K110316

Fisher & Paykel HEALTHCARE

AUG 19 2011

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

4 August 2011

510(k) SUMMARY

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

(a)(1) Contact Details

Company Details:	Refer to information above.
Contact Person:	James Thompson, Regulatory Affairs Manager - OSA

(a)(2) Name of the Device

Model Number / Name:	**InfoGSM**
Classification Name:	Noncontinuous Ventilator (IPPB) Anesthesiology Devices 21 CFR §868.5905 Class II, BZD

(a)(3) Identification of Legally Marketed Devices

K081029	SleepStyle 200 Auto Series HC254	Fisher & Paykel Healthcare Ltd
K083862	MedApps 2.0 Remote Patient Monitoring System	MedApps Inc

(a)(4) Description of the Device

The InfoGSM is an accessory for use with Fisher & Paykel Healthcare ICON Series CPAP devices to provide wireless compliance monitoring and remote settings update functions. The system consists of the InfoGSM and InfoSmart Web Software.

- **InfoGSM** is an accessory module that attaches via USB cable to the data output port of Fisher & Paykel Healthcare ICON CPAP devices. Compliance data is transferred from the ICON CPAP and uploaded via wireless modem to a secure database server.

- InfoSmart Web is server database and internet application software for review of compliance data uploaded from the InfoGSM. It includes display, reporting, and data management functions to assist in assessing CPAP usage and effectiveness, and allows for remotely updating ICON CPAP device settings.

(a)(5) Statement of the Intended Use

The F&P InfoGSM™ is intended for home and clinical use as an accessory for the F&P ICON™ CPAP device. The F&P InfoGSM™ transmits patient compliance and efficacy data from the CPAP device and allows this data to be reviewed by a clinician. In addition, remote adjustment of CPAP device settings is possible.

The InfoGSM™ is intended for use with F&P Healthcare ICON™ CPAP devices only and should not be connected to any other device.

(a)(6) Technological Characteristics Summary

Technological characteristics of the InfoGSM system are equivalent to the predicate devices listed above. Equivalent features between the devices include: transfer of compliance and efficacy data from an attached CPAP device; microprocessor control and use of a pre-approved RF wireless module; power supply from a rechargeable internal battery; interface to a secure server database via RF wireless technology to upload CPAP usage data; and website review software providing for patient data review and reporting functions.

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

Non-clinical testing of the InfoGSM has been carried out to cover functional verification and device performance. This included completion of software verification procedures, with performance testing of the modem and software to ensure data is transferred, uploaded, and displayed accurately, and that CPAP settings updates were accurately communicated back to the device. This established correct functionality of the InfoGSM according to requirements.

Third party testing of the InfoGSM for compliance to IEC 60601 series standards for electrical safety and electromagnetic compatibility, IEC 60068 series standards for environmental testing, and FCC and CTIA PTCRB industry certification requirements for GSM mobile devices, will be completed by accredited laboratories before marketing of the device.

(b)(2) Discussion of the Clinical Tests

Clinical testing was not required to demonstrate the safety and effectiveness of the InfoGSM System. The product functionality has been adequately assessed by bench testing as above.

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

Hardware testing carried out for the InfoGSM indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and the system configuration functions equivalently to the predicate devices. The device will meet specified standard requirements for electrical safety, electromagnetic compatibility, environmental performance, and industry certification requirements for GSM mobile devices, before marketing.

This information indicates that the InfoGSM is equivalent to the predicate devices in terms of device safety and effectiveness.

13 June 2011

INDICATIONS FOR USE

510(k) Number: K110316

Device Name: **InfoGSM**

Indications for Use:

The F&P InfoGSM™ is intended for home and clinical use as an accessory for the F&P ICON™ CPAP device. The F&P InfoGSM™ transmits patient compliance and efficacy data from the CPAP device and allows this data to be reviewed by a clinician. In addition, remote adjustment of CPAP device settings is possible.

The InfoGSM™ is intended for use with F&P Healthcare ICON™ CPAP devices only and should not be connected to any other device.

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)

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

Mr. James Thompson
Regulatory Affairs Manager – OSA
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
Auckland
New Zealand 1701

AUG 19 2011

Re: K110316
Trade/Device Name: InfoGSM
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: August 4, 2011
Received: August 5, 2011

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. 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,

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

13 June 2011

INDICATIONS FOR USE

510(k) Number: K110316

Device Name: **InfoGSM**

Indications for Use:

The F&P InfoGSM™ is intended for home and clinical use as an accessory for the F&P ICON™ CPAP device. The F&P InfoGSM™ transmits patient compliance and efficacy data from the CPAP device and allows this data to be reviewed by a clinician. In addition, remote adjustment of CPAP device settings is possible.

The InfoGSM™ is intended for use with F&P Healthcare ICON™ CPAP devices only and should not be connected to any other device.

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: K 110316