September 19, 2022

Winner Medical Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co, Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K221819
Trade/Device Name: 35g Standard SMMS Surgical Gown; 35g Reinforced SMMS Surgical Gown; 43g Standard SMMS Surgical Gown; 43g Reinforced SMMS Surgical Gown; 50g Standard SMMS Surgical Gown; 50g Reinforced SMMS Surgical Gown; BVB Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: May 18, 2022
Received: June 23, 2022

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, M.D., 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

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)*

K221819

Device Name

35g Standard SMMS Surgical Gown, 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown, 50g Reinforced SMMS Surgical Gown, BVB Surgical Gown

Indications for Use *(Describe)*

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, 35g Standard SMMS Surgical Gown met the requirements for Level 2 classification; 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown and 50g Reinforced SMMS Surgical Gown met the requirements for Level 3 classification; BVB Surgical gown met the requirements for Level 4 classification. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to the end users after EtO sterilization validation to ISO 11135-1.

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.

510(k) Summary

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

The assigned 510(k) Number: K221819

1. Date of Preparation: 09/19/2022

2. Sponsor Identification

Winner Medical Co., Ltd.
Winner Industrial Park, No.660 Bulong Road, Longhua District, Shenzhen Guangdong, China 518109

Establishment Registration Number: 9616433

Contact Person: Mingni Liu
Position: Regulatory Affairs
Tel: +86-755-28138888-8822
Email: 2346@winnermedical.com

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: 35g Standard SMMS Surgical Gown;
35g Reinforced SMMS Surgical Gown;
43g Standard SMMS Surgical Gown;
43g Reinforced SMMS Surgical Gown;
50g Standard SMMS Surgical Gown;
50g Reinforced SMMS Surgical Gown;
BVB 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

Indications for Use:

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, 35g Standard SMMS Surgical Gown met the requirements for Level 2 classification; 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown and 50g Reinforced SMMS Surgical Gown met the requirements for Level 3 classification; BVB Surgical gown met the requirements for Level 4 classification. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to the end users after EtO sterilization validation to ISO 11135-1.

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 and non-sterile. For non-sterile surgical gowns, they shall be sterilized by EO prior to use.

The proposed devices are available in two materials, SMMS and BVB. SMMS surgical gowns are available in three gram weights, 35g/m^2, 43g/m^2 and 50 g/m^2, while BVB surgical gown is available only in 64g/m^2. All SMMS surgical gowns are provided in two types, standard and reinforced. And all types of SMMS surgical gown and BVB surgical gown are available in six product sizes, including M, L, LL, XL, XLL and XXL.

The barrier protection level for 35g Standard SMMS Surgical Gown meet AAMI Level 2; The barrier protection level for 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown and 50g Reinforced SMMS Surgical Gown meet AAMI Level 3; The barrier protection level for BVB Surgical gown meet AAMI Level 4.

Table 1. Specification

Proposed device	Size	Gram weight	Color	Style	AAMI Level	Sterilization
35g Standard SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	35 g/m^2	Blue	Standard	2	Sterile/ Non-sterile
35g Reinforced SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	35 g/m^2	Blue	Reinforced	3	Sterile/ Non-sterile
43g Standard SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	43 g/m^2	Blue	Standard	3	Sterile/ Non-sterile
43g Reinforced SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	43 g/m^2	Blue	Reinforced	3	Sterile/ Non-sterile
50g Standard SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	50 g/m^2	Blue	Standard	3	Sterile/ Non-sterile
50g Reinforced SMMS Surgical Gown	M, L, LL, XL, XLL, XXL	50 g/m^2	Blue	Reinforced	3	Sterile/ Non-sterile
BVB Surgical Gown	M, L, LL, XL, XLL, XXL	64 g/m^2	Blue	Standard	4	Sterile/ Non-sterile

5. Identification of Predicate Devices

Predicate Device 1
510K Number: K211422
Trade Name: Level 2 Standard Surgical Gown
Level 3 Standard Surgical Gown
Level 3 Reinforced Surgical Gown

Predicate Device 2
510K Number: K192290
Trade Name: SMS Standard Surgical Gown
SMS Surgical Gown with Reinforcement
BVB Surgical Gown (used as predicate device 2)
BVB Splicing Surgical Gown

