K040506

MAY - 5 2004

17 February 2004

510(k) Summary of Safety and Effectiveness Information

Trade Name:	**Flexifit™ Series HC431 Full Face Mask**
Classification Name:	Accessory to Noncontinuous ventilator (IPPB) - 73 BZD Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Devices:	Resmed, Full Face Mask Series 2, K023244
	Fisher & Paykel Healthcare, Oracle Oral Mask, K033087 (predicate for non-rebreathing valve and biocompatibility)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The Flexifit™ Series HC431 Full Face Mask is an accessory to a Noncontinuous ventilator (IPPB) according to 21 CFR §868.5905. It constitutes the patient to ventilator interface in a noncontinuous ventilator system.

The Flexifit™ Series HC431 Full Face Mask is a respiratory mask which covers the mouth and nose. The mask is connected to the output breathing tube of the ventilator. The ventilator supplies air at CPAP or Bilevel pressures (typically in the range 3 - 25 cm H_2O) which is available at the mask.

The mask is positioned over the patient's nose and mouth during CPAP or Bilevel treatment. The HC431 Full Face Mask is designed to ensure the desired positive airway pressure is delivered to the patient with minimal leakage and that the mask is held securely over the nose and mouth while asleep.

The non-rebreathing valve prevents CO_2 re-breathing in the event of pressure loss due to power outage or ventilator machine failure. The elbow on the front of the mask facilitates freedom of movement while maintaining circuit integrity. Bias slots on the mask provide a means to purge exhaled gases from the breathing circuit.

510(k) Summary of Safety and Effectiveness Information (continued)

(a)(5) Statement of the Intended Use

The Flexifit™ Series HC431 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. A CPAP or Bilevel ventilator is typically used to treat obstructive sleep apnea (OSA) and may be used in the home, hospital or sleep laboratory.

The mask may be reprocessed and reused by healthcare facilities to allow multi patient use. The mask may be reprocessed up to 20 times.

The Flexifit™ Series HC431 Full Face Mask is designed to function as intended for up to 12 months of daily use when cared for as specified by the User Instructions by a single patient in the home.

(a)(6) Technological Characteristics Summary

The technological characteristics of the Flexifit™ Series HC431 Full Face Mask are equivalent to the predicate devices listed above.

The silicone seal is designed to fit around a patient's nose and mouth, and provide an airtight seal by which positive airway pressure is supplied to the patient. The seal is designed to be contoured and flexible to provide a good fit for most of the population. The seal fits under the patient's chin to provide stability to the mask and prevent the mask sliding up the face of the user. The seal is available in two sizes, both of which fit the single size mask base.

The base is manufactured from a rigid polycarbonate, and is designed to provide attachment points for the seal, headgear and breathing circuit. The upper headgear attaches to the base via the forehead rest, while the lower headgear straps attach to the base via the Glider™. The forehead rest holds the forehead cushion, and gives additional stability to the mask while preventing the seal from being over-tightened onto the bridge of the nose.

The Glider™ provides a sliding attachment between the headgear and the base, so that as the user turns their head, the Glider™ can slide through the mask base without becoming tight, as headgear does if it is rigidly attached to the base. The Glider™ has two straps, which help to maintain the mask stability. The Glider™ is held onto the mask base by the glider cover. The Glider™ is manufactured from Nylon 6, which provides good flexibility and strength, while maintaining a low coefficient of friction between the Glider™ and the polycarbonate base.

One end of the Glider™ is attached to the headgear by a clip, which incorporates a quick release cord. In case of claustrophobia, vomiting or other emergency, the patient can pull the quick release strap to release the mask from their face. The clip is manufactured from acetal, which provides good flexibility and toughness. The other end of the Glider™ is attached to the headgear via a tight hook. Both the clip and the hook allow the user to remove the mask without adjusting the headgear strap length settings.

