May 17, 2023

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

Re: K223696
Trade/Device Name: F&P Solo Mask Range
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 2, 2023
Received: May 2, 2023

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,

Rachana Visaria -S

Rachana Visaria, 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)*
K223696

Device Name
F&P Solo Mask Range

Indications for Use *(Describe)*

A-Model

The F&P Solo mask is intended to be used by adults weighing ≥66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home.

SL A-Model

The F&P Solo mask is intended to be used by adults weighing ≥66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

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.

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	Alec O'Connell-Biddlecombe Regulatory Affairs Associate
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	16 May 2023

II. DEVICE

Name of Device	F&P Solo Mask Range
Common/Usual Name	Nasal Mask
Classification Name	Non Continuous Ventilator (IPPB)
Regulatory Class	Class II (21 CFR §868.5905)
Product Code	BZD

III. PREDICATE DEVICE

- Predicate device:
  - F&P Evora™ Nasal Mask, K200089

- Reference devices:
  - F&P Brevida™ Nasal Mask, K161412
    - Used to support claims of substantial equivalence with respect to design and performance

IV. DEVICE DESCRIPTION

The Solo Mask, is a non-invasive patient interface with cushions that seal against the airway entrance of the nose. The mask is held on the face with a headgear and connects to a single breathing tube by a 22mm male swivel adaptor to receive pressurized air from a continuous Positive Airway Pressure device (CPAP or Bi-level). The exhaust bias holes on the frame of the mask allow exhaled air to be flushed out while the system is in operation. The F&P Solo Mask is a prescription only device, provided in a non-sterile state.

A list of the subject device product codes can be found below:

Model	Product Code	Product Description
A-Model The A Model is intended for single- patient use in a home environment only. The mask is available in seven different configurations which differ only in the size and type of the cushions made available in the packaging (Nasal: S, M, L and W; Pillows: S, M and L).	**SLN1SA**	Solo Nasal Mask Small A Model
	SLN1MA	Solo Nasal Mask Medium A Model
	SLN1LA	Solo Nasal Mask Large A Model
	SLN1WA	Solo Nasal Mask Wide A Model
	SLP1SA	Solo Pillows Mask Small A Model
	SLP1MA	Solo Pillows Mask Medium A Model
	SLP1LA	Solo Pillows Mask Large A Model
	SLNSMLA	Solo Nasal Mask Fit Pack/SML A Model
	SLPSMLA	Solo Pillows Mask Fit Pack/SML A Model
SL A-Model The Sleep Lab A Model is intended for single patient use in a home environment as well as for multi-patient use in the hospital or other clinical setting. The mask is available in seven different configurations which differ only in the size and type of cushions made available in the packaging (Nasal: S, M, L and Wide; Pillows: S, M and L).	**SLN1SSLA**	Solo Nasal Mask Small Sleep Lab A
	SLN1MSLA	Solo Nasal Mask Medium Sleep Lab A
	SLN1LSLA	Solo Nasal Mask Large Sleep Lab A
	SLN1WSLA	Solo Nasal Mask Wide Sleep Lab A
	SLP1SSLA	Solo Pillows Mask Small Sleep Lab A
	SLP1MSLA	Solo Pillows Mask Medium Sleep Lab A
	SLP1LSLA	Solo Pillows Mask Large Sleep Lab A
	SLN1SMLSLA	Solo Nasal Mask Fit Pack Sleep Lab A
	SLP1SMLSLA	Solo Pillows Mask Fit Pack Sleep Lab A

IV. INDICATIONS FOR USE

A-Model

The F&P Solo mask is intended to be used by adults weighing ≥66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home.

SL A-Model

The F&P Solo mask is intended to be used by adults weighing ≥66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

V. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

The comparison of features, performance data and intended use demonstrate that the F&P Solo Mask Range is substantially equivalent to the predicate device, F&P Evora™ Nasal Mask (K200089). Please see the table below.

