November 19, 2025

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

Re: K250651
Trade/Device Name: OptiPAP Junior Flexi Tube US (OPTIPAPFUS); OptiPAP Junior Nasal Prongs XXS (OPTIPAPPXXS); OptiPAP Junior Nasal Prongs XS (OPTIPAPPXS); OptiPAP Junior Nasal Prongs S (OPTIPAPPS); OptiPAP Junior Nasal Prongs M (OPTIPAPPM); OptiPAP Junior Nasal Prongs L (OPTIPAPPL); OptiPAP Junior Nasal Prongs XL (OPTIPAPPXL); OptiPAP Junior Nasal Mask XXS (OPTIPAPMXXS); OptiPAP Junior Nasal Mask XS (OPTIPAPMXS); OptiPAP Junior Nasal Mask S (OPTIPAPMS); OptiPAP Junior Nasal Mask M (OPTIPAPMM); OptiPAP Junior Nasal Mask L (OPTIPAPML); OptiPAP Junior Nasal Mask XL (OPTIPAPMXL); OptiPAP Junior Bonnet Kit 17-22cm (OPTIPAPB1722); OptiPAP Junior Bonnet Kit 20-26cm (OPTIPAPB2026); OptiPAP Junior Bonnet Kit 24-33cm (OPTIPAPB2431); OptiPAP Junior Bonnet Kit 29-36cm (OPTIPAPB2936); OptiPAP Junior Bonnet Kit 34-45cm (OPTIPAPB3445)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: SGR
Dated: October 15, 2025
Received: October 15, 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,

John S. Bender -S

for Ethan Nyberg, Ph.D.
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

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)*
K250651

Device Name
F&P OptiPAP Junior

Indications for Use *(Describe)*
Fisher & Paykel Healthcare OptiPAP Junior is for single-patient use and is intended to deliver noninvasive positive airway pressure (PAP) therapy to spontaneously breathing patients who require respiratory support.

OptiPAP Junior is designed for use in hospital environments where the patient is continually monitored and must be prescribed by a physician. It is intended for use by trained medical professionals on a pediatric subpopulation that includes neonates and infants from birth up to two years of age.

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 15 Maurice Paykel Place East Tamaki Auckland 2013, New Zealand Telephone: +64 9 574 0100
Prepared and Submitted by	Roshika Reddy Senior Regulatory Affairs Specialist
Contact Person	Reena Daken Regulatory Affairs Manager Telephone: +64 9 574 0100 Email: reena.daken@fphcare.co.nz
Date Prepared	12 November 2025

II. DEVICE

Name of Device	F&P OptiPAP™ Junior
Common/Usual Name	Positive Airway Pressure Nasal Interface
Classification Name	Ventilator, Continuous, Facility Use
Classification	21 CFR 868.5895
Regulatory Class	II
Product Code	SGR

III. PREDICATE DEVICES

Primary Predicate Device: Clarissa Infant n-CPAP Cannula, K032922.
Secondary Predicate Device: Hudson C.P.A.P Nasal Cannula, K871157.
Reference Device: F&P FlexiTrunk Interface, K100011.
Reference Device: F&P Optiflow Junior 2, K222197.

IV. DEVICE DESCRIPTION

The F&P OptiPAP Junior is intended to deliver heated and humidified Positive Airway Pressure (PAP) therapy to neonates and infants requiring respiratory support.

The F&P OptiPAP Junior is a prescription-only device provided in a non-sterile state and intended to be used in a hospital environment and must be prescribed by a physician. The F&P OptiPAP Junior is for single- patient-use up to 14 days. The F&P OptiPAP Junior will be offered in multiple size variants.

V. INDICATIONS FOR USE

Fisher & Paykel Healthcare OptiPAP Junior is for single-patient use and is intended to deliver noninvasive positive airway pressure (PAP) therapy to spontaneously breathing patients who require respiratory support.

