&P Eson™ 2 Nasal Mask and Eson™ Nasal Mask are constructed from similar materials. Differences in materials from the predicate underwent cytotoxicity, sensitization and extractables and leachables testing to demonstrate that the device is biocompatible as per ISO 10993.

Non-Clinical Tests

Testing of the F&P Eson™ 2 Nasal Mask was compared to the predicate K121597 Eson Nasal Mask for performance and biocompatibility. These tests demonstrate substantial equivalence of the F&P Eson™ 2 Nasal Mask to the predicate device.

The F&P Eson™ 2 Nasal Mask has been tested to the following standards:

- ISO 17510-2:2007 Sleep Apnoea Breathing Therapy – Part 2: Masks and Applications Accessories
- ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

Specific tests used to show conformance to these standards include:

- Transportation and storage testing to provide evidence that the mask will perform as intended once it arrives to the prescribed user. Results were that the product had no

visible deformations, sufficiently removed CO2 through the exhaust vents, had no visible lint on the seal, had no offensive odour, that the packaging was still intact.

- Automatic High-Level Disinfection to provide evidence that the mask can effectively be disinfected in a certified washer disinfector. The mask was able to achieve the minimum 6 log reduction.
- Thermal Disinfection to provide evidence that the mask can effectively be disinfected through thermal disinfection cycles of 75°C for 30min, 80°C for 10min and 90°C for 1min. The mask was able to be thermally disinfected through the predetermined cycles.
- Sound Emissions to provide evidence that the sound pressure level is less than 25 dBA. Mask was able to achieve a sound pressure level of less than 25dBA with the diffuser system.
- Carbon Dioxide Flushing to determine if the mask is able to meet the minimum carbon dioxide flush rate. Under the worst case scenario, the mask was able to sufficiently flush carbon dioxide at a suitable rate.
- Shelf Life Assessment to show that the materials used in the mask have the ability to retain their structural integrity during storage. It was determined that the mask's materials have well known properties, are very stable and present a very remote risk of degradation within a shelf life of 10 years.

Clinical Tests

Not applicable – no clinical testing was performed with respect to the Eson™ 2 nasal mask.

Conclusion

The comparison of features, performance, and intended use demonstrate that the F&P Eson™ 2 Nasal Mask is substantially equivalent to the predicate K121597 Eson Nasal Mask.