SECTION 5 – 510K Summary

K103786

MAR 2 4 2011

Fisher & Paykel HEALTHCARE
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Auckland, New Zealand
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0148
Website: www.fphcare.com

Contact person	Tina Mason
Date Prepared	14th December 2010
Trade Name	Zest™ Petite 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 K092835 Respironics ComfortGel Blue Nasal Mask K061236 Fisher & Paykel Healthcare Flexifit HC432 Full Face Mask (predicate for material biocompatibility)

5.1 Description

The Zest™ Petite Nasal Mask 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 receive pressurized gases. On the mask base are exhalation vents (bias holes) that allow exhaled gases to be continually flushed and removed to room air. The silicone seal is contoured for comfort and to reduce leakage.

5.2 Intended Use

The Zest™ Petite Nasal Mask is intended to be used by individuals greater than 66lbs (30kg) who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The Zest™ Petite Nasal Mask is intended for Single Patient Use in the home and Multiple Patient 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 Zest™ Petite Nasal Mask is very similar to the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask. Both masks are for non continuous ventilation, and deliver CPAP gasses through the nose. The main difference is that the Zest Petite Nasal Mask is a smaller size than the Zest Nasal Mask. The overall dimensions of the Zest Petite Nasal Mask are smaller and the silicone seal is smaller. All the technology, features and specifications are identical. The only difference is that it will fit patients with smaller faces.

5.4 Non-clinical Tests

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

5.5 Conclusion

The comparison of features, performance, and biocompatibility are identical the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask (K083832) and the HC432 Full Face Mask (K061236) for biocompatibility.

The comparison of intended use 66lbs (30kg) is identical to the predicate Respironics ComfortGel Blue Nasal Mask (K092835) and is identical to the Fisher & Paykel Healthcare Zest™ Nasal Mask (K083832) in terms of Single Patient Use in the home and Multiple Patient Use in the hospital or other clinical setting.

The Zest™ Petite Nasal Mask is proven to be safe and effective for CPAP and Bi-level ventilation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tina Mason
Regulatory Affairs Engineer
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place
East Tamaki, Auckland
NEW ZEALAND 2013

MAR 2 4 2011

Re: K103786
Trade/Device Name: Zest™ Petite Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 20, 2010
Received: December 27, 2010

Dear Ms. Mason:

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 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 Zest™ Petite Nasal Mask

Indications for Use:

The Zest™ Petite Nasal Mask is intended to be used by individuals greater than 66lbs (30kg) who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The Zest™ Petite Nasal Mask is intended for Single Patient Use in the home and Multiple Patient Use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K103786