Design/ Technological Characteristics	Subject Device F&P Solo Mask	Predicate Device F&P Evora Nasal Mask (K200089)	Comments
Classification			
Legal Manufacturer	Fisher & Paykel Healthcare Ltd.	Fisher & Paykel Healthcare Ltd.	Identical
Product Code	BZD	BZD	
Device classification	21 CFR 868.5905	21 CFR 868.5905	
Classification panel	Anaesthesiology	Anaesthesiology	
Indications for Use			
Indications for Use	**A-Model:** The F&P Solo mask is intended to be used by adults weighing ≥ 66 lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single- patient use in the home. **SL A-Model:** The F&P Solo mask is intended to be used by adults weighing ≥ 66lbs (30 kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The F&P Solo mask is intended for single-patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.	**A-Model:** The F&P Evora™ Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or bilevel by a physician. The F&P Evora Nasal Mask is intended for single patient use in the home **SL Model:** The F&P Evora Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or bilevel by a physician. The F&P Evora Nasal Mask is intended for single patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between uses.	Identical

Design/ Technological Characteristics	Subject Device F&P Solo Mask	Predicate Device F&P Evora Nasal Mask (K200089)	Comments
Availability	Prescription use only	Prescription use only	Identical
Patient Population	PAP Therapy	PAP Therapy	Identical
Patient Population	Adult (>30kg)	Adult (>30kg)	Identical
Patient Consciousness	Responsive and able to remove mask	Responsive and able to remove mask	Identical
Operating Environment	Home, hospital or other clinical setting	Home, hospital or other clinical setting	Identical
Technical Specifications and Features			
Breathing Circuit	Single Inspiratory Tube	Single Inspiratory Tube	Identical
Breathing Tube connection to mask	22mm ISO Taper	22mm ISO Taper	Identical
Seal sizes	Nasal Cushion: Available in four sizes: Small, Medium, Large, Wide Pillows Cushion: Available in three sizes: Small, Medium, Large	Predicate: Available in four sizes: Small, Medium, Large, Wide	While the subject device's Nasal cushions are identical, the Pillows cushion offers three additional sizes. The subject device is designed to be in conformance to ISO 17510:2015.
Headgear Sizes	One size	One size	Identical
Exhalation Vent	Numerous vent holes in Mask Frame	Numerous radial vent holes in Mask Frame	Identical. The subject device vent holes are located on the frame, whilst the predicate has vent holes organized in a radial pattern, also located on the frame. The subject device is designed to be in conformance to ISO 17510:2015.

Design/ Technological Characteristics	Subject Device F&P Solo Mask	Predicate Device F&P Evora Nasal Mask (K200089)	Comments
Technical Specifications			
Pressure Range	4 to 20 cm H_2O	4 to 25 cm H_2O	The subject device is designed to be in conformance with ISO 17510:2015
Resistance to Flow	Pressure drop through Nasal Cushion: Small 50 L/min: 0.84 cmH_2O Medium 50 L/min: 0.59 cmH_2O Large 50 L/min: 0.54 cmH_2O Wide 50 L/min: 0.58 cmH_2O Small 100 L/min: 3.63 cmH_2O Medium 100 L/min: 2.73 cmH_2O Large 100 L/min: 2.50 cmH_2O Wide 100 L/min: 2.65 cmH_2O Pressure drop through Pillows Cushion: Small 50 L/min: 2.17 cmH_2O Medium 50 L/min: 1.05 cmH_2O Large 50 L/min: 0.89 cmH_2O Small 100 L/min: 8.56 cmH_2O Medium 100 L/min: 4.42 cmH_2O Large 100 L/min: 3.83 cmH_2O	Nasal (F&P Evora Nasal, predicate device): Pressure drop through small 50 L/min: 1.0 ± 0.1cmH_2O Pressure drop through medium 50 L/min: 1.0 ± 0.1 cmH_2O Pressure drop through large 50 L/min: 1.0 ± 0.1 cmH_2O Pressure drop through wide 50 L/min: 1.0 ± 0.1 cmH_2O Pressure drop through small 100 L/min: 1.4 ± 0.25 cmH_2O Pressure drop through medium 100 L/min: 1.2 ± 0.25 cmH_2O Pressure drop through large 100 L/min: 1.2 ± 0.25c mH_2O Pressure drop through wide 100 L/min: 1.3 ± 0.25 cmH_2O	The pressure drop for the subject device is disclosed in labelling in accordance with ISO 17510:2015. The reference device (Brevida, K161412) has been used to support claims of substantial equivalence for pressure drop values with respect to the 'Pillows Cushion'.
Dead Space	Nasal: Small: 29.6 cc Medium: 26.8 cc Large: 31.1 cc Wide: 36.9 cc Pillows: Small: 25.8 cc Medium: 27.7 cc Large: 30.5 cc	Small: 28 cc Medium: 26 cc Large: 28 cc Wide: 34 cc	Measured dead space is disclosed in labelling in accordance with ISO 17510:2015.
Sound	Sound Power Level of the Mask is 31.5 dBA, with uncertainty 2.5 dBA Sound Pressure Level of the Mask 23.6 dBA, with uncertainty 2.5 dBA	Sound Power Level of the Mask is 26.8 dBA, with uncertainty 2.5 dBA Sound Pressure Level of the Mask 18.8 dBA, with uncertainty 2.5 dBA	Measured sound power level is disclosed in labelling in accordance with ISO 17510:2015.
Shelf-Life	2 year	1 year	The subject device claims a 2-year shelf life.

