November 30, 2022

Paneffort, LLC
% Shilpa Gampa
Delivery Manager and US Agent
Freyr Solutions
150 College Rd W #102
Princeton, New Jersey 08540

Re: K212717
Trade/Device Name: Paneffort AAMI Level 3 Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: October 19, 2022
Received: October 20, 2022

Dear Shilpa Gampa:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212717

Device Name
Paneffort AAMI Level 3 Isolation Gown

Indications for Use *(Describe)*
The Paneffort AAMI Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. Paneffort AAMI Level 3 Isolation Gowns meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.

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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510(k) Summary – K212717
Paneffort AAMI Level 3 Isolation Gown

1. Submitter Information:

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Contact Person:	Harry Xu
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Date Prepared:	28-Nov-2022

2. Device Identification:

Device Trade Name:	Paneffort AAMI Level 3 Isolation Gown
Device Common Name:	Gowns, Isolation, Surgical
Classification Name:	Surgical Isolation Gown/Surgical Apparels
Device Class:	Class II
Regulation Number:	21 CFR 878.4040
Product Code:	FYC

Predicate Device:

Table 1 List of Predicate Devices

Device Name	510(k) Number
PRIMAGARD Isolation Gown (AAMI PB70 Level 3)	K160361

3. Device Description

The Paneffort AAMI Level 3 Isolation Gown is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code FYC. The Paneffort AAMI Level 3 Isolation Gown is a single use, disposable medical device provided non-sterile. Paneffort AAMI Level 3 Isolation Gown is offered in one color (blue) and six different sizes of Small, Medium, Regular/Large, X-Large, 2X-Large, and 3X-Large. Each model is constructed of a nonwoven Spunbond-Meltblown-Spunbond (SMS) material that is tested according to ANSI/AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3.

The Paneffort AAMI Level 3 Isolation Gown consists of one critical zone throughout the entire gown including seams, but excluding cuffs, hems, and bindings as per AAMI PB70:2012. It is a protective tape sealed gown along with other design features like tie-neck, elastic cuffs, and belt tie, that meets AAMI PB70 Level 3 barrier performance for protective apparel.

4. Intended Use/Indications for Use

The Paneffort AAMI Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. Paneffort AAMI Level 3 Isolation Gowns meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.

5. Device and Predicate Device Technical Characteristics

The fundamental scientific technology, materials of construction and mechanism of operation are identical between the subject Paneffort AAMI Level 3 Isolation Gown and the predicate device. **Table 2** summarizes the comparison of technological characteristics between the subject and predicate devices.

Table 2 Technological Characteristics Comparison of Proposed device and Predicate device

S.No.	Parameters	PRIMAGARD Isolation Gown (AAMI PB70 Level 3) (Predicate Device)	Paneffort AAMI Level 3 Isolation Gown (Subject Device)	Remarks
1.	Manufacturer	Primed Medical Products Inc.	Paneffort (Cambodia) Garment Co. Ltd.	N/A
2.	Product Class and Code	Class II, FYC	Class II, FYC	Same
3.	510(k) Number	K160361	K212717	N/A
4.	Regulation Number	21CFR 878.4040	21CFR 878.4040	Same
5.	Intended use/ Indications for use	PRIMAGARD Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. The PRIMAGARD Isolation Gowns of this 510(k) meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.	The Paneffort AAMI Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material. Paneffort AAMI Level 3 Isolation Gowns meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.	Same
6.	Level of barrier protection AAMI PB70	Level 3	Level 3	Same
7.	Material composition	Non-woven Polypropylene (SMS)	SMS non-woven (polypropylene)	Same
8.	Design	5 Models: Apron Neck Closure, Tape Tab Neck Closure, Hook and Loop Closure,	Tie neck, Full back, Elastic cuffs, Blue belt tie,	Similar[1]

