September 5, 2023

Fisher & Paykel Healthcare Ltd
Reena Daken
Regulatory Affairs Manager - North America
15 Maurice Paykel Place, East Tamaki
Auckland, 2013
New Zealand

Re: K223684
Trade/Device Name: F&P 820 Humidification System
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: December 8, 2022
Received: December 8, 2022

Dear Reena Daken:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223684

Device Name
F&P 820 Humidification System

Indications for Use *(Describe)*

F&P 820 System Humidifier Base:
The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.
This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.
The F&P 820 System is designed for adult and pediatric patients (excluding neonate), requiring a flow range ≥ 5 L/min. It is designed for use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

F&P 820A10 Breathing Tubes:
The F&P 820 series breathing tubes are an accessory to the F&P 820 System and are compatible with F&P 820 series humidifiers.
The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.
This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.
This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

F&P MR325 Humidification Chamber:
The MR325 humidification chamber is an accessory to the F&P 820 System and is compatible with F&P 820 series humidifiers.
The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.
This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.
This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

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

K223684

As required by 21 CFR 807.92

I. SUBMITTER

Company Name and Address	Fisher & Paykel Healthcare Limited 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Prepared and Submitted by	Arisha Samad Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	05 September 2023

II. DEVICE

Name of Device	F&P 820 Humidification System
Common/Usual Name	Respiratory Humidifier
Classification Name	Respiratory Gas Humidifier
Regulatory Class	Class II
Primary Classification Product Code	BTT (21 CFR §868.5450)

III. PREDICATE DEVICE

- Primary Predicate device:

510(k) Number	Device Name
K143646	F&P MR810 Respiratory Humidifier

- Secondary Predicate devices:

510(k) Number	Device Name	Reason for secondary predicate
K983112	Adult breathing circuit (RT102)	Used as a predicate for the F&P 820A10J accessory breathing circuit kits.
K003973	F&P humidification chamber (HC325)	Used as a predicate for the F&P MR325 accessory humidification chamber.

- Reference device(s):

510(k) Number	Device Name	Reason for reference
K152029	Hamilton-BC4022- Adult single limb breathing set	Used to address the technological differences between the subject and predicate device and support claims of safety and effectiveness with respect to breathing circuit use in patient population
K143646	F&P Adult breathing circuit (900MR810)	Used to address the technological differences between the subject and predicate device.

IV. DEVICE DESCRIPTION

The Fisher & Paykel 820 Humidification (also referred to as F&P 820 System) is designed to provide respiratory humidification by providing heat, humidity, and delivering respiratory gases to patients.

The F&P 820 System is a revision of the predicate device platform, the Fisher & Paykel MR810 Respiratory Humidifier (K143646).

V. INDICATIONS FOR USE STATEMENT

F&P 820 System Humidifier Base:

The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.

This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.

The F&P 820 System is designed for adult and pediatric patients (excluding neonate), requiring a flow range $\geq$ 5 L/min. It is designed for use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

F&P 820A10 Breathing Tubes:

The F&P 820 series breathing tubes are an accessory to the F&P 820 System and are compatible with F&P 820 series humidifiers.

The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.

This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.

This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

F&P MR325 Humidification Chamber:

The MR325 humidification chamber is an accessory to the F&P 820 System and is compatible with F&P 820 series humidifiers.

The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases when using a continuous or intermittent ventilator system or a continuous gas flow.

This system is intended for both noninvasive and invasive therapies. The addition of heat and humidity to the supply of cold and dry respiratory gases provided through noninvasive or invasive ventilation is beneficial to prevent drying of the patient's airways.

This system is designed for adult and pediatric (excluding neonate) use in hospitals, long term care facilities and homes, under the prescription of qualified medical professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: Subject Device and Primary Predicate Comparison Table

Design / Technological Characteristics	Subject Device F&P 820 System – Humidifier Base	Predicate Device F&P MR810 Respiratory Humidifier (K143646)	Comments
Indications for use statement	The Fisher & Paykel 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow. The 820 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive or invasive ventilation is beneficial to prevent drying of the patient airways. The 820 System is for adult and pediatric (excluding Neonatal) patients requiring a flow range ≥5 L/min. For use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.	The Fisher & Paykel MR810 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow system. The MR810 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive or invasive ventilation is beneficial to prevent drying of the patient airways. The MR810 System is for use for adult and pediatric patients requiring a flow range ≥5 L/min. The MR810 System is designed for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.	**Identical**
Application	Non-invasive Invasive	Non-invasive Invasive	**Identical**
Use Environment	Hospital Home	Hospital Home	**Identical**
Patient Population	Adult and Paediatric (Excluding Neonatal)	Adult and Paediatric (Excluding Neonatal)	**Identical**
Intended User Group	Medical or clinical professionals. Technical healthcare professionals. Professional Care givers. Lay users.	Medical or clinical professionals. Technical healthcare professionals. Professional Care givers. Lay users.	**Identical**
Operating Principle	Provides heat and humidity to the respiratory gases by passing the gas through a humidification chamber and heated breathing tube.	Provides heat and humidity to the respiratory gases by passing the gas through a humidification chamber and heated breathing tube.	**Identical**

