June 18, 2025

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

Re: K243583
Trade/Device Name: F&P Nova Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 19, 2025
Received: May 19, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243583

Device Name
F&P Nova Nasal Mask

Indications for Use *(Describe)*

A-Model

The F&P Nova Nasal Mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 ks) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova Nasal mask is intended for single-patient use in the home.

SLA-Model

The F&P Nova Nasal mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

As Required by 21 CFR 807.92

I. SUBMITTER

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Prepared and Submitted by Jung Yun Lee
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Date Prepared 19 May 2025

II. DEVICE

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

III. PREDICATE DEVICE

Predicate device: F&P Evora Nasal Mask, K200089.

Reference device: F&P Eson 2 Nasal Mask, K153505.

IV. DEVICE DESCRIPTION

The F&P Nova Nasal Mask is a non-invasive, Positive Airway Pressure (PAP) therapy nasal mask that features an over-the-nose cushion that seals the patient's nose, held in place by adjustable headgear straps. The mask is designed to aid in the delivery of PAP by providing an interface between the flow generator and tubing, and the patient. The F&P Nova Nasal Mask is a prescription-only device, provided in a non-sterile state.

The Nova Nasal Mask range is available in three cushion sizes – Small, Medium, and Large.

The mask has two models: A-Model and Sleeplab (SL) A-Model. Both models are identical except for their Indications for Use, Operating Environment, and Reusability. The A-Model is intended to be single-patient use in the home, while the SL A-Model is intended to be used on multiple patients in a hospital or other clinical setting where proper disinfection of the device can occur between patient uses.

A list of product codes in the scope of this submission includes:

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 three different sizes (S, M, L).	NVN1SA	Nova Nasal Mask Small A-Model
	NVN1MA	Nova Nasal Mask Medium A-Model
	NVN1LA	Nova Nasal Mask Large A-Model
Fit Pack A-Model The A-Model Fit Pack is intended for single-patient use in a home environment only.	NVN1SMLA	Nova Nasal Mask Fit Pack/SML A-Model
SLA-Model The Sleep Lab A-Model is intended for single-patient use in a home environment as well a for multi-patient use in the hospital or other clinical setting. The mask is available in three different sizes (S, M, L).	NVN1SSLA	Nova Nasal Mask Small Sleep Lab A-Model
	NVN1MSLA	Nova Nasal Mask Medium Sleep Lab A-Model
	NVN1LSLA	Nova Nasal Mask Large Sleep Lab A-Model
Fit Pack SLA-Model The Sleep Lab A-Model Fit Pack is intended for single-patient use in a home environment as well as for multi-patient use in the hospital or other clinical setting.	NVN1SMLSLA	Nova Nasal Mask Fit Pack Sleep Lab A-Model

In addition to the main models, the following accessory and spare parts will be available:

- **Accessory**: Oxygen / Pressure Port Connector (900HC452), which will be packaged and sold separately.
- **Spare components**: The following spare components will be packaged and sold separately:
  - Nova Nasal Cushion Spare (available in Small, Medium, Large)
  - Nova Nasal Mask Headgear Spare (available in Small, and Medium-Large)
  - Nova Nasal Mask (without Headgear) Spare (available in Small, Medium, Large)
  - Nova Nasal Mask Frame Assembly Spare
  - Nova Nasal Tube Clip Spare
  - Nova Nasal Diffuser Spare
  - Nova Nasal Headgear Pad Spare

V. INDICATIONS FOR USE

A-Model

The F&P Nova Nasal Mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 ks) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova Nasal mask is intended for single-patient use in the home.

SLA-Model

The F&P Nova Nasal mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design/Technological Characteristic	Subject Device F&P Nova Nasal Mask	Predicate Device F&P Evora Nasal Mask (K200089)	Comments
Classification			
Legal Manufacturer	Fisher & Paykel Healthcare Limited	Fisher & Paykel Healthcare Limited	Identical.
Product Code	BZD	BZD	
Device Classification	21 CFR §868.5905	21 CFR §868.5905	
Classification Panel	Anaesthesiology	Anaesthesiology	
Indications for Use/Intended Use			
Indications for Use/Intended Use	**A-model:** The F&P Nova Nasal Mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 ks) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova Nasal mask is intended for single-patient use in the home. **SLA-model:** The F&P Nova Nasal mask is intended to be used by adults aged 22 years and older weighing ≥ 66 lb (30 kg) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or Bi-Level by a physician. The Nova 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.	**A-model:** The F&P Evora Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed noninvasive 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 noninvasive 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.	Identical.
Availability	Prescription use only	Prescription use only	
Patient Population	Adults aged 22 years and older weighing ≥ 66lbs (30kgs)	Adults weighing ≥ 66lbs (30kgs)	

