May 9, 2024

Fisher & Paykel Healthcare
Reena Daken
Regulatory Affairs Manager
15 Maurice Paykel Place
Auckland, 2013
New Zealand

Re: K222292
Trade/Device Name: F&P myAirvo 3
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: April 17, 2024
Received: April 17, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
OHT1: Office of Ophthalmic, Anesthesia, 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)*
K222292

Device Name
F&P myAirvo3

Indications for Use *(Describe)*
The myAirvo 3 is for the treatment of spontaneously breathing patients, infant to adult, who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The myAirvo 3 is for patients in homes and long-term care facilities.

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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1 510(k) Summary

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	Hannah Matthews Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: Reena.Daken@fphcare.co.nz
Date Prepared	17 April 2024

II. DEVICE

Name of Device	F&P myAirvo 3
Common/Usual Name	Respiratory Humidifier
Classification Name	Respiratory Gas Humidifier
Regulatory Class	Class II (21 CFR §868.5450)
Product Code	BTT

III. PREDICATE DEVICE

- Predicate Device

FDA Clearance Number	Device Name
K131895	myAIRVO 2 Humidifier

IV. REFERENCE DEVICES

- Reference Devices

510(k) Number	Device Name	Reason for Reference
K102465	BiPAP Avaps Ventilatory Support System	Used to support claims of substantial equivalence with respect to the following performance: • Use of SpO_2 sensing in a medical device.
K162553	Nasal Cannula Infant Nasal Cannula Pediatric	Used to support claims of substantial equivalence with respect to the following performance: • Use of pediatric patient interfaces with the myAirvo 3.

V. DEVICE DESCRIPTION

The F&P myAirvo 3 device is a heated humidifier flow source. The subject device is intended to treat spontaneously breathing patients, pediatrics and adults, who would benefit from receiving high flow, warmed and humidified entrained air and oxygen (if required).

The F&P myAirvo 3 is comprised of two main connected functional units: the blower and the humidifier.

The blower is a motorized fan assembly that provides air flow. The fan speed is directly related to the delivered flow and it is controlled by the software. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the F&P myAirvo 3 device is a heated Passover humidifier. The water is contained in a humidification chamber positioned on a heater plate at the front of the unit. The gas is warmed and humidified in the chamber to the dew point set temperature, transported through the heated breathing tube and delivered to the patient through the selected interface.

VI. INDICATIONS FOR USE

The myAirvo 3 is for the treatment of spontaneously breathing patients, infant to adult, who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The myAirvo 3 is for patients in homes and long-term care facilities.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: Subject Device Comparison with Predicate Devices

Feature/Characteristic for Comparison	**Subject Device F&P myAirvo 3**	**Predicate Device myAIRVO 2 Humidifier (K131895)**	**Comment**
Device Image			**N/A**
Classification			
Legal manufacturer	Fisher & Paykel Healthcare Ltd	Fisher & Paykel Healthcare Ltd	**Identical**
Device Regulation	Class II, Regulation: 21 CFR §868.5450	Class II, Regulation: 21 CFR §868.5450	**Identical**
Product code	BTT	BTT	**Identical**
Classification name	Respiratory gas humidifier	Respiratory gas humidifier	**Identical**
Classification Panel	Anesthesiology	Anesthesiology	**Identical**
Intended Use/ Indications for Use			

Feature/Characteristic for Comparison	Subject Device F&P myAirvo 3	Predicate Device myAIRVO 2 Humidifier (K131895)	Comment
Indications for use	The myAirvo 3 is for the treatment of spontaneously breathing patients, infant to adult, who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The myAirvo 3 is for patients in homes and long-term care facilities.	The myAIRVO 2 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 – 60 L/min depending on the patient interface. The myAIRVO 2 is for patients in homes and long-term care facilities.	**Identical**
Operation and Safety Features			
Availability	Prescription use only (Part 21 CFR 801 Subpart D)	Prescription use only (Part 21 CFR 801 Subpart D)	**Identical**
Patient Population	Spontaneously breathing patients, infant to adult.	Spontaneously breathing patients	**Equivalent** Despite the difference in terminology, the patient populations covered by the subject device are identical to that of the predicate device. This has previously been discussed in Q181564/S003 This difference does not raise any new questions of safety and effectiveness.
Intended User Group	Patients and healthcare professionals	Patients and healthcare professionals	**Identical**
Patient Consciousness	Spontaneously Breathing Patients	Spontaneously Breathing Patients	**Identical**

