October 11, 2019

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

Re: K190713
Trade/Device Name: F&P Vitera Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: September 18, 2019
Received: September 20, 2019

Dear Masar Mohammad:

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
Division 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)*
K190713

Device Name
F&P Vitera Full Face Mask

Indications for Use *(Describe)*
A Model: 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.

SL Model: 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.

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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5 510(k) Summary

As Required by 21 CFR 807.92 (c)

Contact person/submitter	Masar Mohammad
Date prepared	11 October 2019
Contact details	Address: 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Trade name	F&P Vitera Full Face Mask
Common name	Full Face Mask
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	F&P Simplus™ Full Face Mask (K130328)

5.1 Device Description

The F&P Vitera Full Face Mask is a non-invasive patient interface with a seal that encloses the oral and nasal airway. 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 continuous 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 Vitera Full Face Mask is a prescription only device, provided in a non-sterile state.

Refer below to Vitera Full Face Mask part numbers that are used to differentiate the mask sizes and models.

Sizes	A model	SL model
Small	VIT1SA Vitera Mask Full Face Small A VIT1SSA Vitera Mask Seal Small / Small A	VIT1SSL Vitera Mask Full Face Small Sleep Lab
Medium	VIT1MA Vitera Mask Full Face Medium A VIT1MMA Vitera Mask Seal Medium / Medium A	VIT1MSL Vitera Mask Full Face Medium Sleep Lab
Large	VIT1LA Vitera Mask Full Face Large A VIT1LLA Vitera Mask Seal Large / Large A	VIT1LSL Vitera Mask Full Face Large Sleep Lab

5.2 Intended Use / Indications for Use

A Model: 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.

SL Model: 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.

5.3 Technological Characteristics Comparison

5.3.1 Similarities between the subject and predicate devices:

The F&P Vitera Full Face mask has the following similarities to the previously cleared predicate Simplus Full Face Mask.

- Same intended use with same patient population and operating environment.
- Same product code, device classification and classification panel.
- Same breathing circuit which is a single inspiratory tube with the connection mechanism via a 22mm male connector.
- Same mode of operation whereby masks deliver gases through the nose and mouth.
- Same seal and headgear size category.
- Same exhaust system consisting of a series of holes on the facial seal.
- Both have a single non-rebreathing valve (NRV) flap design on the elbow.
- Same axis rotation between the elbow and the tube.
- Both are prescription devices only that can be reprocessed.
- Same mask components and accessory.

5.3.2 Differences between the subject and predicate devices:

The key differences to the predicate device are that the F&P Vitera Full Face mask:

- Has colour cues (**VisiBlue™**) added to swivel, frame, and headgear components to aid the user in the reassembly and orientation of the mask.
- The **headgear** been modified:
  - **Materials**:
    - VentiCool™: has a new mesh fabric designed to improve breathability by allowing air and moisture to escape.
    - Soft tab: has a new tab material to assist the user during headgear adjustments.
    - Headgear clips: has a new clip material to assist the user during the assembly and disassembly of the headgear to the mask.
  - **Headgear Release and Clips**: the headgear has only 3 connection points to the frame due to the introduction of a new forehead clip. The buckle on the crown strap of the predicate headgear has been removed as its functions have been integrated into the subject device headgear.
- Has a **detachable elbow** to aid in mask cleaning and disinfection during multi-patient use.
- The **NRV flap** that has a sealing bead along with a curved hinge. Also, it features two locating prongs with the Elbow Lower component.
- Has "**RollFit™ XT**" that adapts to the face and allows for a greater range of motion.

5.4 Non-Clinical Performance Data

Performance testing of the F&P Vitera Full Face Mask was completed to determine that device design changes, compared to F&P Simplus Full Face Mask (K130328) do not raise questions of safety or effectiveness. These tests demonstrate substantial equivalence of the F&P Vitera Full Face Mask to the predicate device. A summary of the testing conducted for the F&P Vitera Full Face 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 Vitera Full Face Mask does not adversely affect safety and effectiveness.
    - o CO2 rebreathing during normal use and single fault conditions
    - o Non-rebreathing valve (NRV) activation / deactivation pressure
    - 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.

Testing of the F&P Vitera Full Face Mask was compared to the predicate F&P Simplus Full Face Mask (K130328) for performance. These tests demonstrate substantial equivalence of the F&P Vitera Full Face Mask to the predicate device. The results of the comparative bench testing do not raise any new or different questions of safety or effectiveness for the F&P Vitera Full Face Mask.

The F&P Vitera Full Face 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 10993-1:2009, 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 10993-11:2006, 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)

Table 1: Comparison of Technological Characteristics with the Predicate Device

	Subject Device		Predicate	Comments
Device Name	**F&P Vitera Full Face Mask (A model)**	**F&P Vitera Full Face Mask (SL model)**	**F&P Simplus Full Face Mask**	
Indications for use and intended use				
Intended Use	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.	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.	The F&P Simplus Full Face Mask is intended to be used by **individuals** who have been diagnosed by a physician as requiring CPAP or Bi-Level Ventilator treatment. The F&P Simplus Full Face Mask is intended for single-patient adult use in the home and multiple-patient adult use in the hospital or other clinical setting where proper disinfection of the device can occur between patients.	Substantially equivalent. Identical intended use, patient population and operating environment. The Intended Use of the F&P Vitera specifies the minimum weight of an adult patient. Specifying the weight of an adult patient was not found to introduce any new risks to the device and does not alter the intended use of the device.
Availability	Prescription use only		Prescription use only	Identical
Patient Population	Adult		Adult	Identical
Classification				
Product Code	BZD		BZD	Identical
Device classification	868.5905		868.5905	Identical
Classification panel	Anaesthesiology		Anaesthesiology	Identical

