August 8, 2018

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

Re: K173193
Trade/Device Name: F&P SleepStyle ™
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 5, 2018
Received: July 9, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

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)*

K173193

Device Name

F&P SleepStyle™

Indications for Use *(Describe)*

The device is for use on adult patients for the treatment of Obstructive Sleep Apnoea (OSA). The device is for use in the home or sleep laboratory.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact person/submitter	Jayanti Karandikar
Date prepared	04 Aug 2018
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 SleepStyle™
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	F&P ICON (K094040)

Intended Use and Indications for Use

The device 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.

Device Description

The F&P SleepStyle™ is a non-invasive, auto adjusting Continuous Positive Airway Pressure (CPAP) flow generator, incorporating a heated respiratory humidifier. The device is intended to treat Obstructive Sleep Apnea (OSA) by delivering a flow of positive airway pressure at a level prescribed by a physician to splint open the airway and prevent airway collapse.

The F&P SleepStyle™ system is comprised of the following devices/accessories:

- F&P SleepStyle™ models SPSAAN and SPSCAN;
- Breathing tubes:
  - ThermoSmart™ heated breathing tube;
  - Standard breathing tube, i.e. non-heated, and elbow connector;
- Water chamber and water chamber seal;
- USB stick (F&P InfoUSB)

The F&P SleepStyle™ system is available in two modes, fixed and auto-adjusting CPAP.

Similar to the predicate device, the SleepStyle™ works by pressurizing room air which is then transported to a patient interface. The delivery of positive air pressure to the patient holds the soft tissue in the throat open, preventing airway collapse and thus disruptions to the patient's breathing and sleep.

Humidified CPAP devices include a water chamber which holds water that is heated by a heating element in the CPAP device, thus adding water vapor to the gas prior to delivery to the patient. This is integrated into the device. The humidifier reduces nasal dryness and improves patient comfort.

An optional heated breathing tube (ThermoSmart) reduces condensation and improves humidity delivery to the patient.

The proposed device has integrated Bluetooth which allows therapy data to be sent to general wellness applications which can be used by patients for self-assessment and monitoring of therapy progress.

The proposed device also has an integrated modem which automatically uploads therapy data to the software reporting tool InfoSmart (K161686) managed by the healthcare provider. Alternatively data from the device can be stored onto an USB stick and uploaded to the software reporting tool InfoSmart (K161686).

The following table outlines the features of the F&P SleepStyle™ models.

Table 1: Performance features

Performance features	SleepStyle Auto CPAP (SPSAAN)	SleepStyle CPAP (SPSCAN)
Fully integrated humidifier	●	●
Auto-adjusting pressure	●	
ThermoSmart technology	●	●
SensAwake	●	●
Expiratory relief	●	●
Ramp	●	●
Auto-altitude adjustment	●	●
Leak compensation	●	●
Efficacy reporting	●	●
Compliance reporting	●	●
F&P InfoUSB	●	●
Bluetooth wireless technology	●	●

Cellular modem	●	●

Technological Characteristics Comparison

Design / technological characteristic for comparison	Subject device (F&P SleepStyle™ CPAP)	Predicate device (F&P ICON SERIES CPAP, K094040)	Comments
Intended Use and Indications for Use			
Intended Use/ Indications for use	The device 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.	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.	Identical
Classification			
Device classification	II (868.5905)	II (868.5905)	Identical
Product code	BZD	BZD	Identical
Classification panel	Anesthesiology	Anesthesiology	Identical
Pressure delivery			
Fixed CPAP	Yes	Yes	Identical feature offered
Automatic adjusting pressure	Yes (Auto CPAP model)	Yes (Auto CPAP model)	Identical feature offered
Algorithm			
Automatic adjusting CPAP algorithm	Yes	Yes	Modified algorithm – Refer to §5.3.1 a)
AHI measurement algorithm	Yes	Yes	Modified algorithm – Refer to §5.3.1 b)

Design / technological characteristic for comparison	Subject device (F&P SleepStyle™ CPAP)	Predicate device (F&P ICON SERIES CPAP, K094040)	Comments
Performance specifications			
Pressure range	4 – 20 cmH_2O	4 – 20 cmH_2O	Identical
Humidity output	≥ 10 mg/L, as required by ISO 8185	≥ 10 mg/L, as required by ISO 8185	Identical
Features			
Altitude adjustment	0 to 3000m (0 to 9000ft)	0 to 3000m (0 to 9000ft)	Identical
Leak compensation	Yes	Yes	Identical feature offered
Comfort features			
Pressure ramp	Up to 20 minutes	Up to 20 minutes	Identical feature offered
Humidification	Yes	Yes	Similar feature with option of 7 comfort settings for both, subject and predicate device.
SensAwake™	Yes	Yes	Similar feature offered – Refer to §5.3.1 c)
Expiratory Relief	Yes	No	New comfort feature – Refer to §5.3.1 c)
User interface			
User controls	Buttons	Dial	Updated user interface – Refer to §5.3.1 d)
Menu	Text	Symbols	
Reuse / sterilization / shelf life			
Reuse	Multi-patient, multi-use	Multi-patient, multi-use	Similar. The SleepStyle heated breathing tube is not intended for multi-patient use

