JUL 10 1998

Fisher & Paykel
HEALTHCARE

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K973161

7 August, 1997

510(k) Summary of Safety and Effectiveness Information

Model Number / Name: **HC200 CPAP Humidifier**
Classification Name: Ventilator, Non-Continuous (Respirator) - 73 BZD
Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Devices: Respironics Inc, Solo™ CPAP System, K961626
ResCare Ltd, Sullivan® III Nasal CPAP System, K930656
Fisher & Paykel, HC100 Respiratory Humidifier, K915460

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Fisher & Paykel Healthcare HC200 CPAP Humidifier is a Continuous Positive Airway Pressure flow generator, as per 73 BZD, 21 CFR §868.5905. It includes a Heated Respiratory Humidifier, as per 73 BTT, 21 CFR §868.5450.

The HC200 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 relieves the drying and irritating effects on patient airways which may arise from use of a CPAP system.
The HC200 is for use on adult, spontaneously breathing (non ventilator-dependent) patients and is a prescription-use device.

A motorized fan assembly provides positive air pressure, which can be adjusted as prescribed by a physician. The fan speed is directly related to air pressure, and is controlled by software. An air filter is located at the back of the device leading to the input of the fan assembly. Warmth and moisture are added to the air as it passes over a heated body of water in a humidification chamber, which slides into place on a heaterplate at the front of the unit. The chamber connects directly to the CPAP generator section via a port at the back of the chamber. The temperature of the heaterplate can be adjusted by the user. Temperature is controlled by software, with the level of humidification delivered dependent on heaterplate temperature, rate of air flow, and ambient conditions of temperature and humidity.

Safety features for the device consist of software monitoring of CPAP generator, humidifier and power supply parameters, electronic monitoring of the microprocessor and a thermal cut-out on the heaterplate.

Controls include a pressure set potentiometer and mains power switch, on the right side of the device, with the mains power cord. A heaterplate adjustment potentiometer, mask test mode button and display LED are located on the front control panel.

The case enclosure components are a polycarbonate thermoplastic, and the heaterplate is cast aluminum. The humidification chamber is a clear thermoplastic top with an aluminum base. Accessories for the HC200 consist of a delivery tube and replacement humidification chambers.

The technological characteristics of the HC200 are equivalent to those of the predicate devices. The devices operate in the same CPAP operating pressure and heaterplate temperature ranges, and have similar features available to the user in both CPAP and humidification sections. The size, materials and technology used in the devices are equivalent, including the power supply, motor, control technology, enclosure components and air filter sections. The CPAP devices use microprocessor control with associated software safety features, and the humidifier devices use the same electronic and thermal safety features. They comply with international device safety standards for electromedical devices including IEC 601-1.

Testing carried out on the HC200 demonstrates that the device has equivalent performance in provision of both constant positive airway pressure and humidity to the two predicate device types.
The HC200 has equivalent pressure drop vs flowrate and dynamic pressure variation characteristics to the predicate CPAP systems. It provides the same levels of temperature and humidity over varying flowrates as the predicate humidifier, at the same heaterplate temperatures.

signed: _____ date: 7 August 1997

Chris Mander
Fisher & Paykel Healthcare

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1998

Mr. Chris Mander
Fisher & Paykel Electronics Limited
25 Carbine Road
Panmure, Auckland
NEW ZEALAND

Re: K973161
HC200 CPAP Humidifier
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: May 20, 1998
Received: May 22, 1998

Dear Mr. Mander:

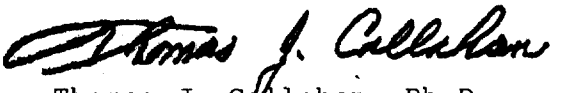
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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[510(k)] Number: K973161

6 August, 1997

Fisher & Paykel HC200 CPAP Humidifier

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare HC200 CPAP Humidifier is a combined Continuous Positive Airway Pressure Blower and Heated Respiratory Humidifier (as per 73 BZD, 21 CFR §868.5905 and 73 BTT, 21 CFR §868.5450).

The HC200 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 the device (normally included as an accessory to CPAP therapy) relieves the drying and irritating effects on the patient airways which may arise from use of a CPAP system.

The HC200 is for use on adult, spontaneously breathing (non ventilator-dependent) patients and is a prescription-use device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973161

Prescription Use ✓