Design/ Technological Characteristics	Subject Device F&P Solo Mask	Predicate Device F&P Evora Nasal Mask (K200089)	Comments
Operating and Storage Conditions	Operating Temperature: 5 to 40 °C Storage Temperature: -20 to 50°C	Operating Temperature: 5 to 40 °C Storage Temperature: -20 to 50°C	Identical
Cleaning and High-Level Disinfection			
Sterility	Device not provided sterile	Device not provided sterile	Identical
Reusability	Reusable – Multi Patient Use	Reusable – Multi Patient Use	Identical
High Level Disinfection Methods	**Thermal Disinfection:** 75°C (167°F) for 30 mins 80°C (176°F) for 10 mins	**Thermal Disinfection:** 75°C (167°F) for 30 mins 80°C (176°F) for 10 mins 90°C (194°F) for 1 min	The subject device contains a subset of the high-level disinfection methods compared to the predicate.
Design / Components			
Mask Components	Cushion Frame Headgear Tube Swivel	Seal Frame Headgear Tube Swivel	Identical – name of seal changed to cushion.
Cushion	Soft pliable cushion between mask base and nares (nasal cushion). Soft pliable cushion between mask base, extending into the nares (pillows cushion).	Soft pliable seal between mask base and nares, without any of the seal extending into the nares.	The subject device has cushions which seal under the nose (nasal) and into the nares (pillows) when compared to the predicate device.
Frame	Connection for tube, cushion, and headgear.	Connection for tube, seal and headgear.	Identical – name of seal changed to cushion.
Headgear	Adjustable headgear made up of stretch and non-stretch portions.	Adjustable headgear made up of two components: • Moulded front and top straps that are permanently joined together. • Single backstrap	Both the subject and predicate devices have stretch and non-stretch sections. The subject device headgear is one assembly with adjustment built in.
Tube	Permanently attached to mask frame	Permanently attached to mask frame	Identical
Swivel	Permanently attached to the mask tube, while still allowing rotation, with 22mm taper allowing connection to industry-standard breathing tubes	Removable 22mm taper allowing connection to industry-standard breathing tubes	The subject device has a permanently attached swivel, while still allowing rotation.
Accessories			
Accessory	Oxygen/Pressure Port (900HC452) Available as a separate part, not provided with device.	Oxygen/Pressure Port (900HC452) Available as a separate part, not provided with device.	Identical

VI. PERFORMANCE DATA

Summary of Non-Clinical Tests

- Cleaning Validation
- High-Level Disinfection Validation
- Leak
- Dead Space Analysis
- Human Factors/Usability Engineering
- Mechanical Integrity
- Shelf-Life, Storage and Transportation

The F&P Solo Mask Range has been tested to applicable requirements to the following standards:

- ISO 17510:2015 Sleep apnoea breathing therapy – Masks and application accessories
    - CO_2 Rebreathing
    - Pressure-Flow Curve
    - Exhaust Flow
    - Resistance to Flow (Pressure Drop)
    - Vibration and Noise
- ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for 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 10993-10:2021 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 10993-17:2002 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials 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
- ISO 18562-2 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate
- ISO/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

VII. CONCLUSIONS

The F&P Solo Mask Range 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.