SECTION 6 – 510K Summary

K083382

MAR 1 6 2009

Fisher & Paykel HEALTHCARE

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Contact person	Tina Mason
Date Prepared	18th December 2008
Trade Name	Zest™ Nasal Mask
Common Name	Nasal Mask
Classification Name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate Devices	K080209 Fisher & Paykel Healthcare Zest Nasal Mask K063036 Fisher & Paykel Healthcare HC482 Direct Nasal Mask

6.1 Description

Identical to Predicate Device: K080209 Fisher & Paykel Healthcare Zest™ Nasal Mask

The Zest™ 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.

6.2 Intended Use

The Zest™ 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 Zest™ 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.

6.3 Technological Characteristics Comparison

Identical to Predicate Device: K080209 Fisher & Paykel Healthcare Zest™ Nasal Mask

6.4 Non-clinical Tests

Identical to Predicate Device: K080209 Fisher & Paykel Healthcare Zest™ Nasal Mask

6.5 Conclusion

The comparison of features, performance, and biocompatibility are identical the predicate Fisher & Paykel Healthcare Zest™ Nasal Mask (K080209).

The comparison of intended use Single Patient Adult Use and Multiple Patient Adult Use is identical to the predicate Fisher & Paykel Healthcare HC482 Direct Nasal Mask (K063036).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2009

Ms. Tina Mason
Regulatory Affairs Engineer-OSA
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland, NEW ZEALAND

Re: K083832
Trade/Device Name: Zest™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: March 6, 2009
Received: March 9, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Susan Runner

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5 – Indications for Use Statement

510(k) Number K083832

Device Name Zest™ Nasal Mask

Indications for Use:

The Zest™ 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 Zest™ 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 ___✓___ 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, Dental Devices

510(k) Number: K083832