S.No.	Parameters	PRIMAGARD Isolation Gown (AAMI PB70 Level 3) (Predicate Device)	Paneffort AAMI Level 3 Isolation Gown (Subject Device)	Remarks
		Apron Neck Closure, Tie Neck Closure	taped seams.	
9.	Color	Blue, Yellow	Blue	Similar[2]
10.	Sterility	Non-Sterile	Non-Sterile	Same
11.	Use	Single Use	Single Use; Disposable	Same
12.	Basis weight ASTM D3776	39.97 ± 1.61 g/m^2 (1.17 oz/yd^2 ± 0.05)	Tested to ASTM D3766. Met the acceptance criteria.	Similar[3]
13.	LBP: Hydrostatic Pressure AATCC 127	≥ 50 cm H_2 O	Pass, Met the standard's requirement (≥ 50 cm H_2 O)	Same
14.	LBP: Impact Penetration AATCC 42	≤ 1 g	Pass, Met the standard's requirement (≤ 1.0 g)	Same
15.	Flammability: 16 CFR Part 1610.7	Class I	Class I	Same
16.	Breaking strength (MD) ASTM D5034	Tested to ASTM D5034. Met acceptance criteria	Tested to ASTM D5034. Met acceptance criteria	Similar[4]
17.	Breaking strength (CD) ASTM D5034			Similar[5]
18.	Tearing strength (MD) ASTM D5587-08	Tested to ASTM D5587. Met acceptance criteria	Tested to ASTM D5587. Met acceptance criteria	Similar[6]
19.	Tearing strength (CD) ASTM D5587			Similar[7]
20.	Linting (ISO 9073-10)	Tested to NWSP 160.1.R0.	Met acceptance criteria.	Similar[8]

S.No.	Parameters	PRIMAGARD Isolation Gown (AAMI PB70 Level 3) (Predicate Device)	Paneffort AAMI Level 3 Isolation Gown (Subject Device)	Remarks
		Met acceptance criteria.		
21.	Seam Strength	Tested to ASTM D5035. Met acceptance criteria.	Tested to ASTM D5035. Met acceptance criteria.	Similar[9]
22.	Thermal and Evaporative Resistance ASTM F1868	Tested to ASTM F1868 PART C. Met acceptance criteria	Tested to ASTM F1868 PART C. Met acceptance criteria	Similar[10]
23.	Air Permeability ASTM D737	Tested to ASTM D737. Met acceptance criteria.	Tested to ASTM D737. Met acceptance criteria.	Similar[11]
24.	Irritation	Under the conditions of the study, not an irritant.	Under the conditions of the study, not an irritant.	Same
25.	Sensitization	Under the conditions of the study, not a sensitizer.	Under the conditions of the study, not a sensitizer.	Same
26.	Cytotoxicity	Under the conditions of the study the device is non-cytotoxic.	Under the conditions of the study the device is non-cytotoxic.	Same

Note:

N/A –refers that the section is Not applicable/ available.

Similar[1]: The subject device design is similar to the predicate except for few additional features. The additional features do not raise any issues related the safety and effectiveness of the device. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

Similar[2]: The subject device is offered only in single color variant i.e., Blue, while the predicate is offered in both Blue and Yellow colors. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives. Therefore, the difference does not raise any questions on the safety and effectiveness of the device.

Similar[3]: The gowns were tested using the ASTM D3776 standard test method. As there were no ASTM defined limits for this test, we compared the test values obtained with a similar FDA approved (K203415) device. The test values for predicate and subject were less than the value reported for similar FDA approved

device, so we considered the difference in basis weight for both gowns as acceptable. Therefore, the difference does not raise any questions related to the safety and effectiveness of the device.

Similar[4] and Similar[5]: The subject device and predicate devices were tested for Breaking Strength using the ASTM F2407 recommended ASTM D5034 test method. The breaking strength of subject device differed from the predicate but were within the recommended range of the ASTM F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities. Therefore, the difference does not raise any questions on the safety and effectiveness of the device.