6. Summary of Technological characteristics

Table 2. General Comparison for SMMS Surgical Gown

Item	Proposed Device K221819	Predicate Device 1 K211422	Remark
Product Name	35g Standard SMMS Surgical Gown, 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown, 50g Reinforced SMMS Surgical Gown	Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown	/
Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indication for Use	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	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	Same

	barrier performance and classification of protective apparel and drapes intended for use in health care facilities, 35g Standard SMMS Surgical Gown met the requirements for Level 2 classification; 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown and 50g Reinforced SMMS Surgical Gown met the requirements for Level 3 classification.	barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Level 3 standard surgical gowns and Level 3 reinforced surgical gowns met the requirements for Level 3 classification.	
Style	Standard/Reinforced	Non-reinforced/Reinforced	Same
Use	Single use, disposable	Single use, disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 3. Safety and Effectiveness Comparison for SMMS Surgical Gown

Item	Proposed Device K221819	Predicate Device 1 K211422	Remark
Product Name	35g Standard SMMS Surgical Gown, 35g Reinforced SMMS Surgical Gown, 43g Standard SMMS Surgical Gown, 43g Reinforced SMMS Surgical Gown, 50g Standard SMMS Surgical Gown, 50g Reinforced SMMS Surgical Gown	Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown	/
Weight per square (g)	35g Standard SMMS Surgical Gown and 35g Reinforced SMMS Surgical Gown: 35g/m^2 43g Standard SMMS Surgical Gown and 43g Reinforced SMMS Surgical Gown: 43g/m^2 50g Standard SMMS Surgical Gown and 50g Reinforced SMMS Surgical Gown: 50g/m^2	Level 2 Standard Surgical Gown: 35g/m^2 Level 3 Standard Surgical Gown: 43g/m^2 Level 3 Reinforced Surgical Gown: 35g/m^2 and 28g/m^2	Different
Size	M, L, LL, XL, XLL, XXL	XS, S, M, L, XL, XXL, XXXL	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	35g Standard SMMS Surgical Gown (Non-sterile): Average 40.57cm;	Level 2 Standard Surgical Gown: >20 cm;	Different

	35g Standard SMMS Surgical Gown (Sterile): Average 40.21cm; 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 83.53cm; 35g Reinforced SMMS Surgical Gown (Sterile): Average 83.57cm; 43g Standard SMMS Surgical Gown (Non-sterile): Average 60.50 cm; 43g Standard SMMS Surgical Gown (Sterile): Average 60.48 cm; 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 99.59 cm; 43g Reinforced SMMS Surgical Gown (Sterile): Average 98.90 cm; 50g Standard SMMS Surgical Gown (Non-sterile): Average 83.19 cm; 50g Standard SMMS Surgical Gown (Sterile): Average 83.02 cm; 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 108.37 cm; 50g Reinforced SMMS Surgical Gown (Sterile): Average 108.37 cm;	Level 3 Standard Surgical Gown: >50 cm; Level 3 Reinforced Surgical Gown: >50 cm	
Water impact	35g Standard SMMS Surgical Gown (Non-sterile): Average 0.041g; 35g Standard SMMS Surgical Gown (Sterile): Average 0.03g; 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 0.03g; 35g Reinforced SMMS Surgical Gown (Sterile): Average 0.029g; 43g Standard SMMS Surgical Gown (Non-sterile): Average 0.036g; 43g Standard SMMS Surgical Gown (Sterile): Average 0.033g; 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 0.032g; 43g Reinforced SMMS Surgical Gown (Sterile): Average 0.032g; 50g Standard SMMS Surgical Gown (Non-sterile): Average 0.031g;	≤1.0 g	Different

