K094040

APR 2 7 2010

SECTION 5 – 510K Summary

Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P O Box 14 348, Panmure
Telephone: +64 9 574 0100
Facsimile: +64 9 574 0158
Website: www.fphcare.com

Contact person	James Thompson
Date prepared	9 April 2010
Trade name	F&P ICON™ Series CPAP
Common name	F&P ICON™
Classification name	Non continuous ventilator IPPB, Class II (21 CFR § 868.5905, product code BZD)
Predicate devices	K081029 Fisher & Paykel Healthcare Sleepstyle™ 200 Auto Series HC254, and K041900 Fisher & Paykel Healthcare HC604 CPAP Humidifier
Establishment Registration	9611451

5.1 Description

The F&P ICON™ Series CPAP is a non-invasive Continuous Positive Airway Pressure (CPAP) flow generator, incorporating a heated respiratory humidifier.

The F&P ICON™ Series CPAP is made up of three main models (Auto, Premo and Novo). Features of each of the F&P ICON™ Series CPAP models vary across the model range. Details of each of the models and the technologies and features each of these models include are displayed in the table below. The full-featured Auto model has the ability to operate as both a conventional CPAP and an auto-adjusting CPAP.

Features	Auto	Premo	Novo
ThermoSmart™ Heated Breathing Tube	•	•	•
Ambient Tracking™ Plus	Backup for ThermoSmart™	Backup for ThermoSmart™	Backup for ThermoSmart™
Auto Adjusting Pressure	•		
Efficacy Reporting (AHI, Leak)	•	•	
Compliance Reporting	•	•	•
SmartStick™ Removable Media	•	•	•
SensAwake™ Pressure Relief	•		
Proportional Ramp	•	•	•
Altitude Adjustment	Automatic	Automatic	Manual
Leak Compensation	•	•	
Clock and AlarmTunes™ Function	•	•	•
InfoSmart™ Technologies	•	•	•
Ramp	•	•	•

Note: The display of efficacy data may be restricted by the healthcare provider

The Auto model of the F&P ICON™ Series CPAP detects apneas, hypopneas, and flow-limitation in the same way that the predicate HC254 device does. The Auto model of the F&P ICON™ Series CPAP also contains an algorithm, called SensAwake™, which is capable of detecting breathing patterns that are indicative of the "anxious" awake state. The SensAwake™ algorithm is identical to that of the predicate HC254 device.

An available treatment efficacy reporting software accessory is InfoSmart™. The package offers detailed reporting on therapy effectiveness, including compliance, AHI, leak and pressure. The supplied SmartStick™ fitted at the side of the device transfers this information via USB technology.

The device incorporates a ramp feature whereby the delivered pressure gradually increases over a period of 20 minutes until the set pressure is reached. This allows the user to fall asleep at a lower pressure.

The F&P ICON™ Series CPAP also includes features such as the SmartDial™, Clock, Alarm and AlarmTunes™. If the Alarm function is turned on by the user, the patient can choose a standard alarm bell sound, or AlarmTunes™, which allows personalised music from the SmartStick™.

5.2 Intended Use

The F&P ICON™ Series CPAP is for use on adult patients for the treatment of Obstructive sleep Apnea (OSA). The device is for use in the home or sleep laboratory

5.3 Technological Characteristics Comparison

The F&P ICON™ Series CPAP is substantially equivalent to the Fisher & Paykel Healthcare Sleepstyle™ 200 Auto Series HC254 in terms of intended use, operating principle, fundamental technological characteristics and manufacturing process.
The ThermoSmart™ technology is identical to that of the HC604 CPAP humidifier cleared under 510K number K041900

Differences between the F&P ICON™ Series and the Sleepstyle™ 200 Auto Series HC254 include;
- ThermoSmart™ technology as used in HC604 predicate device (K041900)
- InfoSmart™ accessory compatibility
- Clock & customized AlarmTunes™
- Modified user interface
- Modified device aesthetics, with top-loading chamber design.