Design / technological characteristic for comparison	Subject device (F&P SleepStyle™ CPAP)	Predicate device (F&P ICON SERIES CPAP, K094040)	Comments
Sterility	Components (including accessories) are not provided sterile or intended to be sterilized	Components (including accessories) are not provided sterile or intended to be sterilized	Identical
Cleaning	• Single patient, multi-use: cleaning • Multi-patient, multi-use: disinfection of components in the humidified air path	• Single patient, multi-use: cleaning • Multi-patient, multi-use: disinfection of components in the humidified air path	Similar types of cleaning identified for single-patient, multi-use and multi-patient, multi-use – Refer to §5.3.1 e)
Shelf Life	2 years	Not defined	Shelf life defined for SleepStyle accessories: heated breathing tube, standard breathing tube, water chamber, inlet filter
Data reporting			
Data reporting tool	InfoSmart (K161686)	InfoSmart (K094040)	Identical – Refer to §5.3.1 f)
USB data stick	Yes	Yes	Similar function of data storage and data transfer – Refer to §5.3.1 g)
Cellular modem	Yes (built-in)	Yes (external – InfoGSM, K110316)	Similar function of data transfer – Refer to §5.3.1 h)
Bluetooth®	Yes	No	New feature – Refer to §5.3.1 i)
Accessories			
Heated breathing tube	Available	Available	Identical accessory offered
Non-heated breathing tube	Available	Available	Identical accessory offered

Design / technological characteristic for comparison	Subject device (F&P SleepStyle™ CPAP)	Predicate device (F&P ICON SERIES CPAP, K094040)	Comments
Water chamber	Yes	Yes	Identical accessory type offered; detachable lid seal added – Refer to §5.3.1 j)
Operating conditions			
Temperature	12 to 35° C 54 to 95° F	5 to 35° C 41 to 95° F	Similar
Humidity	15 to 90% RH	5 to 95%RH	
Altitude	0 to 3000m 0 to 9,000 ft	0 to 3000m 0 to 9,000 ft	Identical
Storage and Transport conditions			
Temperature	-10 °C to 60 °C 14 to 140 °F	-10 °C to 60 °C 14 to 140 °F	Identical
Humidity	15 to 90% RH	Not specified	Humidity has been specified for the SleepStyle device storage conditions.
Electrical ratings			
Supply voltage	100–115 V	100–115 V	Identical
Current input	1.2 A (2.5 A max.)	1.27 A (1.43 A max.)	Similar
Supply Frequency	50–60 Hz	50–60 Hz	Identical

Key Differences

The key differences between the subject device and predicate device, are that F&P SleepStyle™:

a) Has a revised auto adjusting CPAP algorithm. The algorithm from the predicate device has been modified.

b) Has a revised AHI measurement algorithm. Changes were made to the algorithm used in the predicate device.

c) Has a revised SensAwake algorithm and new comfort feature - expiratory relief. Changes were made to the SensAwake algorithm used in the predicate device. Expiratory relief reduces pressure delivered to the patient each time the patient exhales.

d) Uses a modified user interface - The SleepStyle™ device uses dedicated buttons for key features i.e. therapy on/off and a graphical display to display text.

e) Has similar reprocessing instructions to the predicate device, with additional disinfection options. Performance and verification testing was conducted as per the recommendations of FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validations Methods and Labelling." Similar to the predicate device, chemical disinfection for SleepStyle™ parts (excluding the heated breathing tube) can be performed using Cidex OPA.

