K061236

SECTION 5 – 510K Summary

AUG 2 9 2006

Fisher & Paykel HEALTHCARE

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Contact person	Reena Daken
Date prepared	27 April 2006
Trade name	Flexifit™ HC432 Full Face Mask
Common name	Full Face Mask
Classification name	Non continuous ventilator IPPB (21 CFR § 868.5905, product code BZD)
Predicate devices	K040506 Fisher & Paykel Healthcare Flexifit HC431 Face Mask K033087 Fisher & Paykel Healthcare Oracle Oral Mask (predicate for material biocompatibility)

5.1 Description

The Flexifit™ HC432 Full Face Mask is a non invasive patient interface that covers the patient's mouth and nose. The mask is held on the face with headgear straps and a quick release clip. It connects to a single breathing tube by a non-rebreathing valve and a swivel adaptor, to receive pressurized gases. The non-rebreathing valve is designed to prevent carbon dioxide build up in the mask in the event of cessation of airflow from the breathing circuit. On the body, or base, of the mask are exhalation vents (bias holes) 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, which is fitted with a foam cushion for comfort and to reduce leakage.

5.2 Intended Use

The Flexifit™ HC432 Full Face Mask is designed for adult patients requiring CPAP or Bilevel ventilator treatment in the home, hospital or other clinical setting. The mask may be reprocessed and reused by healthcare facilities to allow multi-patient use. The mask may be reprocessed up to 20 times.

5.3 Technological Characteristics Comparison

The Flexifit™ HC432 Full Face Mask is very similar to the predicate Flexifit™ Series HC431 Full Face Mask. It uses the same base shape and seal, headgear, quick release clip and also contains a non-rebreathing valve. Both masks are for non continuous ventilation. The Flexifit™ HC432 Full Face Mask differs with the use of the exhalation vent containing holes, rather than the slots of the predicate mask, and the holes are positioned above the nasal bridge whereas the slots on the predicate mask are above and below the mouth. It also differs in using a foam cushion. The predicate mask does not use a foam cushion. The foam cushion is designed to provide comfort and better sealing, hence minimising air leaks.

5.4 Non-clinical Tests

Testing of the Flexifit™ HC432 Full Face Mask was compared to the predicate Flexifit™ Series HC431 Full Face Mask for performance and biocompatibility. These tests demonstrate substantial equivalence of the Flexifit™ HC432 Full Face 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 Flexifit™ HC432 Full Face Mask is substantially equivalent to the predicate Flexifit™ Series HC431 Full Face Mask. The Flexifit™ HC432 Full Face Mask is proven to be safe and effective for CPAP and Bilevel ventilation therapy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2006

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

Re: K061236
Trade/Device Name: Flexifit™ HC432 Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 26, 2006
Received: July 31, 2006

Dear Ms. Daken:

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.

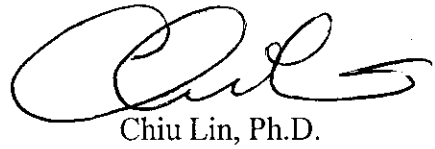
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

SECTION 4 – Indications for Use Statement

510(k) Number K061236

Device Name Flexifit™ HC432 Full Face Mask

Indications for Use:

The Flexifit™ HC432 Full Face Mask is intended for multiple patient or single patient adult use by individuals who have been diagnosed by a physician as requiring CPAP or Bilevel ventilator treatment in the home, hospital or other clinical setting.

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)

...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...) Number: K061236