K023559

JUN 12 2003

October 17, 2002

510(k) Summary of Safety and Effectiveness Information

Trade Name:	**Fisher & Paykel Healthcare Oracle Oral Mask**
Model:	HC451A
Classification Name:	Accessory to Noncontinuous ventilator (IPPB) - 73 BZD Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Device:	Fisher & Paykel Healthcare, LTD., Oracle Oral Mask, Model 900HC451, K003894

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 Oracle Oral 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 Oracle Oral Mask consists of a mouthpiece and flexible breathing tube. The flexible breathing tube is connected to the output breathing tube of the ventilator. The ventilator supplies air at CPAP or Bilevel pressures (typically in the range 3 - 19 cm H_2O) which is available at the Oral Mask mouthpiece.

The mouthpiece is positioned in the patient's mouth during CPAP or Bilevel treatment. Features of the mouthpiece ensure the desired positive airway pressure is delivered to the patient with minimal leakage and that the mouthpiece is retained in the mouth while asleep.

The flexible breathing tube provides a transition between the more rigid output tube of the ventilator and the mouthpiece, facilitating freedom of movement while maintaining circuit integrity. An exhaust port adjacent to the mouthpiece provides 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 Oral Mask is intended for adult patient 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 laboratory. The positive air pressure supplied by the ventilator is delivered via the Oral Mask to the patient's mouth.

The Oral 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 patient in the home.

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

(a)(6) Technological Characteristics Summary

The technological characteristics of the Oral Mask are equivalent to the predicate device listed above. The only differences consist of a change of some of the materials, removal of the pressure ports, addition of a provision for mask adjustment and revised user labelling.

The Oral Mask mouthpiece is designed to assure unobstructed access to the patient's airway and to create an air-seal around the patient's mouth to facilitate sustained delivery of positive airway pressure. The Oral Mask mouthpiece is retained inside the mouth during sleep by action of the SnapFlap™ which rests against the patient's cheeks. The SnapFlap™'s flexibility allows the mouthpiece to accommodate a wide range of face shapes and sizes. The position of the SnapFlap™ can be adjusted by the patient to any one of three positions to further improve the fit.

The mouthpiece is connected to the elbow of a flexible breathing tube. The elbow incorporates a pattern of holes which constitute the exhaust port for bias airflow. The exhaust port allows the purging of exhaled gases. Product labelling states that the Oral Mask must not be used unless connected to a ventilator supplying the minimum specified ventilation pressure at which sufficient bias airflow is available to guarantee minimal re-breathing.

The flexible breathing tube allows the patient freedom of movement by way of the elbow and swivel joint rotation and flexure of the tubing itself. The swivel joint at the end of the flexible breathing tube is a press fit to industry standard breathing tube (ISO 5356-1, ASTM F1054: 22mm conical fitting). This allows effective connection to a wide range of CPAP and Bilevel ventilators.

The Oral Mask is manufactured from materials that meet appropriate requirements of ISO 10993-1.

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

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

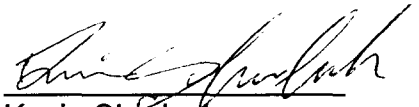
Tests, relevant to the modifications, were performed on the new Oral Mask to demonstrate substantial equivalence to the predicate device. These demonstrated effective performance in terms of strength, durability and biocompatability. Testing has shown that the Oral Mask can be effectively sterilised and that this process does not adversely affect the function, durability or safety of the Oral Mask.

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

When used as intended, the Oral Mask has been shown to be as safe and effective as the predicate device. Specifically:

- The Oral Mask is a safe patient to ventilator interface when used as an accessory to a Noncontinuous ventilator
- The Oral Mask is an effective means of delivering positive airway pressure in the treatment of OSA
- The Oral Mask is a reliable device when used and maintained as specified in the Device Instructions
- The Oral Mask can be reprocessed effectively to achieve a sterile product which can be safely used on multiple patients

This information verifies that the Oral Mask is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed:  date: 17.10.2002

Kevin Sherlock
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Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

Mr. James Thompson
Regulatory Affairs Engineer - OSA
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Post Office Box 14-348, Panmure
Auckland, New Zealand

Re: K023559
Trade/Device Name: Fisher and Paykel Healthcare Oracle Oral Mask
Regulation Number: 868.5905
Regulation Name: Accessory to Non-Continuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 28, 2003
Received: May 5, 2003

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.

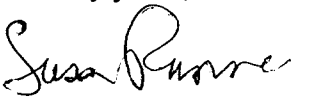
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Susan Runner, DDS, MA
Interim 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: K023559

October 17, 2002

Fisher & Paykel Healthcare - Oral Mask

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare Oracle Oral Mask is an accessory to a Noncontinuous ventilator (IPPB) as per 73 BZD, 21 CFR §868.5905.

The Oral 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 orally. The Oral Mask is a reusable device for use on the prescription of a suitably qualified physician. The Oral Mask may be reprocessed for multi-patient use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K023559

✓ Prescription Use
(Per 21 CFR §801.109)