Feature/Characteristic for Comparison	Subject Device F&P myAirvo 3	Predicate Device myAIRVO 2 Humidifier (K131895)	Comment
Environment of use	Homes and Long-Term Care Facilities	Homes and Long-Term Care Facilities	**Identical**
Reusability	Multi-patient reusable when reprocessed between patients	Multi-patient reusable when reprocessed between patients	**Identical**
High Level Disinfection Methods	High-Level Disinfection using Disinfection Kit Thermal Disinfection (with automated washer-disinfector)	High-Level Disinfection using Disinfection Kit	This difference does not raise new questions of safety and effectiveness. The High-Level Disinfection method using the disinfection kit is identical to the predicate device (myAIRVO 2 – K131895) except for addition of a single rinsing step. The High-Level Disinfection using an automated Washer-Disinfector is not available for the predicate device, but testing has been completed to validate the efficacy.
Sterility	Device not provided sterile	Device not provided sterile	**Identical**
Life Supporting or Life Sustaining	No	No	**Identical**
Service Life	5 years	5 years	**Identical**
Physical Specifications			
Device Dimensions	180 mm x 295 mm x 170 mm (7.0” x 11.7” x 6.6”)	175 mm x 295 mm x 170 mm x (6.9” x 11.6” x 6.7”)	**Equivalent** The subject device is 5mm wider than the predicate device. This difference does not raise any

Feature/Characteristic for Comparison	Subject Device F&P myAirvo 3	Predicate Device myAIRVO 2 Humidifier (K131895)	Comment
			new questions of safety or effectiveness
Technology			
Operating principle	Heated humidifier with integrated flow source for delivering constant flow of warmed and humidified respiratory gases when connected to a breathing circuit and patient interface.	Heated humidifier with integrated flow source for delivering constant flow of warmed and humidified respiratory gases when connected to a breathing circuit and patient interface.	**Identical**
Humidity source	Heated humidification chamber.	Heated humidification chamber.	**Identical**
SpO_2 Sensing	Ability to connect an external (non F&P) pulse oximeter to USB port, displays sensed SpO_2 and pulse rate on user interface	No SpO_2 Sensing	**New Feature** F&P has conducted testing that demonstrates that the SpO_2 and pulse rate values calculated by the Nonin pulse oximetry system are not corrupted during communication to the myAirvo 3 and are displayed accurately on the user interface.
Performance Specifications			
Flow range	2 – 60 L/min delivered	10 – 60 L/min delivered (Default) 2 – 25 L/min delivered (Junior mode)	**Equivalent** Despite the difference in terminology, the flow ranges covered by the subject device are identical to that of the predicate device. This difference does not raise any new questions of safety and effectiveness.
Maximum Oxygen	15 L/min	15 L/min	**Identical**

Feature/Characteristic for Comparison	Subject Device F&P myAirvo 3	Predicate Device myAIRVO 2 Humidifier (K131895)	Comment
Flowrate			
Oxygen Fraction Range	21-100%	21-100%	**Identical**
Temperature range	31 – 37 °C	31 – 37 °C	**Identical**
Operating Conditions			
Ambient operating temperature range	18 – 28 °C	18 – 28 °C	**Identical**
Alarms			
Alarm method	Visual and audible alarm system. Mute button.	Visual and audible alarm system. Mute button.	**Identical**
Electrical System Characteristics			
Supply Frequency	50-60 Hz	50-60 Hz	**Identical**
Supply Voltage	100 – 115 VAC 220 – 240 VAC	100 – 115 VAC 220 – 240 VAC	**Identical**
Accessories			
Patient interfaces	Nasal Interface And Tracheostomy Interface And Vented Mask	Nasal Interface And Tracheostomy Interface And Vented Mask	**Identical**
Heated Breathing Tube	Heated breathing tube: single-lumen, spiral heater wires	Heated breathing tube: single-lumen, spiral heater wires	**Identical**

VIII. PERFORMANCE DATA

Summary of non-clinical tests

The F&P myAirvo 3 has been tested to the applicable requirements of the following standards:

Standards and Designation Number	Standards Title
ISO 5367: 2014	Anaesthetic and respiratory equipment. Breathing sets and connectors
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
IEC 62304:2015 Consolidated Version	Medical device software – software lifecycle processes
AIM 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
IEC 62366-1:2015 + AMD:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of materials
ISO 18562-1:2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 18562-2: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
ISO 18562-3: 2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 1-: General requirements for basic safety and essential performance – Collateral standard: Usability
ANSI AAMI IEC 60601-1-8:2006 and A1:2012	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 (Second Edition)	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 80601-2-61:2017	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 80601-2-74:2017	Medical electrical equipment – Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications – Part 1: General Requirements
ISO 17664-1: 2021	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems
ISTA 2A	Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or less. Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration, and shock vibration

IX. CONCLUSIONS

The F&P myAirvo 3 is substantially equivalent to the predicate based on patient population, intended uses, comparison of the technological characteristics and performance. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed predicate device.