June 2, 2020

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

Re: K200089
Trade/Device Name: F&P Evora Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 23, 2020
Received: April 30, 2020

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,

for Michael Ryan
Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
F&P Evora Nasal Mask

Indications for Use *(Describe)*

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 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

Date prepared	02 June 2020
Company Name and Address	Fisher & Paykel Healthcare Ltd. Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Prepared and Submitted by	Sylvia Wonner Regulatory Affairs Associate
Contact Person	Reena Daken Senior Regulatory Affairs Specialist Telephone: +64 9 574 0100 Reena.Daken@fphcare.co.nz
Trade name	F&P Evora™ Nasal Mask
Common name	Nasal Mask
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	F&P Brevida™ Nasal Pillows Mask (K161412)

Device Description

The F&P Evora Nasal Mask is a non-invasive patient interface with a seal that encloses the airway entrance of the nose. The mask is held on the face with a headgear. The mask connects to a single breathing tube by a 22mm male swivel adaptor to receive pressurized gases from a Positive Airway Pressure device (CPAP or Bi-Level). The exhaust holes on the seal of the mask allow exhaled gases to be flushed out while the system is in operation.

The F&P Evora Nasal Mask is a prescription only device, provided in a non-sterile state. The mask will be available in 2 different main models: A-Model, and Sleeplab (SL)-Model. Both models are identical except for Intended Use, Operating Environment; Reusability and High Level Disinfection Methods. This is because the A model is used only by single patients in the home while the SL model is used both by single patients in the home and multiple patients use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

A Model: Offered in 4 different sizes (Small, Medium, Large, Wide), the packaging contains a single mask and a single size seal, intended for single patient use. In addition, to the 4 sizes, a so-called Fit Pack model (EVO1SMLA) is offered which contains a single mask with 3 seal sizes (Small, Medium and Large).

Sleeplab (SL)-Model: Offered in 4 different sizes (Small, Medium, Large, Wide) contains a single mask and a single size seal, intended for single patient use and multi-patient use. In addition, to the 4 sizes, a so-called Fit Pack model (EVO1SMLSL) is offered which contains a single mask with 3 seal sizes (Small, Medium and Large).

Besides the main models, an accessory and spare parts will be made available.

- **Accessory**: The only accessory available for the F&P Evora Nasal Mask will be an Oxygen / Pressure Port Connector, which will be packaged and sold separately.
- **Spare parts**: F&P Evora Nasal has the below components which are available for purchase as spare parts:
    - Evora Nasal Seal Spare (Small, Medium, Large and Wide)
    - Evora Nasal Headgear Spare
    - Evora Nasal Backstrap Spare
    - F&P Swivel White
    - Evora Nasal Tube & Frame Spare
    - Evora Nasal Mask No H/G (Small, Medium, Large and Wide)

Intended Use / Indication for Use

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 patient uses.

Non-Clinical Performance Data

Performance testing of the F&P Evora Nasal Mask was completed to determine that device design changes compared to F&P Brevida Nasal Pillows Nasal Mask (K161412) do not raise different questions of safety or effectiveness. These tests demonstrate substantial equivalence of the F&P Evora Nasal Mask to the predicate device. A summary of the testing conducted for the F&P Evora Nasal Mask device is provided below.

- Shelf life simulation was based on ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- Transportation simulation was based on ISTA 2A Packaged-Products weighing 150lb (68kg) or less.
- Performance testing was completed to confirm the F&P Evora Nasal Mask does not adversely affect safety and effectiveness.
    - o CO_2 rebreathing during normal use
    - o Total mask exhaust flow
    - o Resistance to flow and pressure drop
- Mechanical integrity and performance of the new device was also verified after normal and reasonable abuse scenarios. This included simulations of home use/cleaning; multi-patient use/reprocessing; accelerated ageing (shelf life) and simulated transportation and storage.

