December 21, 2021
Fugou County Shenxiang Manufacturing Co., LTD.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K212869
Trade/Device Name: Disposable Surgical Gown, Disposable Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA

Dear Diana Hong:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter for your device cleared on December 13, 2021. Specifically, FDA is updating this SE letter due to the clearance date not appearing on the original letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Clarence W. Murray III, Assistant Director of Office of Surgical and Infection Control Devices, at Tel: 301-796-0270 or Email: Clarence.Murray@fda.hhs.gov.

Sincerely,

Bifeng Qian -S

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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Re: K212869
Trade/Device Name: Disposable Surgical Gown, Disposable Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: August 19, 2021
Received: September 9, 2021

Dear Diana Hong:

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

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K212869

Device Name
Disposable Surgical Gown, Disposable Reinforced Surgical Gown

Indications for Use *(Describe)*
Disposable Surgical Gown and Disposable Reinforced Surgical Gown are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.

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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K212869

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 12/13/2021

2. Sponsor Identification

Fugou County Shenxiang Manufacturing Co., LTD.
Industrial Clusters, No.2 Road, Fugou County, Henan Province, China

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Disposable Surgical Gown, Disposable Reinforced Surgical Gown
Common Name: Surgical Gown

Regulatory Information

Classification Name: Gown, Surgical
Classification: II;
Product Code: FYA;
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital;

Indication for use:

Disposable Surgical Gown and Disposable Reinforced Surgical Gown are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.

Device Description:

The proposed devices are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The proposed devices are single use, disposable medical devices and are provided in sterile.

There are two types of surgical gown: Disposable Surgical Gown and Disposable Reinforced Surgical Gown. And each type of surgical gown is available in six product sizes, including S, M, L, XL, XXL and XXXL. Disposable Surgical Gown have two models: ML515M45U and GD524ME65. Disposable Reinforced Surgical Gown have one model: PA528ME45R. Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.

Table 1. Surgical Gowns Description

Proposed	Model	Size	Color	Style	AAMI	Material

device					Level	
Disposable Surgical Gown	ML515M45U	S, M, L, XL, XXL, XXXL	Blue	Non-reinforced	3	45g/m^2 PP SMS nonwoven, Polyester, Blue masterbatch
	GD524ME65	S, M, L, XL, XXL, XXXL	Blue	Non-reinforced	4	45g/m^2 SMS nonwoven, 20g/m^2 PE film, Polyester, Blue masterbatch
Disposable Reinforced Surgical Gown	PA528ME45R	S, M, L, XL, XXL, XXXL	Blue	Reinforced	4	45g/m^2 PP SMS nonwoven, 25g/m^2 PE film reinforced film, Polyester, Blue masterbatch

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K211422
Product Name: Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown

Predicate Device 2
510(k) Number: K192290
Product Name: SMS Standard Surgical Gown; SMS Surgical Gown with Reinforcement; BVB Surgical Gown; BVB Splicing Surgical Gown

Predicate Device 3
510(k) Number: K121152
Product Name: Surgical Gown

6. Summary of Clinical Testing

No clinical study is included in this submission.

7. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics for Level 3 Surgical Gown

Item	Proposed Device	Predicate Device K211422	Remark
Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indication for Use	Disposable Surgical Gown and Disposable Reinforced Surgical Gown are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Level 2 standard surgical gowns met the requirements for Level 2 classification, the Level 3 standard surgical gowns and Level 3 reinforced surgical gowns met the requirements for Level 3 classification.	Same
Style	Non-reinforced	Non-reinforced	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Weight per square (g)	45g/m^2	Level 3 Standard Surgical Gown: 43g/m^2	Different
Size	S, M, L, XL, XXL, XXXL	XS, S, M, L, XL, XXL, XXXL	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cm	Level 3 Standard Surgical Gown: >50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same

Breaking strength	>20N	>20N	Same
Tearing strength	>20N	>20N	Same
Linting	Log_{10}<4	Log_{10}(particle count) <4	Same
Air permeability	>30 $ft^3/min/ft^2$	>30 $ft^3/min/ft^2$	Same
Barrier protection level	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
Material	SMS, Polyester, Blue masterbatch	Level 3 Standard Surgical Gown: SMS nonwoven, Polyester and Polyamide	Different
Biocompatibility			
Cytotoxicity Irritation Sensitization	Under the conditions of the study, the device is non-toxic, non-irritating, and non-sensitizing.	Under the conditions of the study, the device is non-toxic, non-irritating, and non-sensitizing.	Same
Sterilization	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Same

