July 25, 2022

Paneffort, LLC
℅ Vardhini Kirthivas
Regulatory Correspondent
Freyr Solutions
Level 4, Building No. H-08, Phoenix SEZ, Phase 2, Gachibowli
Hyderabad, Telangana 500081
India

Re: K221409
Trade/Device Name: Paneffort 3-ply Surgical and Procedural Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 8, 2022
Received: June 10, 2022

Dear Vardhini Kirthivas:

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
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K221409

Device Name
Paneffort 3-Ply Surgical and Procedural Masks

Indications for Use *(Describe)*
Paneffort 3-Ply Surgical and Procedural Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

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

Submitter Information:

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Fax Number (including area code): +855 12284810
Date Prepared: 11 May 2022

Device Identification:

Device Trade Name:	Paneffort 3-ply Surgical and Procedural Masks
Device Classification name:	Surgical Mask
Regulation Name:	Surgical Apparel
Regulation Medical Specialty:	General & Plastic Surgery
Device Class:	II
Regulation Number:	21 CFR 878.4040
Product Code:	FXX

Predicate Devices:

Table 1 List of Predicate Devices

Device Name	510(k) Number	
Medical surgical Masks-Non-sterile	K202594	Primary Predicate
Surgical Face Masks (Ear loops and Tie-on)	K160269	Additional Predicate Device

Device Description

The Paneffort 3-Ply Surgical and Procedural masks are flat pleated 3-ply device, which consist of three layers, i.e., Outer layer is made of Spunbond Polypropylene, Middle/Filter layer is made of Melt-blown Polypropylene and Inner layer is made of Spunbond Polypropylene. There are two options for the mask to be secured on the user, viz. earloops or tie-on.

Earloops are made of spandex and polyamide and the tie-on model are made of spunbond polypropylene. The nosepiece is made up of Iron wire, polypropylene and Zinc, and is encased between Outer and Middle later.

Paneffort 3-ply Surgical and Procedural masks are available in blue colour.

Models:

Sr. No.	Variants	ASTM Level	Mask style	Colors	Item Number
1.	Paneffort Procedure Masks	Level 2	3-ply Earloop Mask	Blue	(3PML2-EXEL-11)
2.	Paneffort Procedure Masks	Level 3	3-ply Earloop Mask	Blue	(3PML3-EXEL-11)
3.	Paneffort Surgical Masks	Level 2	3-ply Tie-On Mask	Blue	(3PML2-SRTB-11)
4.	Paneffort Surgical Masks	Level 3	3-ply Tie-On Mask	Blue	(3PML3-SRTB-11)

Intended Use & Indications for Use

Paneffort 3-ply Surgical and Procedural masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.

Comparison of Technological Characteristics

Table 2 Substantial Equivalence Table

S.No	Parameters		Subject device	Primary Predicate	Additional Predicate Device	Comments
1.	Product Name		Paneffort 3-ply Surgical and Procedural mask	Medical surgical Masks-Non-sterile	Surgical Face Masks (Ear loops and Tie-on)	N/A
2.	510(k) Number		To be assigned	K202594	K160269	N/A
3.	Manufacturer		PANEFFORT (CAMBODIA) GARMENT CO. LTD.	Shandong T&F Nonwoven Co. Ltd	SAN – M PACKAGE CO., LTD	N/A
4.	Product Code		FXX	FXX	FXX	Same
5.	Regulation Number		878.4040	878.4040	878.4040	Same
6.	Intended Use/Indications of Use		Paneffort 3-ply Surgical and Procedural Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.	The Medical Surgical Masks-Non-Sterile is intended to be worn to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. The Medical Surgical Masks – Non-Sterile is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile	The Surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids this is a single use, disposable device, provided non-sterile.	Same
7.	Material of Construction	Inner Layer	Spunbound polypropylene	Polypropylene non-woven fabric	Polypropylene	Same
		Outer Layer	Spunbound polypropylene	Polypropylene non-woven fabric	Polypropylene	Same
		Middle Layer	Melt blown polypropylene filter	Polypropylene meltblown fabric	1. Polypropylene Spunbound 2. Polypropylene Meltblown	Same