The polycarbonate glider cover also provides the bias slots. The bias slots are thin slots, which taper gently outwards to allow the bias flow to escape from the base while remaining attached to the sidewalls of the slot. This results in minimal velocity and noise. The cover provides one sidewall of the slot, while the mask base provides the other.

The breathing circuit is attached to the mask base via the elbow and the non-rebreathing valve. The polycarbonate elbow has a free rotating swivel-snap connection on both ends. This means that the user can adjust the breathing circuit to any position they prefer. The free rotation reduces the torque transferred from the breathing circuit to the mask, so the mask disturbance is minimised.

Attached to the other end of the elbow is the non-rebreathing valve. The valve is designed to prevent carbon dioxide build up in the mask in the event of cessation of airflow from the breathing circuit. The valve consists of a thin silicon flap and two polycarbonate housings, which are ultrasonically welded together. During normal operation, the valve's silicon flaps are held open by the CPAP flow. When the flow ceases, the flaps return to their natural position, occluding the circuit and preventing back flow. This forces any exhaled air to exit the mask via the bias slots, thereby preventing CO_2 build up in the mask. The valve has a standard 22mm conical connector, which the breathing circuit attaches to.

The headgear provides four attachment points to the mask. The length of each strap can be adjusted using Velcro tabs, and each strap can also be unhooked without altering or undoing the length adjustment. The headgear is made of Breath-o-prene, which helps prevent sweating. The headgear also provides an attachment point for the other end of the quick release cord.

510(k) Summary of Safety and Effectiveness Information (continued)

(b)(1) and b(2) Discussion of Non-Clinical Tests

Tests performed on the Flexifit™ Series HC431 Full Face Mask demonstrate substantial equivalence to the predicate devices.

Non-clinical tests have demonstrated effective performance in terms of strength, durability, pressure and flow characteristics, and conformance of connections to industry standards.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

When used as intended, the Flexifit™ Series HC431 Full Face Mask has been shown to be as safe and effective as the predicate device. Specifically:

- The Flexifit™ Series HC431 Full Face Mask is a safe patient to ventilator interface when used as an accessory to a Noncontinuous ventilator
- The Flexifit™ Series HC431 Full Face Mask is an effective means of delivering positive airway pressure in the treatment of OSA
- The Flexifit™ Series HC431 Full Face Mask is a reliable device when used and maintained as specified in the Device Instructions

This information verifies that the Flexifit™ Series HC431 Full Face Mask is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: _____ date: 17/2/04

James Thompson
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAY - 5 2004

Mr. James Thompson
Regulatory Affairs Engineer
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East Tamaki Auckland, 1701
NEW ZEALAND

Re: K040506
Trade/Device Name: Fisher & Paykel Healthcare-Flexifit™
Series HC431 Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 17, 2004
Received: February 27, 2004

Dear Mr. Thompson:

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.

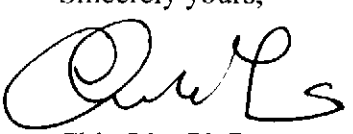
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

[510(k)] Number: K040506

17 February 2004

Fisher & Paykel Healthcare – Flexifit™ Series HC431 Full Face Mask

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare Flexifit™ Series HC431 Full Face Mask is an accessory to a Noncontinuous ventilator (IPPB) as per 73 BZD, 21 CFR §868.5905.

The Flexifit™ Series HC431 Full Face Mask is indicated for use by adults requiring CPAP or Bilevel ventilator treatment in home, hospital and laboratory environments for the treatment of Obstructive Sleep Apnea (OSA). It constitutes the patient to ventilator interface in a noncontinuous ventilator system. The device administers positive airway pressure via a mask which covers the nose and mouth. The HC431 Full Face Mask is a multi-patient reusable device for use on the prescription of a suitably qualified physician.

Prescription Use ✓ (Per 21 CFR subpart D) and/or Over-the-Counter Use ___ (Per 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)

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

510(k) Number: K040506