Different - Weight per square

The weight per square for the proposed surgical gowns is different from the predicate device. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrated that the proposed surgical gowns can meet the barrier protection level 3 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Size

The size for the proposed surgical gowns is different from the predicate device. The proposed surgical gowns are available in 6 product sizes, including S, M, L, XL, XXL and XXXL. However, the difference in the size will not affect the device performance. And the specifications of the proposed device can be covered by the predicated products. Different size can be selected by surgeon's condition. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different- Material

The material for the proposed surgical gowns is different from the predicated device. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Table 2 Comparison of Technology Characteristics for Level 4 Surgical Gown

Item	Proposed Device	Predicate Device K192290	Predicate Device K121152	Remark
Product Code	FYA	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	II	Same
Indication for Use	Disposable Surgical Gown and Disposable Reinforced Surgical Gown are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, SMS Standard Surgical Gown and SMS Surgical Gown with Reinforcement met the requirements for Level 3 classification; BVB Surgical Gown and BVB Splicing Surgical Gown met the requirements for Level 4 classification.	Jiangsu Guangda's Reinforced Surgical Gowns, Model Number GD-SG-01, are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. This product may be sterilized using Ethylene Oxide (EO) following the Validation and routine control under ANSI/AAMI/ISO 11135.	Same
Style	Non-reinforced/Reinforced	Non-reinforced	Reinforced	Different
Durability	Disposable	Disposable	Disposable	Same
Color	Blue	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Weight per	Level 4 Standard Surgical	68 g/m^2	45 g/m^2	Different

square (g)	Gown: 45g/m^2 and 20g/m^2 PE film Level 4 Reinforced Surgical Gown: 45g/m^2 and 25g/m^2 PE film reinforced film			
Size	S, M, L, XL, XXL, XXXL	M, L, XL, XXL, XXXL, XXXL-XLONG	XL	Different
Flammability	Class I	Class I	Class I	Same
Hydrostatic pressure	Level 4 Standard Surgical Gown: >50 cm; Level 4 Reinforced Surgical Gown: >50 cm	>50 cm	>20	Same
Water impact	≤1.0 g	≤1.0 g	≤1.0 g	Same
Breaking strength	Level 4 Standard Surgical Gown: latitude: 111 N longitude: 184 N Level 4 Reinforced Surgical Gown: latitude: 109 N longitude: 122 N	latitude: 92.3N longitude: 177.11N	Passed	Different
Tearing strength	Level 4 Standard Surgical Gown: latitude: 90 N longitude: 137 N Level 4 Reinforced Surgical Gown: latitude: 80 N longitude: 137 N	latitude: 35.30N longitude: 56.46N	Passed	Different
Linting	Log_{10}<4	Log_{10}<4	Log_{10}<4	Same
Bacterial Penetration	No detectable transfer of the Phi-X174 Bacteriophage	No detectable transfer of the Phi-X174 Bacteriophage	No detectable transfer of the Phi-X174 Bacteriophage	Same
Barrier protection level	Level 4 per AAMI PB 70	Level 4 per AAMI PB 70	Level 4 per AAMI PB 70	Same
Material	Level 4 Standard Surgical Gown: SMS nonwoven, PE film, Polyester and blue masterbatch; Level 4 Reinforced Surgical Gown: SMS nonwoven,	SMS nonwoven, white knitted cuff, white spunbond, and BVB	SMS and PE+PP two layer compound	Different

	Polyester, PE film reinforced film and Blue masterbatch			
Biocompatibility				
Cytotoxicity	Under the conditions of the study, the device is non-toxic, non-irritating, and non-sensitizing.	No Cytotoxicity No Irritation No Sensitization	Passed	Same
Irritation			Passed	
Sensitization			Passed	
Sterilization	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Ethylene Oxide (EO)	Although sold non-sterile, gowns can be EO Sterilized	Same

Different - Style

The style of the proposed device is different from the predicate device. The proposed device is available in two styles, non-reinforced and reinforced, which can be covered by predicate device K192290 and reference device K121152. The proposed device offers more options that physician can choose based on clinical conditions. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Weight per square

Although the weight per square of the proposed device and the weight per square of the predicate device are different, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrated that the proposed surgical gowns can meet the barrier protection level 4 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Size