Design / Technological Characteristics	Subject Device F&P 820 System – Humidifier Base	Predicate Device F&P MR810 Respiratory Humidifier (K143646)	Comments
Humidity Performance	≥ 12 mg/L in Settings 1, 2 or 3 For 5 - 70 L/min Flow Range ≥ 33 mg/L in Setting 4 For 5 - 40 L/min Flow Range	≥ 10 mg/L in Setting Low, Med or High: For 5 - 60 L/min Flow Range ≥ 33 mg/L in Setting High For 5 - 30 L/min Flow Range	**Equivalent** The 820 System meets the applicable requirements of ISO 80601-2-74:2017
Gas temperature at patient end of breathing tube for flow range	Setting 1: 26-30 °C Setting 2: 29-37 °C Setting 3: 32-40 °C For 5 - 70 L/min Flow Range Setting 4: 35-43 °C For 5 - 40 L/min Flow Range	Setting Low: 28 - 29 °C Setting Medium: 28 - 31 °C For 5 - 60 L/min Flow Range Setting High: 33 - 36°C For 5 - 30 L/min Flow Range	**Equivalent** The 820 System meets the applicable requirements of ISO 80601-2-74:2017
Time to reach set temperature	<60 mins	<60 mins	**Identical**
Ambient Temperature Range	18 – 26 °C	18 - 26 °C	**Identical**
Alarms	Alarms exceed 45 dbA @1m Auditory alarm pause: 120 seconds	No audio alarm functionality	**Different** The subject device conforms to IEC 60601-1-8:2006 + A1:2012
Transport Conditions	-25 to 70 Deg °C	-10 to +50 Dec °C	**Equivalent** The subject device has broader storage conditions than the primary predicate device.
Service Life	7 Years	7 Years	**Identical**
IEC 60601-1 Classification	CLASS II	CLASS I	**Different** The subject device conforms to AAMI/IEC 60601-1:2005 + AMD1:2012

Table 2: F&P 820A10J – Circuit Heated Single Limb to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device F&P 820A10J	Secondary Predicate Device F&P RT102 (K983112)	Comments
Intended Use	Deliver heated and humidified respiratory gases.	Deliver heated and humidified respiratory gases.	**Identical**
Indications for Use	The breathing set is an accessory to the F&P 820 System. The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow. The 820 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive or invasive ventilation is beneficial to prevent drying of the patient airways. The 820 System is for adult and pediatric (excluding Neonatal) for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.	The heated-wire breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas, to reduce condensation. They are accessories for the Fisher & Paykel MR850 Respiratory Gas Humidifier.	**Equivalent** Both the subject and secondary predicate device are indicated to provide heat and humidity to respiratory gases delivered to patients.
Operating Principle	The heated breathing tube is kept warm by the heater wire (controlled by the Humidification Base) to minimize condensation and maintain the desired temperature and level of humidity before being delivered to the patient interface.	The heated breathing tube is kept warm by the heater wire (controlled by the Humidification Base) to minimize condensation and maintain the desired temperature and level of humidity before being delivered to the patient interface.	**Identical**
Patient Population	Adult and paediatric patients (excluding neonates) >10 kg	Adult patients	**Different** The subject device is compliant to the pneumatic requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Non-invasive and invasive interfaces	Non-invasive and invasive interfaces	**Identical**
Duration of Use	14 Days	7 Days	**Different**
Shelf Life	3 years	5 years	**Equivalent** The subject device falls within the secondary predicate device shelf life duration.
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Equivalent** The subject device falls within the secondary predicate device storage condition range.