Similar[6] and Similar[7]: The subject device and predicate devices were tested for Breaking Strength using the ASTM F2407 recommended ASTM D5587 test method. The tearing strength of the subject device is different than the predicates, but it is within the recommended range of the ASTM F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities. Therefore, the difference does not raise any questions related to the safety and effectiveness of the device.
Similar[8]: Both the subject device and Predicate device were tested for Seam Strength of the Gown using different test methods of ASTM D1683/D1683M-11a and ASTM D5035, respectively. Here, the Subject device tested as per ASTM D1683/D1683M-11a test method yielded the values within the recommended range of the ASTM F2407 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities. While the Predicate device was tested according to ASTM D5035, which specifically utilizes cut strip test procedures for determining the breaking force and elongation of most textile fabrics within the recommended range of the ASTM F2407 Standard Specification. As both the test methods were performed to indicate the durability of the fabric with test values within the acceptable ranges, the difference does not raise any questions on the safety and effectiveness of the device.

Similar[9]: Both the subject device and Predicate device were tested for Lint generation using the ISO 9073-10 standard recommended test method. As per the applicable ISO testing standard, there is no acceptance criteria specific to Linting. However, the standard states that depending on the choice of particle counter, the size ranges can fall within the limits of 0.3 µm or 0.5 µm to 25 µm. As test values obtained were within this particle size limit, the difference does not raise any questions related to the safety and effectiveness of the device.

Similar[10]: Both the subject device and Predicate device were tested for Thermal and Evaporative Resistance using the ASTM F1868-17 test method. As per the ASTM F1868 standard, the acceptance criteria are available only for the total evaporative resistance measured for the specimen (R_{et}), that includes the test specimen (fabric/textile) and test plate covered with a liquid barrier. There are no acceptance criteria for the R_{ef} sample (fabric/textile) alone. However, as both the gowns were tested as per the applicable standard method, the difference does not raise any questions related to the safety and effectiveness of the device.

Similar[11]: Both the subject device and Predicate device were tested for Air Permeability using the ASTM D737 test method. There is no minimum performance expectation for the air permeability parameter and ASTM defined acceptance criteria for Isolation gowns. Therefore, the difference does not raise any questions related to the safety and effectiveness of the device.

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6. Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

1. ASTM F2407-20 - Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
2. AAMI ANSI PB70:2012 - Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities
3. ASTM D3776/D3776M-2020 - Test Methods for Mass Per Unit Area (Weight) of Woven Fabric
4. ASTM D5034-09(2013)- Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
5. ASTM D5587-08- Standard Test Method for Tearing Strength of Fabrics by Trapezoid
6. AATCC 127-2017 - Water Resistance: Hydrostatic Pressure Test
7. AATCC 42:2018 -Water Resistance: Impact Penetration Test
8. ISO 9073 Part 10: 2003 (for non-woven fabric) - Lint and other particles generation in the dry state (Lint Generation test)
9. ASTM D737-18 - Standard Test Method for Air Permeability of Textile Fabrics
10. ASTM D1683/D1683M-11a - Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
11. ASTM F1868-17 - Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate
12. 16 CFR Part 1610-2008 - Standard for the Flammability of Clothing
13. ISO 13938-2:2019 - Pneumatic method for determination of bursting strength and bursting distension

The test summary table mentioned below includes the brief information for all the ASTM F2407-20 - Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities recommended tests that demonstrates the performance of Level 3 Isolation gowns.