Patient Consciousness	Responsive and able to remove mask	Responsive and able to remove mask	
Operation and Features			
Operating Environment	A-model: Home SLA-model: Home, hospital or other clinical setting	A-model: Home SL-model: Home, hospital or other clinical setting	Identical.
Face Coverage	Nasal	Nasal	
Operating Temperature Range	5 to 40 °C (41 to 104 °F).	5 to 40 °C (41 to 104 °F).	
Breathing Circuit	Single Inspiratory Tube	Single Inspiratory Tube	
Breathing Tube Connection to Mask	22mm ISO Taper	22mm ISO Taper	
Cushion Sizes	Available in three sizes: • Small • Medium • Large	Available in four sizes: • Small • Medium • Large • Wide	Equivalent.
Headgear Sizes	Two sizes	One size	Equivalent.
Exhalation Vent	Vent hole array in Mask Frame	Numerous radial vent holes in Mask Frame	Equivalent.
Technical Specifications			
Pressure Range	4 to 30 cm H_2O	4 to 25 cm H_2O	Equivalent.
Resistance to Flow	Pressure drop through the mask with Diffuser at 50 L/min: 0.3 ± 0.1 cmH_2O Pressure drop through the mask without Diffuser at 50 L/min: 0.3 ± 0.1 cmH_2O Pressure drop through the mask with Diffuser at 100 L/min: 1.5 ± 0.3 cmH_2O Pressure drop through the mask without Diffuser at 100 L/min: 1.5 ± 0.3 cmH_2O	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 ± 0.25 cmH_2O Pressure drop through wide 100 L/min: 1.3 ± 0.25 cmH_2O	The subject device is designed to be in conformance with ISO 17510:2015 and the pressure drop is disclosed in labeling in accordance with ISO 17510:2015.
Dead Space	Small: 68.6 cc Medium: 75.0 cc Large: 86.8 cc	Small: 28 cc Medium: 26 cc Large: 28 cc Wide: 34 cc **<u>Reference device (K153505):</u>** Small: 69 cc Medium: 86 cc Large 98 cc	Measured dead space is disclosed in labeling in accordance with ISO 17510:2015.

Sound	**With Diffuser:** Sound Power Level of the mask is 25.5 dBA, with uncertainty 2.5 dBA. Sound Pressure Level of the mask is 17.5 dBA, with uncertainty 2.5 dBA. **Without Diffuser:** Sound Power Level of the mask is 30.0 dBA, with uncertainty 2.5 dBA. Sound Pressure Level of the mask is 22.0 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. **Reference device (K153505):** **With Diffuser:** Sound power level: 21.3 dBA with uncertainty 2.5 dBA. Sound pressure level: 13.3 dBA with uncertainty 2.5 dBA. **Without Diffuser:** Sound power level: 31.4 dBA with uncertainty 2.5 dBA. Sound pressure level: 23.4 dBA with uncertainty 2.5 dBA.	Measured sound power level is disclosed in labeling in accordance with ISO 17510:2015.
Shelf-Life	5 years	1 year	The subject device claims a 5-year shelf life.
Cleaning and High-Level Disinfection			
Sterility	Device not provided sterile	Device not provided sterile	Identical.
Reusability	A-model: Single patient reuse SLA-model: Reusable – Multi patient use	A-model: Single Patient reuse SL-model: Reusable – Multi patient use	
High Level Disinfection Methods	**Applies to multi patient use only** **Thermal Disinfection:** 75°C (167°F) for 30 mins 80°C (176°F) for 10 mins 90°C (194°F) for 1 min **Chemical Disinfection:** CIDEX OPA 12-minute soak at 20°C. Headgear is excluded from reprocessing.	**Applies to multi patient use only** **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 has identical disinfection methods and has additional chemical disinfection method.
Design/Components			
High-level Mask Components	Cushion Frame Headgear Tube Swivel Diffuser clip Tube clip Headgear pad	Seal Frame Headgear Tube Swivel **Reference device (K153505):** Seal Frame Headgear Tube Swivel Diffuser	The subject device includes optional components – diffuser clip, tube clip and headgear pad.

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

- Cleaning Validation
- High-Level Disinfection Validation
- Leak
- CO2 rebreathing during normal use
- Resistance to flow and Pressure Drop
- Total mask exhaust flow
- Vibration and Noise Testing
- Dead Space Analysis
- Human Factors/Usability Engineering
- Mechanical Integrity
- Shelf-Life, Storage and Transportation

The F&P Nova Nasal Mask has been tested to applicable requirements to the following standards:

- ISO 17510:2015 Sleep apnoea breathing therapy – Masks and application accessories
- ISO 5356-1:2015 Anesthetic and respiratory equipment – Conical connectors: Part 1: Cones and sockets
- ISTA 2A:2011 Procedure 2A: Packaged-Products weighing 150 lb (68 kg) or less. Basic requirements: Atmospheric conditioning, compression, fixed displacement or random vibration, and shock vibration
- ASTM F1980-16 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 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 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18652-2:2017 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 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- ISO 17664-2:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices.

VIII. CONCLUSION

The F&P Nova Nasal Mask is substantially equivalent to the predicate device 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.