S.No	Parameters		Subject device	Primary Predicate	Additional Predicate Device		Comments
		Ear loops	Spandex and polyamide	Polyamide and Polyurethane	Ear loops : Polyester, polyurethane		Different, does not raise any concerns with safety and effectiveness. Note 1
		Tie-On/Tie strip	Spunbound polypropylene	NA	Tie tapes: Polypropylene Spunbound or polyester Spunbound		Same
		Nose Piece	Iron wire+Polypropylene+Zinc	PP + Iron wire	Polyethylene coated steel wire		Different, does not raise any concerns with safety and effectiveness. Note 2
8.	Dimensions		(9.5 ±3) cm x (17.5 ± 5) cm	Length 17.5±5mm Width 9.5±5mm	Length : 90± 3 mm Width : 175± 5 mm	Length : 90 ± 3 mm Width : 180 ± 5 mm	Similar, does not raise any concerns with safety and effectiveness. Note 1
9.	Mask Style		Flat pleated	Flat Pleated	Flat – pleated		Same
10.	Design Features		Ear loop, tie-on	Ear loops	Ear loop and Tie-On		Same
11.	Sterility		Non- Sterile	Non-sterile	Non – Sterile		Same
12.	Use		Single Use	Single use	Single Use		Same
13.	Latex		Not made with Natural Rubber Latex	Not made with Natural Rubber Latex	Not made with Natural Rubber Latex		Same
14.	ASTM F2100 Level		Level 2 and Level 3	Level 2	Level 2 and Level 3		Same

S.No	Parameters		Subject device		Primary Predicate	Additional Predicate Device		Comments
15.	Bacterial filtration efficiency		**Level 2** Pass at > 99.9 % (ASTM F2101)	**Level 3** Pass at > 99.9 % (ASTM F2101)	>99% (ASTM F2101)	Pass at > 98% (ASTM F2101)	Pass at > 99% (ASTM F2101)	Similar, Note 3
16.	Differential pressure (Delta-P)		3.175 mmH_2O/cm^2 (EN 14683)	3.182 mmH_2O/cm^2 (EN 14683)	< 4.8 mmH_2O/cm^2 (MIL-M36945C)	Pass at 1.6 mmH_2O/cm^2 (MIL-M36945C)	Pass at 2.5 mmH_2O/cm^2 (MIL-M36945C)	Different, Note 4
17.	Sub-micron particulate filtration efficiency		Pass at ≥ 99.20% (ASTM F2299)	Pass at ≥ 99.20 % (ASTM F2299)	>99%	Pass at 99.6% (ASTM F2299)	Pass at 99.7% (ASTM F2299)	Similar, Note 5
18.	Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result		≥ 120 mm Hg (ASTM F1862)	≥ 160 mm Hg (ASTM F1862)	Pass at 120mm Hg (ASTM F1862)	Pass at 120 mm Hg (ASTM F1862)	Pass at 160 mm Hg (ASTM F1862)	Same
19.	Flammability		Class 1 as per 16 CFR Part 1610		Class 1 (16 CFR Part 1610)	Class 1 (16 CFR Part 1610)		Same
20.	Biocompatibility	Cytotoxicity, ISO 10993 5:2009	Pass ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic		Not Cytotoxic	Pass ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic.		Same
		Irritation, ISO 10993-10:2010	Pass ISO 10993-10:2010/ under the conditions of the study, the subject device was non-irritating		Not an irritant	Pass ISO 10993-10:2010/ under the conditions of the study, the subject device was non-irritating.		Same
		Sensitization, ISO 10993-10:2010	Pass ISO 10993-10:2010/ under the conditions of study, the subject device was non-sensitizing		Not Sensitive	Pass ISO 10993-10:2010/ under the conditions of study, the subject device was non-sensitizing.		Same

Note1 & Note2: The differences in the materials do not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation mentioned in Section 14 has been performed on the final finished device which includes all construction materials.