Table 3 Non- Clinical Performance Testing Summary Table

S. No.	Test Performed	Device Description/ Sample Size	Test Methods/ Standards applicable	Acceptance criteria	Unexpected results/ Significant deviations	Conclusion
1.	**Bursting Strength**	Paneffort AAMI Level 3 Isolation Gown, 32 samples each from 3 different lots	ASTM D3786 Standard Test Method for Bursting Strength of Textile Fabrics	≥ 40 kPa (≥5.80 psi)	None	The test meets the Acceptance Criteria
2.	**Basis Weight**	Paneffort AAMI Level 3 Isolation Gown 32 samples each from 3 different lots	**ASTM D3776 / D3776M - 20** : Standard Test Methods for Mass Per Unit Area (Weight) of Fabric; Method C	≥35 g/m2	None	The test meets the Acceptance Criteria
3.	**Linting Test**	Paneffort AAMI Level 3 Isolation Gown 32 samples each from 3 different lots	**ISO 9073-10:2003**: Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state	Co-coefficient of Linting ≤4.2	None	The test meets the Acceptance Criteria
4.	**Air Permeability**	Paneffort AAMI Level 3 Isolation Gown 32 samples each from 3 different lots	**ASTM D737-18**: Standard Test Method for Air Permeability of Textile Fabrics	≥15 ft3/min/ft2	None	The test meets the Acceptance Criteria
5.	Water Resistance: **Hydrostatic Pressure**	Paneffort AAMI Level 3 Isolation Gown, **3 lots** Lot 1: 74 pieces; Lot 2: 72 pieces; Lot 3: 72 pieces.	**AATCC 127-2018**: Test Method for Water Resistance: Hydrostatic Pressure	≥ 50cm H2 O (Ac: 3, Re: 4); AQL: 4% (Level 3 ANSI/ AAMI PB70:2012)	In Lot 1, three samples (out of 32) failed the test. In Lot 2, three samples (out of 32) failed the test. In Lot 3, two samples (out of 32 samples) failed the test.	The test meets the Acceptance Criteria

6.	Water Resistance: **Impact Penetration** .	Paneffort AAMI Level 3 Isolation Gown, **3 lots** Lot 1: 74 pieces; Lot 2: 72 pieces; Lot 3: 72 pieces	**AATCC 42-2017** Test Method for Water Resistance: Impact Penetration	≤ 1.0g (Ac: 3, Re: 4); AQL: 4% (Level 3 ANSI/ AAMI PB70:2012)	None	The test meets the Acceptance Criteria
7.	**Tensile Strength/ Breaking Strength**	Paneffort AAMI Level 3 Isolation Gown, 32 samples each from 3 different lots	**ASTM D5034-09 (2013)**: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	≥30N (≥7 lbf).	None	The test meets the Acceptance Criteria
8.	**Tearing Strength**	Paneffort AAMI Level 3 Isolation Gown, 32 samples each from 3 different lots	**ASTM D5587-08, Option 1**: Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	≥10N (≥2.3 lbf).	None	The test meets the Acceptance Criteria
9.	**Seam Strength**	Paneffort AAMI Level 3 Isolation Gown, 32 samples each from 3 different lots	**ASTM D1683/ D1683M-11a**: Standard Test Method for Failure in Sewn Seams of Woven Fabrics	≥30N (≥ 7lbf).	None	The test meets the Acceptance Criteria
10.	**Flammability**	Paneffort AAMI Level 3 Isolation Gown 32 samples each from 3 different lots	**16 CFR Part 1610 -2008**: Standard for the Flammability of Clothing Textiles	Class I, Textile exhibiting normal flammability.	None	The test meets the Acceptance Criteria
11.	**Water Vapour resistance**	Paneffort AAMI Level 3 Isolation Gown 32 samples each from 3 different lots	**ASTM F1868-17, Procedure Part B**: Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate	0,0-1,0 kPa.m2 / W	None	The test meets the Acceptance Criteria

7. Biocompatibility Testing

Biocompatibility tests were performed as per the ISO 10993-1:2018 Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process. The In-Vitro cytotoxicity, Skin irritation and Skin sensitization parameters were tested as per the below standards:

1. ISO 10993-5:2009 Biological Evaluation of Medical Device, Part 5-Tests for In Vitro cytotoxicity
2. ISO 10993-10:2010 Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization

The Paneffort AAMI Level 3 Isolation gowns passed biocompatibility studies per ISO-10993

8. Clinical Testing

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device, the Paneffort AAMI Level 3 Isolation gown, is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K160361).