Table 3: F&PMR325 – Chamber Manual Fill to Secondary Predicate Comparison Table

Characteristic for comparison	Subject Device F&P MR325	Secondary Predicate Device F&P HC325 (K003973)	Comments
Intended Use	Holds water and adds heat and humidity to respiratory gases	Holds water and adds heat and humidity to respiratory gases	**Identical**
Indications for Use	The MR325 humidification chamber is an accessory to the F&P 820 System and compatible with F&P 820 series humidifiers. The F&P 820 System is intended to provide therapeutic levels of heat and humidity to a patient's inspired respiratory gases, when using a continuous or intermittent ventilator system or a continuous gas flow. The 820 System is intended for both non-invasive and invasive therapies. Addition of heat and humidity to the supply of cold and dry respiratory gases provided through non-invasive or invasive ventilation is beneficial to prevent drying of the patient airways. The 820 System is for adult and paediatric (excluding Neonatal) for use in hospitals, long term care facilities and homes under the prescription of a qualified medical professional.	The HC325 humidification chamber is an accessory to the F&P HC150 Respiratory Humidifier. The HC150 respiratory humidifier is used to warm and humidify gases delivered to patients requiring continuous positive airway pressure (CPAP) therapy or mask ventilation. The HC325 Humidification Chamber has been designed as a Passover humidifier for use with Nasal CPAP and Nasal Mask ventilation systems.	**Different** Subject device tested to ISO 5367:2014, ISO 80601-2-74:2017, ISO 10993-1:2018 and ISO 18562-1:2017 and is equivalent to the secondary predicate device.
Operating Principle	Water in the humidification chamber is heated to add water vapour and heat energy to the passing gas flow. The gas then enters the breathing tube.	Water in the humidification chamber is heated to add water vapour and heat energy to the passing gas flow. The gas then enters the breathing tube.	**Identical**
Patient Population	Adult and paediatric patients (excluding neonates)	Patients requiring positive pressure breathing therapy such as CPAP	**Different** The subject device is compliant to the requirements of ISO 5367 for the indicated patient populations.
Intended Interface	Non-invasive and invasive interfaces	Non-invasive and invasive interfaces	**Identical**
Duration of use	14 days	No-predefined duration of use	**Different** Subject device has a 14-day Duration of use.
Reusability	Single Use	Single Patient Reusable. With cleaning instructions.	**Different** Subject device is for single use.
Shelf Life	3 years	No-predefined shelf-life	**Different** Subject device shelf-life is 3 years
Storage conditions	-10°C – 50°C	-10°C – 50°C	**Identical**

VII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P 820 Respiratory Humidifier has been tested to the applicable requirements* of the following standards:

Standards	Title
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 18562-1:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 1: Evaluation and Testing Within a Risk Management Process
IEC 62304:2015 Consolidated Version	Medical device software – software lifecycle processes
IEC 60601-1-2:2014 + AMD1:2020 Ed 4.1	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.
Standard 7351731 Rev. 2.00 2017-02-23	Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers – An AIM Standard
ISO 5367:2014	Anaesthetic and respiratory equipment – Breathing sets and connectors
ISO 5356-1:2004	Anaesthetic and Respiratory Equipment – Conical Connectors – Part 1: Cones and Sockets.
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (edition 3.1).
ISO 80601-2-74: 2017	Medical Electrical Equipment- Part 2-74: Particular Requirements For Basic Safety and Essential Performance Of Respiratory Humidifying Equipment. *excluding clause 201.12.1.102a
IEC 60601-1-6:2013	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-8:2012	Medical electrical equipment: Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
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
IEC 62366-1:2015 + AMD:2020	Medical devices – Part 1: Application of usability engineering to medical devices

Biocompatibility Testing:
The biocompatibility evaluation for the F&P 820 Humidification System was conducted in accordance with the International Standards ISO 10993-1:2018 “Biological Evaluation of Medical Devices − Part 1: Evaluation and testing within a risk management process,” and ISO 18562--1:2017 “Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process” as recognized by the FDA. FDA's guidance document on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",2020. Testing of the F&P 820 Humidification System demonstrates an appropriate biocompatibility profile for the device.

Electrical Safety, Electromagnetic Compatibility (EMC), and Alarms:
Electrical safety and EMC testing were conducted on the F&P Humidification System. The system complies with ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-2:2014 + AMD1:2020 Ed 4.1 and AIM Standard 7351731 Rev. 2.00 2017-02-23. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device. Alarms testing was performed in accordance with IEC 60601-1-8:2006 and A1:2012.

Software Verification and Validation Testing:
Software verification and validation was conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Human Factors:
A human Factors and Usability Engineering study was conducted on the F&P820 Respiratory Humidifier and accessories, and documentation was updated and provided as recommended by FDA’s guidance. The study demonstrated that the human factors assessment had been sufficiently evaluated and was safe and effective for the intended users, uses, and use environments.

Bench / Performance Testing:
Performance testing was conducted to demonstrate substantial equivalence including:

- Humidification output, thermal overshoot, surface temperature of applied parts in line with ISO 80601-2-74:2017
- Resistance to flow, compliance, and gas leak testing in line with ISO 5367:2014

VIII. CONCLUSION

The F&P 820 Humidification System are substantially equivalent to the predicate devices based on intended uses, comparison of the technological characteristics and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the devices are substantially equivalent to the legally marketed predicate devices.