DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 24, 2017

Fisher & Paykel Healthcare Ltd.
Jayanti Karandikar
Regulatory Affairs Specialist
15 Maurice Paykel Place
East Tamaki, Auckland 2013
New Zealand

Re: K161686
Trade/Device Name: F&P InfoSmart™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 16, 2016
Received: December 22, 2016

Dear Jayanti Karandikar:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161686

Device Name
F&P InfoSmart™

Indications for Use *(Describe)*

InfoSmart™ is a software application for use with compatible Fisher & Paykel Healthcare OSA Flow generators. It allows for remote collection and management of device usage and therapeutic information. It also allows for remote therapy reporting and adjustment of device settings by a clinician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

5 510(k) Summary

Contact person/submitter	Jayanti Karandikar
Date prepared	22 December 2016
Contact details	Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100 Fax: +64 9 574 0158
Trade name	F&P InfoSmart™
Common name	InfoSmart
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	InfoGSM (K110316)

5.1 Device Description

InfoSmart™ is a software reporting tool which provides reports on sleep therapy data including compliance, AHI, leak and pressure. This software can be used to report on data from compatible Fisher & Paykel Healthcare medical devices.

The software enables the Health Service Provider to:

- Access and review a patient's compliance and efficacy reports
- Change device settings
- Manage equipment information
- Manage patient information
- Share the above data with other health service providers and organisations involved in a patient's therapy.

InfoSmart™ may be provided as an on-premises software application, or a web application. Data from a compatible device can be transferred to InfoSmart™ in a number of ways; including a serial cable, a USB stick, or wirelessly though a communications module. Data is transferred to a central database from which it can be accessed and displayed on the health service provider's computer.

5.2 Intended Use and Indications for Use

InfoSmart™ is a software application for use with compatible Fisher & Paykel Healthcare OSA Flow generators. It allows for remote collection and management of device usage and therapeutic information. It also allows for remote therapy reporting and adjustment of device settings by a clinician.

5.3 Technological Characteristics Comparison

Design/ technological characteristic	Subject device (InfoSmart™)	Predicate device (InfoGSM)	Comments
Features	**Web variant:**	**Web variant:**	• InfoSmart™ provides similar features to its predicate with the web variant being identical. • The on-premises variant has similar features to the web except that it does not support web based data transfer. Data is still communicated to the central database via other means ie serial cable, removable media via USB.
	Centralised database	Centralised database	
	Device usage and compliance reports	Device usage and compliance reports	
	Efficacy reports	Efficacy reports	
	Settings management	Settings management	
	Equipment management	Equipment management	
	Patient management	Patient management	
	Support for web based data transfer options	Support for web based data transfer options	
	On-premises variant:		
	Centralised database		
	Device usage and compliance reports		
	Efficacy reports		
	Settings management		
	Equipment management		
	Patient management		
Data upload	**Web variant:** Wireless, removable media **On-premises variant:** Removable media, serial cable	Wireless	Both the InfoSmart™ web variant and the predicate device software provide for wireless data transfer. Removable media and serial data transmission are also supported by one or more variants. Regardless of the transmission medium, identical data is transmitted.
Application type	InfoSmart™ is provided as two variants: Web based application on-premises application	InfoSmart™ Web is provided as a Web based application only.	InfoSmart™ is identical to the predicate device software wherein it provides a web variant. The on-premises of InfoSmart™ consists of a software application that can be installed on a local PC or server. Similar to its web counterpart, InfoSmart™ on-premises version, allows users to download data to the system, generate reports and adjust device settings.