The main differences are described below:

- The heated breathing tube used with the SleepStyle™ is for single-patient use only and therefore is not intended for high level disinfection.
- Thermal disinfection of some SleepStyle™ parts can be carried out at 2 different temperatures: 75°C for 30 min and 90°C for 1 min. Thermal disinfection of the predicate device was validated at 70°C for 30 min.

f) Is compatible with InfoSmart, a software reporting tool. The client version of InfoSmart was cleared with the predicate device through 510K K094040. InfoSmart was recently cleared through K161686 to be able to work with compatible flow generators and incorporated the client and web versions. InfoSmart simply displays data as recorded by the compatible CPAP device. Introducing a new compatible device does not change the basic functionality of InfoSmart.

g) Includes an USB stick which is used to store sleep data that is captured by the device during therapy. The data is transferred from the memory of the CPAP device when the USB stick is inserted into the device's USB port. The USB stick can then be sent to the healthcare provider to view/report on the data, and/or adjust therapy settings. Alternatively, the application in the stick can enable data to be uploaded via the internet to a remote server which can be accessed by the healthcare provider via a web based software called InfoSmart Web (K161686). The stick, in the predicate device, functions in a similar fashion to the stick above but does not have the software application to support web based data transfer.

h) Includes an integrated modem as opposed to an external modem InfoGSM (K110316) which is compatible with the predicate F&P ICON (K094040). The purpose of the integrated modem within the proposed device is to enable data transfer via cellular network to a software reporting tool InfoSmart (K161686).
The external modem used with the predicate device performs a similar function.

i) Includes integrated Bluetooth which enables data transfer by pairing the device with the mobile phone or tablet. This allows the user to view their data on the SleepStyle™ mobile application or the SleepStyle™ website.

j) Includes a water chamber that has a detachable seal to allow easier cleaning, and filling of the water chamber. The predicate device has the chamber seal permanently attached to the chamber.

Non-Clinical Performance Data

Non-clinical performance testing of the SleepStyle™ device was carried out covering mechanical, electrical and thermal safety, environmental conditions, electromagnetic compatibility and functional verification.

The SleepStyle™ device has been tested according to the following standards:

- ANSI/AAMI ES60601-1:2005 (R) 2012, A1:2012, C1:2009 (R) 2012 and A2:2010 (R) 2012. Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (FDA recognition number: 19-4)
- IEC 60601-1-2:2014. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (FDA recognition number:19-8)
- IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 8185:2008 Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems. (FDA recognition number:1-86)
- 10993-1:2009 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing within a Risk Management Process. (FDA recognition number: 2-220)
- ISO 10993-3:2014. Biological Evaluation of Medical Devices -- Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity. (FDA recognition number: 2-228)
- 10993-5:2009 Biological Evaluation of Medical Devices -- Part 5: Tests for in Vitro Cytotoxicity. (FDA recognition number: 2-245)
- ISO 10993-10:2010. Biological Evaluation of Medical Devices -- Part 10: Tests for Sensitization and Irritation. (FDA recognition number: 2-174)
- ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (FDA recognition number:2-176)
- ISO 80601-2-70:2015 Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnea Breathing Therapy Equipment. (FDA recognition number: 1-115)
- ISO 5356-1 Anaesthetic and Respiratory Equipment - Conical Connectors: Part 1: Cones and Sockets. (FDA recognition number: 1-62)
- ISO 5367:2014 Anaesthetic and respiratory equipment – Breathing sets and connector

Functional Bench Testing:

The following functional testing was conducted on the SleepStyle device:

- Static and Dynamic Pressure Accuracy
- Flowrate at Maximum Pressure
- Max Pressure Single Fault
- Noise Verification
- Water Chamber Spillage Test
- Transport, Storage, Drop testing
- Altitude adjustment
- Pull test

Biocompatibility:

The F&P SleepStyle™ is classified as an externally communicating device, tissue contact, permanent duration (>30 days). The humidified gas pathway components of the F&P SleepStyle™ device system were tested together as a full system. The testing of cytotoxicity, sensitization, intracutaneous reactivity, and acute systemic toxicity were conducted based on applicable ISO 10993 test standards. In addition, the chemical characterization study plus a toxicological risk assessment for the identified chemical extractables and leachables were conducted.
The testing of particulate matters and volatile organic compounds (VOCs) for both the humidified and dry gas path, and testing of carbon monoxide, carbon dioxide and ozone for the dry gas pathway were also performed.

Software:

The device software level of concern is moderate and software testing was done as per IEC 62304:2006 (Medical device software – Software life-cycle processes) and ISO 14971:2007 (Medical devices - Application of risk management to medical devices).

Clinical Performance Data

The clinical validation study, involving 50 patients, was conducted at the Fisher & Paykel Sleep Laboratory in New Zealand following GCP guidelines.

Clinical studies were carried out:

- To validate the device, for the treatment of OSA using APAP and CPAP modes with and without pressure relief technologies (expiratory relief and SensAwake).

Conclusion

Results obtained from non-clinical and clinical testing demonstrate that, SleepStyle™ is substantially equivalent to the predicate device F&P ICON (K094040).