Note 3: The performance requirement for BFE as per ASTM F2100 is ≥98%. The performance of the subject device meets the requirements of FDA recognized consensus standard [Rec# 6-425] ASTM F2100-19. The subject device meets the criteria.

Note 4: We understand that MIL-M-36945C is the FDA recommended standard for differential pressure. However, the conformance to FDA Recognized consensus standard [Rec# 6-425], ASTM F2100-19 requires that Differential pressure be performed as per EN 14683:2019, Annex C.

We also understand that as per ASTM F2100-19, passing criteria for an ASTM level 3 and Level 2 mask with respect to differential pressure is <6.0mm H_20/cm^2 when tested in accordance with EN 14683:2019, Annex C. The subject device meets the criteria.

Note 5: The performance requirement for PFE as per ASTM F2100 is ≥98% when tested in accordance with ASTM F2299. The performance of the subject device meets the requirements of FDA recognized consensus standard [Rec# 6-425] ASTM F2100-19. The subject device meets the criteria

Non-Clinical Testing

The following performance tests, in accordance with ASTM F2100 were conducted for the subject device:

- Bacterial filtration efficiency – ASTM F2100-19e1 Clause 9.1
  - ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of surgical masks using a Biological Aerosol of Staphylococcus aureus.
- Differential Pressure - ASTM F2100-19e1 Clause 9.2
  - EN 14683:2019 - Medical face masks - Requirements and test methods Annex C - Method for determination of breathability (differential pressure)
- Sub-micron particulate filtration efficiency at 0.1 micron - ASTM F2100-19e1 Clause 9.3
  - ASTM F2299 - Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
- Resistance to Penetration by Synthetic Blood- ASTM F2100-19e1 Clause 9.4
  - ASTM F1862 Standard test method for resistance of medical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity)
- Flammability - ASTM F2100-19e1 Clause 9.5
  - 16 CFR Part 1610 Standard for The Flammability of Clothing Textiles

Table 3 Table of Non-clinical Testing Standards

S. No	Test Method/Standard	Purpose	Acceptance Criteria	Results
1.	ASTM F2100-19e1 Clause 9.4	Resistance to penetration by synthetic blood	160mm Hg	Pass at 160mm Hg
2.	ASTM F2100-19e1 Clause 9.5	Flammability of Clothing Textiles	Class I	Class I
3.	ASTM F2100-19e1 Clause 9.2	Differential Pressure (Delta-P)	ΔP <6mm H_2O/cm^2	ΔP <6mm H_2O/cm^2
4.	ASTM F2100-19e1 Clause 9.3	Sub-micron particulate filtration efficiency	≥98%	Pass at >99%
5.	ASTM F2100-19e1 Clause 9.1	Bacterial filtration efficiency	≥98%	Pass at >98%

FDA's guidance, "Surgical Masks - Premarket Notification [510(k)] Submissions ", recommends evaluating the biocompatibility as described in the standard ISO10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing” for limited contact devices, contacting intact skin.

The following Biocompatibility End points have been identified and tested in accordance appropriate biocompatibility standards.

- Cytotoxicity (ISO 10993-5)

- Irritation or Intracutaneous Reactivity (ISO 10993-10)
- Sensitization (ISO 10993-10)

Table 4 Biocompatibility Testing – Summary

Biological endpoint	Test Method/Standard	Purpose	Acceptance Criteria	Results
Cytotoxicity	ISO 10993-5	Verify Cytotoxicity potential of the subject device	Non-cytotoxic	Pass - ISO 10993-5:2009/ under the conditions of study the subject device was non-cytotoxic.
Irritation and Sensitization	ISO 10993-10	Verify irritation and sensitization potential of the subject device	Non-irritating and non-sensitizing	Pass ISO 10993-10:2010/ under the conditions of the study, the subject device was non-irritating.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.