JAN 1 4 2004

K033087

September 22, 2003

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, K023559

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 provides a patient to ventilator oral interface in a non-continuous ventilator system. 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 Oracle Oral Mask is supplied with an accessory kit for optional use, consisting of nasal plugs and a non-rebreathing valve, which may be used to reduce oral dryness as a result of nasal leak.

(a)(5) Statement of the Intended Use

The Oracle 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 Oracle Oral Mask to the patient's mouth.

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

(a)(6) Technological Characteristics Summary and Comparison to Predicate

The Oracle Oral Mask in this submission is substantially equivalent to the predicate Oracle Oral Mask. Both masks have the same intended use, operating principle and technological characteristics.

The "Oracle" 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 position of the SnapFlap™ can be adjusted by the patient to any one of three positions to further improve the fit can adjust the position of the SnapFlap™.

The Oral Mask is manufactured from materials that have either been previously cleared for the same intended use, or are compliant with the requirements of ISO 10993-1.

The Oracle Oral Mask outlined in this submission is equivalent to the predicate mask with respect to pressure-flow characteristics, dead space CO_2, and flow impedance.

- The SnapFlap™ material used in the Oracle in this submission continues to be a silicone but is an alternative to that that used in the predicate.

- The "Oracle" is now packaged with an accessory package consisting of nasal plugs and a non-rebreathing valve which may optionally be used to increase compliance in instances where the user experiences dryness from nasal leak.

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 Oracle Oral Mask to demonstrate substantial equivalence to the predicate device. These demonstrated effective performance in terms of strength, durability and biocompatibility.

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

- The "Oracle" Oral Mask as outlined in this submission is substantially equivalent to the predicate Oracle Oral Mask. When used as intended, the Oracle Oral Mask has been shown to be as safe and effective as the predicate device.

signed: _____ date: 24/9/03

James Thompson
Regulatory Affairs Engineer - OSA
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 1 4 2004

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

Re: K033087
Trade Name: Oracle Oral Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 5, 2003
Received: December 16, 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.

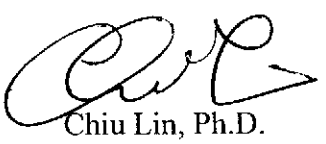
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

INDICATIONS FOR USE

[510(k)] Number: K033087

Device Name: "Oracle" Oral Mask HC451A

Indications For Use:

The Fisher & Paykel Healthcare Oracle Oral Mask is an accessory to a Noncontinuous ventilator (IPPB) as per 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 non-continuous 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.

Prescription Use ✓ AND/OR Over-the-Counter Use____
(Part 21 CFR 801 Subpart D) (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
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