	Subject Device		Predicate	Comments
Device Name	**F&P Vitera Full Face Mask (A model)**	**F&P Vitera Full Face Mask (SL model)**	**F&P Simplus Full Face Mask**	
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 30 cmH_2O		4 to 25 cmH_2O	Substantially equivalent. The upper pressure limit has been increased on the subject device mask allowing the mask to be used at higher pressures if required. The subject device is in conformance with ISO 17510:2015 and the change to the upper pressure limit does not introduce any additional risk to the user.
Resistance to Flow	• Pressure drop through the mask at 50 L/min: 0.24 cmH2O • Pressure drop through the mask at 100 L/min: 0.47 cmH2O		• Pressure drop through the mask at 50 L/min: 0.17 cmH2O • Pressure drop through the mask at 100 L/min: 0.64 cmH2O	Substantially equivalent. The subject device is in conformance with ISO 17510:2015 and this difference does not introduce any additional risk to the user.
Inspiratory & Expiratory Resistance	• Inspiratory Resistance: 1.05 cmH2O • Expiratory Resistance: 0.80 cmH2O		• Inspiratory Resistance: 0.67 cmH2O • Expiratory Resistance: 0.12 cmH2O	Substantially equivalent. 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	Comments
Device Name	**F&P Vitera Full Face Mask (A model)**	**F&P Vitera Full Face Mask (SL model)**	**F&P Simplus Full Face Mask**	
Dead Space	• Small: 245.8 cc • Medium: 274.1 cc • Large: 321.8 cc		• Small: 251 cc • Medium: 278 cc • Large: 310 cc	Substantially equivalent. 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: 29.8 dBA, with uncertainty 2.5 dBA • Sound Pressure Level of the Mask: 21.8 dBA, with uncertainty 2.5 dBA		• Sound Power Level of the Mask: 28.8 dBA, with uncertainty 2.5 dBA • Sound Pressure Level of the Mask: 17.8 dBA, with uncertainty 2.5 dBA	Substantially equivalent. The subject device is in conformance with ISO 17510:2015 and this difference does not introduce any additional risk to the user.
Shelf-Life	5 years		Shelf-life not claimed on labelling	Substantially equivalent. The subject device claims a 5-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: 80°C for 10 mins 75°C for 30 mins 90°C for 1 min	Thermal Disinfection: 80°C for 10 mins	Substantially equivalent. The parameters used for the thermal disinfection are identical. Additional temp/time configurations have been validated for the subject device (75°C for 30 mins and 90°C for 1 min).

	Subject Device		Predicate	Comments
Device Name	**F&P Vitera Full Face Mask (A model)**	**F&P Vitera Full Face Mask (SL model)**	**F&P Simplus Full Face Mask**	
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

5.5 Clinical Performance Data

Clinical study was not required to demonstrate Substantial equivalence.

5.6 Biocompatibility

The F&P Vitera Full Face Mask is classified as an externally communicating device, tissue contact, permanent duration (>30 days). Cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, and extractables evaluations were conducted based on applicable ISO 10993 test standards and particulate and volatile organic compound (VOC) emissions were evaluated based on ISO 18562. Additionally, a biological risk assessment was conducted on the biocompatibility results and concluded the F&P Vitera Full Face Mask is considered safe for use with patients ≥ 30 kg.

5.7 Accessories and Spare Parts

F&P Vitera Full Face Mask has one accessory and multiple spare parts.

- **Accessory**:
  F&P Vitera Full Face Mask has the below accessory that is packaged and sold separately.
  - Oxygen Pressure Port Connector
- **Spare Parts**:
  F&P Vitera Full Face Mask has the below device components which are available for purchase as spare parts:
  - Vitera Seal Small
  - Vitera Seal Medium
  - Vitera Seal Large
  - Vitera Headgear Medium / Large - Vitera Clips and Forehead Clip
    (clips are assembled with the headgear and sold together)
  - Vitera Headgear Small - Vitera Clips and Forehead Clip
    (clips are already assembled with the headgear and sold together)
  - Vitera Clips and Forehead Clip
    (Clips can be purchased separately from the headgear)
  - Vitera Elbow
  - Swivel

5.8 Mask Models

Two proposed model variants of Vitera will be made available for sale in the United States:

- Vitera **A model** is intended for single patient use in the home.
- Vitera **SL model** 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.

5.8.1 Mask Models Sizes

Both models are available in 3 sizes, Small, Medium and Large.

5.8.2 Mask Models Similarities

The F&P Vitera Full Face Mask design is identical in **A** and **SL** models.

5.8.3 Mask Models Differences

The only differences between F&P Vitera Full Face Mask **A** and **SL** models are in the labelling content**.** Differences include: product labels, user instructions, disinfection guide, product direct marking and packaging (product bag) and content.

5.9 Conclusions

The comparison of features, performance, and intended use demonstrate that the F&P Vitera Full Face Mask is substantially equivalent to the predicate F&P Simplus Full Face Mask (K130328).