FEB 2 3 2012

# Section 5 - 510(k) Summary

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K120027

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| **Contact Person** | Tina Mason |
| **Date Prepared** | 19 December 2011 |
| **Trade Name** | Pilairo™ Nasal Pillows Mask |
| **Common Name** | Nasal Pillows Mask |
| **Classification Name** | Non continuous ventilator IPPB<br>(21 CFR § 868.5905, product code BZD) |
| **Predicate Devices** | K063036 Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask<br><br>K083832 Fisher & Paykel Healthcare Zest Nasal Mask<br>(predicate for material biocompatibility) |

## 5.1 Description

The Pilairo™ is a CPAP nasal pillows mask which has an external connector attached to a frame and face seal that encloses the nasal airway entrance, held in place by a single head strap. The external connector allows connection to a CPAP device. The device conveys pressurised air to the nares. 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.

## 5.2 Intended Use

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 treatment. 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.

## 5.3 Technological Characteristics Comparison

The Pilairo™ Nasal Pillows Mask is very similar to the predicate Fisher & Paykel Healthcare Opus HC482 Direct 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 way the seal is achieved; the Pilairo™ Nasal Pillows Mask has a soft and thin seal which inflates and seals on the entrance of the nostrils and around the nose whereas the Opus HC482 seals only on the entrance of the nostrils. Other differences are that the Opus HC482 has a larger head gear with four adjustment points as opposed to the Pilairo™ Nasal Pillows Mask which has a single stretchable strap. The Pilairo™ Nasal Pillows Mask has only one size, whereas the Opus HC482 has 3 sizes (the Pilairo™ Nasal Pillows Mask is designed to fit a large proportion of the patient population with only one size). The Pilairo™ Nasal Pillows Mask has a larger dead space due to the way it achieves a seal around the nose.

## 5.4 Non-Clinical Tests

Testing of the Pilairo™ Nasal Pillows Mask was compared to the predicate Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask for performance and the Zest™ Nasal Mask for biocompatibility. These tests demonstrate substantial equivalence of the Pilairo™ Nasal Pillows 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 Pilairo™ Nasal Pillows Mask is substantially equivalent to the predicate Fisher & Paykel Healthcare Opus HC482 Direct Nasal Mask for performance and materials in the Zest™ Nasal Mask for biocompatibility. The Pilairo™ Nasal Pillows Mask has been demonstrated to be safe and effective for CPAP and Bi-Level ventilation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

FEB 2 3 2012

Ms. Tina Mason
Regulatory Affairs Engineer
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15 Maurice Paykel Place
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Auckland 1701
New Zealand

Re: K120027
Trade/Device Name: Pilairo™ Nasal Pillows Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: January 3, 2012
Received: January 3, 2012

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 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: K120027

Device Name: Pilairo™ Nasal Pillows Mask

Indications for Use:

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 treatment. 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.

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)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120027