5 510(k) Summary K060044

APR 6 2006

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Contact person	Brett Whiston
Date prepared	21 December 2005
Trade name	Acute Care Face Mask
Common name	Face Mask
Classification name	Ventilator, Continuous, Minimal ventilatory support, Facility use (accessory to) (21 CFR § 868.5895, product code MNT)
Predicate device	K040506 Fisher & Paykel Healthcare Flexifit HC431 Face Mask K023135 Respironics Image3 SE Disposable Face Mask

5.1 Description

The Acute Care Face Mask is a nasal-oral non invasive patient interface. The mask is held on the face with headgear straps and a quick release clip. It connects to a single breathing tube by a double swivel adaptor, to receive pressurized gases. On the body, or base, of the mask is an exhalation vent located above the bridge of the nose that allows exhaled gases to be continually flushed and removed to room air. The base is contoured and has a soft facial seal for comfort and to reduce leakage. Oxygen and pressure ports in the base can be used for pressure monitoring and supplemental oxygen tube connection.

5.2 Intended use

Adult patients requiring respiratory support and suitable for noninvasive ventilation have the option of a full face mask as the patient interface. The ventilator is providing positive pressure support by CPAP or bi-level techniques and has alarms and safety systems for ventilator failure. The mask is single patient use to be used on acute care patients who are in the hospital/institutional environment.

5.3 Technological characteristics comparison

The Acute Care Face Mask is very similar to the Flexifit mask. It uses the same base shape and seal, headgear, quick release clip and also contains an exhalation vent. Both are for non continuous ventilation. The Acute Care mask differs with the use of the exhalation vent containing holes, rather than the slots of the Flexifit mask, and the holes are positioned above the nasal bridge whereas the slots are above and below the mouth. It also differs in not using a non rebreathing valve unlike the Flexifit mask that includes one.

The absence of a non rebreathing valve or anti asphyxiation valve is possible when the mask is indicated for use with ventilators that have alarms and safety systems for ventilator failure, as with the Image3 SE mask. The Image3 SE is cleared for continuous ventilator use but like the Acute Care mask encounters the same situation if the ventilator fails.

5.4 Non-clinical tests

Testing of the Acute Care mask was compared to the Flexifit mask for performance and biocompatibility. These tests show that the Acute Care mask has substantial equivalence to the Flexifit mask.

5.5 Conclusion

The Acute Care Face Mask is substantially equivalent to the Flexifit and Image3 SE masks. The comparison of features, performance, and intended use demonstrate that the Acute Care mask is at least as safe and effective for non invasive ventilation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Mr. Brett Whiston
Fisher & Paykel Healthcare, Limited
P.O. Box 14-348, Panmure
Auckland, New Zealand 1701

Re: K060044
Trade/Device Name: Fisher & Paykel Healthcare Acute Care Full Face Mask
Regulation Number: 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: MNT
Dated: December 21, 2005
Received: January 6, 2006

Dear Mr. Whiston:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number

Device Name Fisher & Paykel Healthcare Acute Care Full Face Mask

The Fisher & Paykel Healthcare Acute Care Single Use Face Mask is a nasal-oral patient interface for use as an accessory to ventilators providing noninvasive bi-level and constant positive airway pressure ventilation. The ventilator must have adequate alarms and safety systems for ventilator failure. The mask is for single patient use with spontaneously breathing adult (> 30 kg) patients with respiratory insufficiency or respiratory failure, who are suitable for noninvasive pressure support ventilation in the hospital/institutional environments only.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hospital,
[illegible] Dental Devices

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