The F&P Evora Nasal Mask has been tested to the following standards:

- ISO 17510:2015 Sleep Apnoea Breathing Therapy- Masks and Application Accessories
- 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 10993-2:2006, Biological evaluation of medical devices – Part 2: Animal Welfare requirements

- 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 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference material
- ISO 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005, 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 (VOCs)

Technological Characteristics Comparison

Table 1: Comparison of Technological Characteristics with the Predicate Device

	Subject Device		**Predicate**	
Device Name	**F&P Evora Nasal Mask (A model)**	**F&P Evora Nasal Mask (SL model)**	**F&P Brevida Nasal Pillows Mask**	**Comments**
Indications for use and intended use				
Indications for Use	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.	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 patient uses.	The F&P Brevida Nasal Pillows Mask is intended to be used by individuals who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Brevida Nasal Pillows Mask is intended for single patient adult (≥66 lbs (30 kg)) use in the home and for multiple patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.	Substantially equivalent. Identical intended use, patient population and operating environment.
Patient Population	Adult		Adult	Identical
Operating Environment	Home	Home, hospital or other clinical setting	Home, hospital or other clinical setting	Identical
	A model is intended for single patient use in the home while SL model is intended for single patient use in the home and for multiple patient use in the hospital or other clinical setting.			
Technical Specifications				
Pressure Range	4 to 25 cmH_2O		4 to 25 cmH_2O	Identical
Resistance to Flow	Pressure drop through small 50l/min: 1.0 ± 0.1cmH_2O Pressure drop through medium 50l/min: 1.0 ± 0.1cmH_2O Pressure drop through large 50l/min: 1.0 ± 0.1cmH_2O		Pressure drop through XS-S with diffuser 50L/min: 1.7 cmH_2O +/- 10	Substantially equivalent.

	Subject Device		Predicate	
Device Name	**F&P Evora Nasal Mask (A model)**	**F&P Evora Nasal Mask (SL model)**	**F&P Brevida Nasal Pillows Mask**	**Comments**
	Pressure drop through wide 50l/min: 1.0 ± 0.1cmH_2O Pressure drop through small 100l/min: 1.4 ± 0.25cmH_2O Pressure drop through medium 100l/min: 1.2 ± 0.25cmH_2O Pressure drop through large 100l/min: 1.2 ± 0.25cmH_2O Pressure drop through wide 100l/min: 1.3 ± 0.25cmH_2O		Pressure drop through M-L with diffuser 50L/min: 1.0 cmH_2O +/- 10 Pressure drop through XS-S with diffuser 100L/min: 6.3 cmH_2O +/- 10 Pressure drop through M-L with diffuser 100L/min: 3.8 cmH_2O +/- 10	The pressure drop value of the subject device is different to the predicate device. The subject device is in conformance with ISO 17510:2015 and this difference does not introduce any additional risk to the user.
Dead Space	Small: 28 cc Medium: 26 cc Large: 28 cc Wide: 34 cc		XS-S: 29 cc M-L: 33 cc	Substantially equivalent. The dead space value of the subject device is different to the predicate device. All seal sizes are in conformance with ISO 17510:2015 and this difference does not introduce any additional risk to the user.
Sound	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		Sound Power Level of the Mask with diffuser is 25.4 dBA, with uncertainty 2.5 dBA Sound Pressure Level of the Mask with diffuser is 17.5 dBA, with uncertainty 2.5 dBA Sound Power Level of the Mask without diffuser is 30.6 dBA, with uncertainty 2.5 dBA Sound Pressure Level of the Mask without diffuser is 22.6dBA, with uncertainty 2.5 dBA	Substantially equivalent. The average sound power and pressure level of the subject device is different to the predicate device. The subject device is in conformance with ISO 17510:2015 and this difference does not introduce any additional risk to the user.

	Subject Device		Predicate	
Device Name	**F&P Evora Nasal Mask (A model)**	**F&P Evora Nasal Mask (SL model)**	**F&P Brevida Nasal Pillows Mask**	**Comments**
Shelf-Life	1 year		Shelf-life not claimed on labelling	Substantially equivalent. The subject device claims a One-year shelf life with supporting data.
Cleaning and High-Level Disinfection				
Sterility	Device not provided sterile		Device not provided sterile	Identical
Reusability	Single Patient Use	Reusable – Multi Patient Use	Reusable – Multi Patient Use	Identical
High Level Disinfection Methods	N/A	Thermal Disinfection	Thermal Disinfection	Identical
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

Conclusions

The comparison of features, performance, and intended use demonstrate that the F&P Evora Nasal Mask is substantially equivalent to the predicate F&P Brevida Nasal Pillows Mask (**K161412**).