5.4 Non-Clinical Tests

Non-clinical testing of the F&P ICON™ Series CPAP has been carried out covering mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility, functional verification and performance, biocompatibility and high level disinfection. Copies of these test reports are included in Appendices D, E, F and G.

The F&P ICON™ Series CPAP has been tested and complies with the requirements of the following standards;

- IEC 60601-1 Medical Electrical Equipment – General Requirements for Safety (App F)
- IEC 60601-1-2 Electromagnetic Compatibility Requirements and Tests (incorporating relevant IEC61000 series reference standards) (App F)
- ISO 17510-1 Sleep Apnea Therapy Devices (App G)
- ISO 8185 Respiratory Humidification Systems (App G)

Biocompatibility testing has been conducted at an external test house on relevant components of the F&P ICON™ Series CPAP as per ISO 10993 series standards, encompassing cytotoxicity, sensitization, genotoxicity, implantation and irritation.

Relevant components have been independently assessed against AAMI TIR12 and TIR30, and ISO14937 to confirm cleaning methods outlined achieve high level disinfection. ICON™ components in the humidified airpath were tested for their ability to withstand 20 cycles of high level disinfection via pasteurisation and Cidex OPA.

The following bench tests have been performed on the F&P ICON™ Series CPAP;

ICON™ Heated Breathing Tube Verification Testing – Determining surface temperature of the heated breathing tube does not exceed 44°C within 250mm of the patient connection, and confirming acceptability to design specifications of condensate formation. Verifying air

temperature at patient connection port will not exceed 43°C. Verifying heated breathing tube and heaterplate are disabled before ambient temperature reaches 37°C.

ICON™ Chamber Verification Testing – Confirming chamber meets spill test requirements.

ICON™ Heaterplate Verification Testing - Confirming the heaterplate power is removed when the air temperature at the patient connection port exceeds 43°C, and in accordance with internal design and safety requirements.

ICON™ Heated Breathing Tube Verification Testing – Ensuring the heated breathing tube would not collapse, occlude or otherwise cause a safety hazard when tested in accordance with ISO 5356 Annex E, including several worst case conditions

ICON™ Product Requirement Verification - Ensuring the Auto model can automatically adjust the delivered pressure within the stated pressure ranges. Ensuring the Auto and Premo models have means to automatically compensate the delivered pressure for ambient pressures within the stated operating envelope. Ensuring the Novo models has means to allow the user to set the altitude from 0 to 3000m.

ICON™ Transportation, Storage and Drop Tests Verification - Transportation, storage, and drop tests were carried out on ICON™ units. Functional tests were carried out on each unit before and after each environmental test.

ICON™ ISO 5356-1:2004 Product Verification Testing - Confirming that all the conical connectors of the ICON Series CPAP meet the gauging requirements of ISO 5356-1:2004.

Results from device testing confirm that the F&P ICON™ Series CPAP is substantially equivalent to the Fisher & Paykel Healthcare HC254 and HC604 predicate devices in terms of safety, effectiveness and performance.

5.5 Clinical Tests

Clinical testing was not required to demonstrate the safety and effectiveness of the F&P ICON™ Series CPAP. Product functionality has been adequately assessed by bench testing as above.

5.6 Conclusion

Testing carried out on the F&P ICON™ Series CPAP indicates that it meets design and performance functional requirements. The proposed device meets the requirements of sleep apnea breathing therapy device standards for safety and performance.

This information indicates that the F&P ICON™ Series CPAP is substantially equivalent to the predicate device in terms of safety, effectiveness and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 27 2010

Mr. James Thompson
Regulatory Affairs Manager - OSA
Fisher & Paykel Healthcare, Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland, New Zealand

Re: K094040
Trade/Device Name: F & P ICON™ Series CPAP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 9, 2010
Received: April 14, 2010

Dear Mr. James 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – Indications for Use Statement

510(k) Number:

Device Name: F&P ICON™ Series CPAP

Indications for Use:

The F&P ICON™ Series CPAP is for use on adult patients for the treatment of Obstructive Sleep Apnea (OSA). The device is for use in the home or sleep laboratory.

Prescription Use ✓ AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (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: K094040