August 23, 2024

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

Re: K233829
Trade/Device Name: F&P Nova Micro Pillows Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: November 30, 2023
Received: December 1, 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 (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.

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,

Binoy J. Mathews -S
Digitally signed by Binoy J. Mathews -S
Date: 2024.08.23 12:36:10 -04'00'

For
Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K233829

Device Name
F&P Nova Micro Pillows Mask

Indications for Use *(Describe)*

A-Model

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

SLA-Model

The F&P Nova Micro Pillows Mask is intended to be used by adults weighing ≥ 66 lbs (30kgs) who have been prescribed non-invasive positive airway pressure therapy such as CPAP or bi-level by a physician. The F&P Nova Micro Pillows Mask is intended for single-patient use in the home and for multiple-patient use in the hospital or other clinical settings 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


| | |
|---|---|
| **Company Name and Address** | Fisher & Paykel Healthcare Limited<br>15 Maurice Paykel Place<br>East Tamaki<br>Auckland 2013, New Zealand<br>Telephone: +64 9 574 0100 |
| **Prepared and Submitted by** | Jung Yun Lee<br>Regulatory Affairs Associate |
| **Contact Person** | Reena Daken<br>Regulatory Affairs Manager<br>Telephone: +64 9 574 0100<br>Email: reena.daken@fphcare.co.nz |
| **Date Prepared** | 01 December 2023 |


## II. DEVICE

| | |
|---|---|
| **Name of Device** | F&P Nova Micro Pillows Mask |
| **Common/Usual Name** | Pillows 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 Solo Mask Range, K223696

## IV. DEVICE DESCRIPTION

The F&P Nova Micro Pillows Mask is a non-invasive, Positive Airway Pressure (PAP) therapy nasal pillows mask with a silicone seal that seals the nasal airway entrance of the patient's face. The Nova Micro Pillows Mask is designed to aid in the delivery of PAP by providing an interface between the flow generator and tubing, and the patient. The Nova Micro Pillows Mask features a pillows cushion with prongs that extend into the entrance of the patient's nasal nares, held in place by adjustable headgear straps. The Nova Micro Pillows Mask is a prescription-only device, provided in a non- sterile state.

The Nova Micro Pillows 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 products codes in the scope of this submission is provided in table 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 three different sizes (S, M, L). | NVP1SA | Nova Micro Pillows Mask Small A Model |
| | NVP1MA | Nova Micro Pillows Mask Medium A Model |
| | NVP1LA | Nova Micro Pillows Mask Large A Model |
| **Fit Pack A-Model** The A-Model Fit Pack is intended for single-patient use in a home environment only. | NVP1SMLA | Nova Micro 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 three different sizes (S, M, L). | NVP1SSLA | Nova Micro Pillows Mask Small Sleep Lab A |
| | NVP1MSLA | Nova Micro Pillows Mask Medium Sleep Lab A |
| | NVP1LSLA | Nova Micro Pillows Mask Large Sleep Lab A |
| **Fit Pack SL A-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. | NVP1SMLSLA | Nova Micro Pillows Mask Fit Pack Sleep Lab A |

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:

  o Nova Micro Pillows Cushion Spare (available in Small, Medium, Large)

  o Nova Micro Pillows Headgear Spare

  o Nova Micro Pillows Mask (without Headgear) Spare (available in Small, Medium, Large)

  o Nova Micro Pillows Frame Assembly Spare

# V. INDICATIONS FOR USE

### A-Model

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

### SLA-Model

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

# VI. COMPARISON OF TECHNOLOGICAL CHARATCERISTICS WITH THE PREDICATE DEVICE

| Design/Technological Characteristic | Subject Device<br>F&P Nova Micro Pillows Mask | Predicate Device<br>F&P Solo (Pillows) Mask (K223696) | 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** | Anesthesiology | Anesthesiology | |
| **Indications for Use/Intended Use** | | | |
| **Indications for Use /Intended Use** | **For mask models intended for single patient use only:**<br>The F&P Nova Micro 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 Solo PAP mask is intended for single-patient use in the home.<br><br>**For mask models intended for single patient and multi-patient use:**<br>The F&P Nova Micro 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. | **For mask models intended for single patient use only:**<br>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 Solo PAP mask is intended for single-patient use in the home.<br><br>**For mask models intended for single patient and multi-patient use:**<br>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 | Identical |

