K050904

MAY 25 2005

06 April 2005

510(k) Summary of Safety and Effectiveness Information

Model No. / Name:	HC238 CPAP Humidifier
Classification Name:	Noncontinuous ventilator (IPPB) - BZD Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Device:	Fisher & Paykel, HC234 CPAP Humidifier, K040941

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 Devices

The HC238 CPAP Humidifier is a non-invasive Continuous Positive Airway Pressure flow generator, incorporating a Heated Respiratory Humidifier.

The HC238 is comprised of two functional units. One is a motorised fan assembly that provides positive air pressure. The fan speed is directly related to air pressure, and is controlled by software. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the HC238 is a heated passover humidifier. The water is contained in the humidification chamber positioned on a heaterplate at the front of the unit. The chamber connects directly to the blower assembly via a port at the back of the chamber. Ambient temperature is monitored in order to reduce breathing tube condensation in cooler operating conditions.

(a)(5) Statement of the Intended Use

The HC238 series CPAP humidifier is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from use of a CPAP system.

The HC238 CPAP humidifier is for use on adult, spontaneously breathing (non-ventilator dependant) patients at home or in the sleep laboratory.

510(k) Summary continued - Fisher & Paykel, HC238 CPAP Humidifier

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

The fundamental technological characteristics of the HC238 CPAP Humidifier are equivalent to the HC234 CPAP Humidifier predicate device listed above. The HC238 is equivalent in terms of intended use, fundamental technological characteristics and manufacturing process. Modifications to the predicate device include;

- Pressure feedback in software to maintain delivered pressure for instances of mouth or mask leaks, changes in ambient air density and dynamic changes in flow due to patient breathing pattern.
- Delivered pressure measurement function and display

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the HC238 CPAP Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance.

The HC238 complies with the requirements of IEC 60601-1 general electromedical and IEC 60601-1-2 EMC standards. It complies with performance and safety requirements of ISO 17510-1 for CPAP devices.

(b)(2) Discussion of the Clinical Tests

Clinical verification studies on the HC238 CPAP Humidifier were not required in order to demonstrate the safety, effectiveness, and performance of the device.

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

The testing carried out for the HC238 CPAP Humidifier indicates that it meets design and performance functional requirements. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from particular standards for humidification systems.

This information indicates that the HC238 CPAP Humidifier is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: _____ date: 23/5/05

James Thompson
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2005

Mr. James Thompson
Regulatory Affairs Manager
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place
East Tamaki
Auckland, New Zealand

Re: K050904
Trade/Device Name: HC238 CPAP Humidifier
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 6, 2005
Received: April 11, 2005

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.

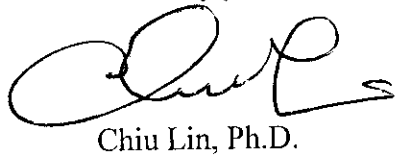
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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 (301) 443-6597 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

510(k) Number: _____

Device Name: HC238 CPAP Humidifier

INDICATIONS FOR USE:

The HC238 CPAP Humidifier is used to assist with patient breathing while sleeping, for th purpose of treating Obstructive Sleep Apnea (OSA). This is by the delivery of Continuou Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition o heated respiratory humidification to this therapy relieves the drying and irritating effects o the patient airways, which may arise from use of a CPAP system.

The HC238 CPAP Humidifier is for use on adult, spontaneously breathing (non-ventilato dependant) patients at home or in the sleep laboratory.

Prescription Use ✓ (21 CFR 801 subpart D) and/or Over-the-Counter Use __ (21 CFR 801 subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050904