Reporting	Therapy compliance and efficacy reporting.	Therapy compliance and efficacy reporting.	**Identical**
Operating Environment	Office, hospital or other clinical setting	Office, hospital or other clinical setting	**Identical**
Compatible Flow Generators	FPH OSA Flow Generators (BZD) **InfoSmart™ Web Version:** • F&P ICON series (Auto/Premo/Novo) • Sleepstyle 200 Auto Series (HC254) **InfoSmart on-premises:** • Sleepstyle 200 series (HC234, 238) • Sleepstyle 600 Series (HC604) • F&P ICON series (Auto/Premo/Novo)	FPH OSA Flow Generators (BZD) **InfoSmart Web version** • F&P ICON series (Auto/Premo/Novo) • Sleepstyle 200 Auto Series (HC254)	**Identical** type of therapy devices
Device Settings changed by the software	**Web version/ On-premises version:** • Device operating mode • Therapeutic pressures • Comfort settings • User Interface	**Web version:** • Device operating mode • Therapeutic pressures • Comfort settings • User Interface	**Identical**
Performance testing	• Functionality • Reporting • Device compatibility	• Functionality • Reporting • Device compatibility	**Identical** • **Reporting**- Report testing focuses on report accuracy, ensuring all data processing performed by the software is accurate, and that this information is correctly reflected in therapy reports. • **Functionality**- Functional acceptance testing covers the functional requirements of the product, ensuring all functions and features perform according to specification. • **Device compatibility testing**- ensures all supported devices function correctly with the software and that data is uploaded from the device. Testing also ensures that device settings can be changed by the software and that these changes are accurately reflected within the device.

Indications for use			
Purpose and function	InfoSmart transmits patient compliance and efficacy data from the CPAP devices and allows this data to be reviewed by a clinician. In addition, remote adjustment of CPAP device settings is possible. InfoSmart™ Web is intended for use with F&P ICON series and Sleepstyle 200 Auto Series flow generators and InfoSmart on-premises is intended for use with F&P ICON series, Sleepstyle 200 series and Sleepstyle 600 Series flow generators.	The F&P InfoGSM™ is intended for home and clinical use as an accessory for the F&P ICON™ CPAP devices. 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.	• InfoSmart™ has a similar purpose over its predicate device software InfoSmart Web in that it allows for remote collection and management of device and therapeutic information. It also allows for adjustment of device settings. • InfoSmart™ consists of an on-premises which is a software application that can be installed on a local PC or server. • Similar to its web counterpart InfoSmart™ on-premises version, allows users to download data to the system, generate reports and adjust device settings. • Expanding the scope to include additional F&P devices does not affect the functionality or safety of InfoSmart™.

The key differences are that InfoSmart™:

- Has an intended use with an expanded scope to be used with compatible F&P devices versus the predicate which was indicated to be used with the ICON CPAP devices only. Plus the subject device includes an on-premises variant which is to be installed on a PC or server. Introduction of additional compatible F&P devices and an on-premises variant does not introduce any safety or functionality concerns.
- Supports various means of data transfer. Depending on the variant, data can be obtained from a device via removable media, serial cable or wirelessly. The web variant of InfoSmart™ is identical to the predicate device software where in data can be obtained wirelessly from a compatible device via a communications module. The on-premises variant uses other methods via removable media or serial cable which does not affect the data transmitted.

5.4 Non-Clinical Performance Data

Verification and validation testing on the subject InfoSmart™ was carried out ensuring data was transferred, uploaded and displayed accurately and that device settings updates were accurately communicated back to the compatible device. All tests confirmed that the software met the predetermined acceptance criteria.

The testing above also demonstrated comparable safety and effectiveness of InfoSmart™ in comparison to the predicate.

5.5 Clinical Performance Data

Clinical tests were not required to demonstrate the safety and effectiveness of InfoSmart™. Product functionality has been adequately assessed by non-clinical tests.

5.6 Conclusions

Results obtained from non-clinical testing demonstrate that, InfoSmart™ meets the design and functional requirements providing performance and is as safe and as effective as the predicate device. The differences between the subject and predicate do not raise new issues of safety and effectiveness.

It is therefore concluded that InfoSmart™ is substantially equivalent to the predicate device.