OptiPAP Junior is designed for use in hospital environments where the patient is continually monitored and must be prescribed by a physician. It is intended for use by trained medical professionals on a pediatric subpopulation that includes neonates and infants from birth up to two years of age.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design/technological Characteristic	**Subject device** F&P OptiPAP™ Junior (K250651)	**Primary Predicate device** Clarissa Infant n-CPAP Cannula (K032922)	**Secondary Predicate device** Hudson C.P.A.P Nasal Cannula (K871157)	**Comment**
Classification				
Device Classification	Regulation: 21 CFR 868.5895 Class II	Regulation: 21 CFR 868.5895 Class II	Regulation: 21 CFR 868.5895 Class II	Equivalent
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Equivalent
Product Code	SGR	CBK	BZD	Equivalent
Intended Use / Indications for Use				
Intended Use / Indications for Use Statement	Fisher & Paykel Healthcare OptiPAP Junior is for single-patient use and is intended to deliver noninvasive positive airway pressure (PAP) therapy to spontaneously breathing patients who require respiratory support. OptiPAP Junior is designed for use in hospital environments where the patient is continually monitored and must be prescribed by a physician. It is intended for use by trained medical professionals on a pediatric subpopulation that includes neonates and infants from birth up to two years of age.	The Clarissa Infant nCPAP Cannula is intended to be used for the administration of continuous positive airway pressure (CPAP) on continuously monitored neonatal and infant patients in the hospital/institutional environment.	To deliver Positive Airway Pressure to neonates and infants requiring respiratory support.	Equivalent
Availability	Prescription use	Prescription use	Prescription use	Equivalent
Patient Population	Neonates and Infants	Neonates and Infants	Neonates and infants	Equivalent
Environment of use	Hospital	Hospital/institutional environment	Intended for use by qualified medical personnel.	Equivalent
Sterility	Device not provided sterile	Device not provided sterile	Device not provided sterile	Equivalent
Reusability	Single use	Single use	Single Use	Equivalent
Device Design				
Principle of Operation	F&P OptiPAP Junior is intended to seal in/around the patient's nose via a sealing component (nasal Prongs or nasal Mask). An inlet flow is connected to one end of F&P OptiPAP Junior and gas flows to the Mask/Prongs. F&P OptiPAP Junior is connected to a suitable pressure generator, e.g., the F&P bubble generator (K100011) or a ventilator. F&P OptiPAP Junior is retained to the head/face via a Bonnet and straps with hook/loop Velcro attachments. F&P OptiPAP Junior is a conduit for the delivery of therapy.	The Clarissa Cannula is intended to seal in the patient's nares via a sealing component (nasal Prongs). An inlet flow is connected to one end of the Clarissa cannula and gas flows to the Prongs. The cannula is to be connected to a suitable pressure generator, e.g. continuous flow CPAP circuits or ventilators. The Clarissa cannula is retained to the head/face via a Bonnet and straps with hook/loop Velcro attachments. The Clarissa Cannula is a conduit for the delivery of therapy.	The Hudson Cannula is intended to seal in the patient's nares via a sealing component (nasal Prongs). An inlet flow is connected to one end of the Hudson Cannula and gas flows to the Prongs. The cannula is connected to a suitable pressure generator e.g. F&P bubble generator, K100011. The Hudson Cannula is retained to the face/head via a stockinette cap and strips, with hook/loop Velcro attachments. The Hudson Cannula is a conduit for the delivery of therapy.	Equivalent
System Compatibility	For use with pressure based systems, such as the F&P bubble CPAP system or ventilators, in conjunction with a heated humidifier.	For use with pressure based systems, such as continuous flow CPAP circuits or ventilators attached to a heated humidifier.	For use with pressure based systems, such as the F&P bubble CPAP system in conjunction with a heated humidifier.	Equivalent
Sealing Component	Nasal Mask and Prongs	Nasal Prongs	Nasal Prongs	Equivalent
Retention System	The retention system includes a bonnet and straps, with Velcro hook/loop attachments.	The retention system includes a bonnet and straps, with hook/loop attachments.	The retention system includes a stockinette cap and strips, with hook/loop attachments.	Equivalent
Humidification	Indicated to deliver heated and humidified air.	Indicated to deliver heated and humidified air.	Indicated to deliver heated and humidified air.	Equivalent
Sizes	The FlexiTube will be provided in one size that is universal to all patients within the intended patient population. The Mask and Prongs will be provided in multiple size variants, XXS, XS, S, M, L, XL. The Bonnet Kits will be provided in 5 sizes.	The Clarissa Cannula is provided in multiple size variants, Extra Small, Small and Medium. The Bonnet is provided in 3 sizes.	The Hudson Cannula is available in multiple size variants, Small, Medium, Large and Extra Large. The Stockinette cap is provided in 4 sizes.	Equivalent

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

Performance testing of F&P OptiPAP Junior was completed and demonstrates substantial equivalence of the subject device to the predicate devices.

The F&P OptiPAP Junior has been tested to the applicable requirements to the following standards:

Standards	Title
ISO 14971 Third Edition 2019	Medical devices – Application of risk management to medical devices.
IEC 62366-1 Edition 1.1 2020 Consolidated Version	Medical devices – Part 1: Application of usability engineering to medical devices.
ISO 14155 Third Edition 2020	Clinical investigation of medical devices for human subjects – Good clinical practice
ISO 10993-1 Fifth Edition 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 18562-1 Second edition 2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-23 First edition 2021	Biological evaluation of medical devices – Part 23: Tests for irritation
ISO 10993-3 Third edition 2014	Biological evaluation of medical devices: Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
ISO 18562-2 Second edition 2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Test for emissions of particulate matter
ISO 18562-3 Second edition 2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic Substances
ISO 18562-4 Second edition 2024	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
ISO 10993-17 Second edition 2023	Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituent
ISO 10993-18 Edition 2.1 2020 + AMD1:2022	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 15223-1 Fourth edition 2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
ISO 18190 First edition 2016	Anaesthetic and respiratory equipment – General requirements for airways and related equipment
ISO 20417 First edition 2021	Medical Devices - Requirements for general information to be provided by the manufacturer,
ISO 5356-1 Fourth edition 2015	Anaesthetic and respiratory equipment – Conical connectors: Part 1 Cones and sockets
ISO 17510 First edition 2015	Medical devices – Sleep apnoea breathing therapy – Masks and application accessories

VIII. CONCLUSION

The F&P OptiPAP Junior is substantially equivalent to the predicates based on the intended use, 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.