| Design/Technological Characteristic | Subject Device<br>F&P Nova Micro Pillows Mask | Predicate Device<br>F&P Solo (Pillows) Mask (K223696) | Comments |
|---|---|---|---|
| | The F&P Nova Micro Pillows 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. | 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. | |
| **Availability** | Prescription use only | Prescription use only | Identical |
| **Patient Population** | Adults weighing ≥ 66lbs (30 kgs) | Adults weighing ≥ 66lbs (30 kgs) | Identical |
| **Patient Consciousness** | Responsive and able to remove mask | Responsive and able to remove mask | Identical |
| **Operation and features** | | | |
| **Operating Environment** | Home, hospital or other clinical setting | Home, hospital or other clinical setting | Identical |
| **Face Coverage** | Nasal Pillows | Nasal Pillows | Identical |
| **Operating Temperature Range** | 5 to 40 °C (41 to 104 °F). | 5 to 40 °C (41 to 104 °F). | Identical |
| **Breathing Circuit** | Single Inspiratory Tube | Single Inspiratory Tube | Identical |
| **Breathing Tube connection to mask** | 22mm ISO Taper | 22mm ISO Taper | Identical |
| **Cushion sizes** | Available in three sizes:<br>Small, Medium, Large | Available in three sizes:<br>Small, Medium, Large | Identical |
| **Headgear Sizes** | One size | One size | Identical |
| **Exhalation Vent** | Numerous vent holes in mask frame | Numerous vent holes in mask frame | Identical |
| **Technical Specifications** | | | |
| **Pressure Range** | 4 to 25 cm $H_2O$ | 4 to 20 cm $H_2O$ | The subject device is designed to be in |

| Design/Technological Characteristic | Subject Device<br>F&P Nova Micro Pillows Mask | Predicate Device<br>F&P Solo (Pillows) Mask (K223696) | Comments |
|---|---|---|---|
| | | | conformance with ISO 17510:2015. |
| **Resistance to Flow** | Pressure drop through the mask at 50 L/min:<br>- Small cushion: 2.0 ± 0.2 $cmH_2O$<br>- Medium cushion: 0.9 ± 0.2 $cmH_2O$<br>- Large cushion: 0.7 ± 0.2 $cmH_2O$<br><br>Pressure drop through the mask at 100 L/min:<br>- Small cushion: 7.9 ± 1.0 $cmH_2O$<br>- Medium cushion: 3.8 ± 1.0 $cmH_2O$<br>- Large cushion: 3.1 ± 1.0 $cmH_2O$ | Pressure drop through the Pillows mask at 50 L/min:<br>- Small cushion: 2.17 $cmH_2O$<br>- Medium cushion: 1.05 $cmH_2O$<br>- Large cushion: 0.89 $cmH_2O$<br><br>Pressure drop through the Pillows mask at 100 L/min:<br>- Small cushion: 8.56 $cmH_2O$<br>- Medium cushion: 4.42 $cmH_2O$<br>- Large cushion: 3.83 $cmH_2O$ | The subject device is designed to be in conformance with ISO 17510:2015 and the pressure drop is disclosed in labelling in accordance with ISO 17510:2015. |
| **Dead Space** | Small: 14.1 cc<br>Medium: 14.2 cc<br>Large: 18.2 cc | Small: 25.8 cc<br>Medium: 27.7 cc<br>Large: 30.5 cc | Measured dead space is disclosed in labelling in accordance with ISO 17510:2015. |
| **Sound** | The sound power level of the mask is 21.4 dBA, with uncertainty 2.5 dBA.<br><br>The sound pressure level of the mask is 13.45 dBA, with uncertainty 2.5 dBA. | The sound power level of the mask is 31.5 dBA, with uncertainty 2.5 dBA<br><br>The sound pressure level of the mask 23.6 dBA, with uncertainty 2.5 dBA | Measured sound power level is disclosed in labelling in accordance with ISO 17510:2015. |
| **Shelf-Life** | 3 years | 2 years | The subject device claims a 3-year shelf life. |
| **Cleaning and High-Level Disinfection** | | | |

| Design/Technological Characteristic | Subject Device<br>F&P Nova Micro Pillows Mask | Predicate Device<br>F&P Solo (Pillows) Mask (K223696) | Comments |
|---|---|---|---|
| **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:**<br>75°C (167°F) for 30 mins<br>80°C (176°F) for 10 mins<br>90°C (194°F) for 1 min<br>**Chemical Disinfection:**<br>CIDEX OPA, MetriCide OPA Plus and Rapicide OPA/28.<br>12-minute soak at 20°C.<br>Mask assembly only – headgear is excluded from reprocessing by chemical disinfection. | **Thermal Disinfection:**<br>75°C (167°F) for 30 mins<br>80°C (176°F) for 10 mins | The subject device has identical disinfection methods, except for the additional thermal disinfection method at 90°C, and chemical disinfection method. |
| **Design / Components** | | | |
| **Mask Components** | • Cushion<br>• Frame<br>• Headgear<br>• Tube<br>• Swivel | • Cushion<br>• Frame<br>• Headgear<br>• Tube<br>• Swivel | Identical |

# VII. PERFORMANCE DATA

**Summary of Non-Clinical Tests**

- Cleaning Validation
- High-Level Disinfection Validation
- Leak
- Dead Space Analysis
- CO2 Rebreathing
- Pressure-Flow Curve
- Exhaust Flow
- Resistance to Flow (Pressure Drop)
- Vibration and Noise
- Human Factors/Usability Engineering
- Mechanical Integrity
- Shelf-Life, Storage and Transportation

The F&P Nova Micro 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
- 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 10993-17:2023 Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
- 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 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/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
- ISTA 2A Packaged-Products 150 lb (68 kg) or less

## VIII. CONCLUSION

The F&P Nova Micro Pillows 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.