March 18, 2022

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

Re: K212371
Trade/Device Name: F&P Evora Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: February 18, 2022
Received: February 18, 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,

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)*
K212371

Device Name
F&P Evora™ Full Face Mask

Indications for Use *(Describe)*
The F&P Evora Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Evora Full Face 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.

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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	Nicholas Yap Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	18 March 2022

II. DEVICE

Name of Device	F&P Evora™ Full Face Mask
Common/Usual Name	Full Face 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 Vitera™ Full Face Mask, K190713

- Reference devices:
  - F&P Evora™ Nasal Mask, K200089
    - Used to support claims of substantial equivalence with respect to design and performance

IV. DEVICE DESCRIPTION

The F&P Evora™ Full Face Mask (hereafter named "Evora Full") is a non-invasive compact full-face mask that seals underneath the patient's nose and lips. The mask connects to a single breathing tube by a 22mm male swivel adaptor to receive pressurised air from a continuous positive airway pressure device (CPAP or Bi-level). The exhaust holes on the seal of the mask allow exhaled air to be flushed out while the system is in operation. The Evora Full mask is a prescription only device, provided in non-sterile state

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

Model	Product Code	Product Description
A-Model	**EVF1XA**	Evora Full Face Mask Extra Small A Model
	EVF1MA	Evora Full Face Mask Small-Medium Model
	EVF1LA	Evora Full Face Mask Large A Model
	EVF1XXA	Evora Full Face Mask Double Seal XS/XS A Model
	EVF1MMA	Evora Full Face Mask Double Seal S-M/S-M A Model
	EVF1LLA	Evora Full Face Mask Double Seal Lrg/Lrg A Model
Fit Pack A-Model	**EVF1XMLA**	Evora Full Face Mask Fit Pack A Model
SL A-Model	**EVF1XSLA**	Evora Full Mask Extra Small Sleep Lab A
	EVF1MSLA	Evora Full Mask Small-Medium Sleep Lab A
	EVF1LSLA	Evora Full Mask Large Sleep Lab A
Fit Pack SL A-Model	**EVF1XMLSLA**	Evora Full Mask Fit Pack Sleep Lab A

V. INDICATIONS FOR USE

The F&P Evora Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Evora Full Face 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.

VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

The comparison of features, performance data and intended use demonstrate that the F&P Evora™ Full Face Mask is substantially equivalent to the predicate device, F&P Vitera™ Full Face Mask (K190713). Please see the table below.

Design / Technological Characteristic	Subject Device F&P Evora™ Full Face Mask	Predicate Device F&P Vitera™ Full Face Mask (K190713)	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	
Intended Use/Indications for Use			
Intended Use/ Indications for Use	The F&P Evora Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Evora Full Face 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.	The F&P Vitera Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Vitera Full Face 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.	Identical
Availability	Prescription use only (Part 21 CFR 801 Subpart D)	Prescription use only (Part 21 CFR 801 Subpart D)	Identical

Design / Technological Characteristic	Subject Device F&P Evora™ Full Face Mask	Predicate Device F&P Vitera™ Full Face Mask (K190713)	Comments
Patient Population	Adult (> 30kg)	Adult (> 30kg)	Identical
Application	CPAP or Bi-Level therapy	CPAP or Bi-Level therapy	Identical
Operating Environment	Home, hospital or other clinical setting	Home, hospital or other clinical setting	Identical
Technical Specifications and Features			
Pressure Range	4 to 30 cmH_2O	4 to 30 cmH_2O	Identical.
Resistance to Flow	• Pressure drop through the mask at 50 L/min: 0.9 ± 0.3 cmH_2O • Pressure drop through the mask at 100 L/min: 2.2 ± 0.3cmH_2O	• Pressure drop through the mask at 50 L/min: 0.24 ± 0.15 cmH_2O • Pressure drop through the mask at 100 L/min: 0.47 ± 0.15 cmH_2O	This difference does not raise new questions of safety and effectiveness.
Dead Space	• XS: 165.2 cm^3 • S-M: 162.6 cm^3 • L: 164.1 cm^3	• Small: 245.8 cc • Medium: 274.1 cc • Large: 321.8 cc	This difference does not raise new questions of safety and effectiveness.
Sound Power Level	• Sound Power Level of the Mask: 28.2 dBA, with uncertainty 2.5 dBA • Sound Pressure Level of the Mask: 20.2 dBA, with uncertainty 2.5 dBA	• Sound Power Level of the Mask: 29.8 dBA, with uncertainty 2.5 dBA • Sound Pressure Level of the Mask: 21.8 dBA, with uncertainty 2.5 dBA	Substantially equivalent
Shelf-Life	2 years	5 years	This difference does not raise new questions of safety and effectiveness.
Breathing Circuit	Single Inspiratory Tube	Single Inspiratory Tube	Identical

Design / Technological Characteristic	Subject Device F&P Evora™ Full Face Mask	Predicate Device F&P Vitera™ Full Face Mask (K190713)	Comments
(PAP system – external to the "mask")			
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
Design			
Swivel [4]	22mm ISO conical connector	22mm ISO conical connector	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: 90°C for 1 min	Thermal Disinfection: 80°C for 10 mins 75°C for 30 mins 90°C for 1 min	Equivalent. The subject device contains a subset of the high-level disinfection methods compared to the predicate.
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. The Oxygen/Pressure Port was cleared under K023559.

VII. 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 and Storage
- ISO 17510:2015 Sleep apnoea breathing therapy – Masks and application accessories
    - CO2 Rebreathing
    - Pressure-Flow Curve
    - Exhaust Flow
    - Resistance to Flow (pressure drop)
    - Inspiratory and Expiratory Resistance
    - Open-to-Atmosphere and Closed-to-Atmosphere Pressures
    - Anti-Asphyxia Valve Pressures
    - Vibration and Noise
- ASTM 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISTA 2A International Safety Transit Association Guidelines – Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or less.
- ISO 5356-1:2015 Anaesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- 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
- SIO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials (available in English only)
- 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 10993-33:2015 Biological evaluation of medical devices Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3
- 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

VIII. CONCLUSIONS

The F&P Evora™ Full Face Mask 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.