The size for the proposed surgical gowns is different from the predicate device. The proposed surgical gowns are available in 6 product sizes, including S, M, L, XL, XXL and XXXL. However, the difference in the size will not affect the device performance. Different size can be selected by surgeon’s condition. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Breaking strength

The longitude and latitude breaking strength of the Level 4 Standard Surgical Gown is larger than that of the predicate device K192290, so it is better than the predicate device. Although the Breaking strength

of the longitude of the Level 4 Reinforced Surgical Gown is smaller than that of the predicate device K192290, according to EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods, the acceptance criteria of breaking strength shall be more than 20N and the test result for Level 4 Reinforced Surgical Gown can meet this acceptance criteria. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Tearing strength

Although the longitude and latitude tear strength of the proposed device is different from that of the predicate device K192290, the longitude and latitude tear strength of the proposed device is larger than that of predicate device K192290, so the tearing strength is better than that of the predicate device K192290. Therefore, although the data are different, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The material for the proposed surgical gowns is different from the predicated device. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

8. Summary of Non-Clinical Tests

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:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test;
- AATCC 42: 2017 Water Resistance: Impact Penetration Test;
- ISO 9073-10: 2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State;
- ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics;
- ASTM D5587: 2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D5034: 2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D737: 2018 Standard Test Method for Air Permeability of Textile Fabrics;
- ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;
- ASTM F88/F88M: 2015 Standard Test Method for Seal Strength of Flexible Barrier Materials;

- ASTM F1929: 2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ISO 10993-7: 2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals;
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ASTM F1671/F1671M-13 Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens

Table 3 Summary of Performance Testing

Name of Testing Methodology	Purpose	Acceptance Criteria	Results
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.	Meets Class 1 requirements	Pass
Hydrostatic Pressure	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	>50 cm	Level 3 Standard Surgical Gown: Average 67cm; Level 4 Standard Surgical Gown: Average 196cm; Level 4 Reinforced Surgical Gown: Average 162cm
Water impact	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≤1.0 g	Level 3 Standard Surgical Gown: Average 0.011g; Level 4 Standard Surgical Gown: Average 0.014g; Level 4 Reinforced Surgical Gown: Average 0.017g
Breaking strength	The test was performed in	>20N	Level 3 Standard Surgical

	accordance with ASTM D 5034:2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.		Gown: Latitude: average 96N; Longitude: average 116N; Level 4 Standard Surgical Gown: Latitude: average 111N; Longitude: average 184N; Level 4 Reinforced Surgical Gown: Latitude: average 109N; Longitude: average 122N
Tearing strength	The test was performed in accordance with ASTM D5587:2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure to evaluate the tearing strength of the test sample.	>20N	Level 3 Standard Surgical Gown: Latitude: average 77N; Longitude: average 128N; Level 4 Standard Surgical Gown: Latitude: average 90N; Longitude: average 137N; Level 4 Reinforced Surgical Gown: Latitude: average 80N; Longitude: average 137N
Linting	The test was performed in accordance with ISO 9073-10:2003 Textiles-Test Methods for Nonwovens-Pat 10: Lint and Other Particles Generation in the Dry State to evaluate the linting of the test sample.	Log10(particle count) < 4	Level 3 Standard Surgical Gown: Average 3.1 Level 4 Standard Surgical Gown: Average 3.0 Level 4 Reinforced Surgical Gown: Average 3.1
Air permeability	The test was performed in accordance with ASTM D737: 2018 Standard Test Method for Air Permeability of Textile Fabrics to evaluate the air permeability of the test sample.	>30 $ft^3/min/ft^2$	Level 3 Standard Surgical Gown: Average 40 $ft^3/min/ft^2$

EO/ECH Residue	The test was performed in accordance with ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals to evaluate the level of sterilant residues.	EO:<4mg/device ECH:<9mg/device	Level 3 Standard Surgical Gown: EO: <0.5μg/device ECH: <0.5μg/device Level 4 Standard Surgical Gown: EO: <0.5μg/device ECH: <0.5μg/device Level 4 Reinforced Surgical Gown: EO: <0.5μg/device ECH: <0.5μg/device

Table 4 Summary of Biocompatibility Testing

Name of Testing Methodology	Purpose	Acceptance Criteria	Results
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test sample.	The viability should be ≥ 70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability was ≥70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test sample.	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.
Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

	evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the test sample.		

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate devices K211422, K192290 and K121152.