

Section 5 - 510(k) Summary K12/597**Fisher & Paykel**
HEALTHCARE

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OCT 2 2012

Contact Person	James Thompson
Date Prepared	29 May 2012
Trade Name	F&P Eson™ Nasal Mask
Common Name	Nasal Mask
Classification Name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate Devices	K083832 Fisher & Paykel Healthcare Zest Nasal Mask

5.1 Description

The F&P Eson™ is a respiratory mask which is non-invasive. The silicone seal is positioned over the nose and it seals on the area around the nose and the upper lip. The mask is held on the face with headgear straps. It connects to a single breathing tube via a swivel adaptor to received pressurized gases. On the elbow are exhalation vents (bias holes) that allow exhaled gases to be continually flushed and removed to room air. The F&P Eson™ Nasal Mask has a diffuser system that is designed to diffuse air that is expelled from the mask. This reduces the draft. The diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the diffuser system. The air may also be humidified and/or oxygen enriched.

An oxygen pressure port accessory is available to be used with the device for oxygen therapy and/or gas monitoring (previously covered by K003894 Fisher & Paykel Healthcare Limited Oracle Oral Mask).

5.2 Intended Use

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.

5.3 Technological Characteristics Comparison

The F&P Eson™ Nasal Mask is very similar to the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask. Both masks are intended for non-continuous ventilation via CPAP and Bi-Level therapy, and deliver CPAP gasses through the nose.

The main difference is the seal; the F&P Eson™ has a self-adjusting rolling bridge, marketed as the RollFit Seal, for relieving pressure on the bridge of the nose and strategically thickened and thinned sections for overall structure, support and cushioning, whereas the Zest™ relies on the foam for structure, support and cushioning. Other differences with the F&P Eson™ include:

- A permanently attached ball elbow rather than a detachable swivel elbow used by the Zest™ for increase movement range.
- A diffuser system that is designed to diffuse air that is expelled from the mask. This reduces the draft. The diffuser does not significantly change the amount of air flowing from the mask, therefore the mask can be used with or without the diffuser system.
- Headgear similar to Zest™ but with the addition of the crown straps which is designed to go over the top of the head for increased stability. This adds two more adjustment points (six in total for F&P Eson™) as opposed to four for Zest™. Marketed as Ergofit Headgear.
- The use of the headgear as forehead cushions for the F&P Eson™, rather than silicone forehead pads used by the Zest™ for less parts.
- Headgear clips are incorporated in the lower headgear straps for F&P Eson™ for ease of use.

5.4 Non-Clinical Tests

Testing of the F&P Eson™ Nasal Mask was compared to the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask for performance and biocompatibility. These tests demonstrate substantial equivalence of the F&P Eson™ Nasal Mask to the predicate mask. Copies of test reports are included in Appendix B.

5.5 Conclusion

The comparison of features, performance, and intended use demonstrate that the F&P Eson™ Nasal Mask is substantially equivalent to the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask for performance and biocompatibility. The F&P Eson™ Nasal Mask has been demonstrated to be safe and effective for CPAP and Bi-Level ventilation therapy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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OCT 2 2012

Re: K121597
Trade/Device Name: F&P Eson™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 12, 2012
Received: September 17, 2012

Dear Mr. Thompson:

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.

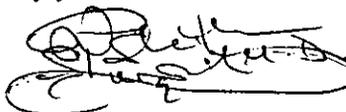
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

For 

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications For Use Statement

510(k) Number:

Device Name: F&P Eson™ Nasal Mask

Indications for Use:

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.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121597