	50g Standard SMMS Surgical Gown (Sterile): Average 0.034g; 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 0.033g 50g Reinforced SMMS Surgical Gown (Sterile): Average 0.031g		
Breaking strength	35g Standard SMMS Surgical Gown (Non-sterile): Latitude: 108.37N; Longitude: 161.87N; 35g Standard SMMS Surgical Gown (Sterile): Latitude: 108.37N Longitude: 161.87N; 35g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 108.72N Longitude: 161.19N; 35g Reinforced SMMS Surgical Gown (Sterile): Latitude: 108.53N Longitude: 161.31N; 43g Standard SMMS Surgical Gown (Non-sterile): Latitude: 113.34N Longitude: 182.30N; 43g Standard SMMS Surgical Gown (Sterile): Latitude: 113.01N Longitude: 181.05 N; 43g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 113.72N Longitude: 181.14 N; 43g Reinforced SMMS Surgical Gown (Sterile): Latitude: 112.60N Longitude: 181.26N; 50g Standard SMMS Surgical Gown (Non-sterile):	>20N	Different

	Latitude: 137.58N Longitude: 190.87 N; 50g Standard SMMS Surgical Gown (Sterile): Latitude: 137.77N Longitude: 188.30 N; 50g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 138.02N Longitude: 191.32N; 50g Reinforced SMMS Surgical Gown (Sterile): Latitude: 138.39N Longitude: 190.07 N;		
Tearing strength	35g Standard SMMS Surgical Gown (Non-sterile): Latitude: 32.49 N Longitude: 39.67 N; 35g Standard SMMS Surgical Gown (Sterile): Latitude: 32.31N Longitude: 39.81N; 35g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 32.44N Longitude: 39.67N; 35g Reinforced SMMS Surgical Gown (Sterile): Latitude: 32.55N Longitude: 39.92N; 43g Standard SMMS Surgical Gown (Non-sterile): Latitude: 33.99N Longitude: 41.40N; 43g Standard SMMS Surgical Gown (Sterile): Latitude: 33.92N Longitude: 41.75N; 43g Reinforced SMMS Surgical Gown (Non-sterile)	>20N	Different

	Latitude: 34.09N Longitude: 41.51; 43g Reinforced SMMS Surgical Gown (Sterile): Latitude: 34.01N Longitude: 41.18N;50g Standard SMMS Surgical Gown (Non-sterile): Latitude: 44.02N Longitude: 54.18N; 50g Standard SMMS Surgical Gown (Sterile): Latitude: 44.36N Longitude: 54.07N; 50g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 43.93N Longitude: 53.96N; 50g Reinforced SMMS Surgical Gown (Sterile): Latitude: 44.30N Longitude: 54.25N;		
Seam strength	35g Standard SMMS Surgical Gown (Non-sterile): Average 41.90N 35g Standard SMMS Surgical Gown (Sterile): Average 42.21N 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 41.75N 35g Reinforced SMMS Surgical Gown (Sterile): Average 41.74N 43g Standard SMMS Surgical Gown (Non-sterile): Average 44.51N 43g Standard SMMS Surgical Gown (Sterile): Average 44.56N 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 44.55N 43g Reinforced SMMS Surgical Gown (Sterile): Average 44.34N 50g Standard SMMS Surgical Gown (Non-sterile): Average 50.52N	>30N	Different

	50g Standard SMMS Surgical Gown (Sterile): Average 50.45N 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 50.45N 50g Reinforced SMMS Surgical Gown (Sterile): Average 50.57N		
Linting	Log10(particle count) <4	Log10(particle count) <4	Same
Air permeability	>30 $ft^3/min/ft^2$	>30 $ft^3/min/ft^2$	Same
Barrier protection level	Level 2 and 3 per AAMI PB 70	Level 2 and 3 per AAMI PB 70	Same
Material	Standard SMMS Surgical Gown: Non-woven SMMS Fabric, Polyester, Mixing polyester with nylon Reinforced SMMS Surgical Gown: Non-woven SMMS Fabric, Polyester, Mixing polyester with nylon, PP and PE fabric	Level 2 Standard Surgical Gown and Level 3 Standard Surgical Gown: SMS nonwoven, Polyester and Polyamide; Level 3 Reinforced Surgical Gown: SMS nonwoven, Polyester, Polyamide and Hydrophilic nonwoven	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/Non-sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Different
Ethylene Oxide Residuals	EO:<4mg/device ECH:<9mg/device	EO:<4mg/device ECH:<9mg/device	Same

Different - Weight per square

The weight per square for the proposed device is different from the predicate device K211422. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrated that the proposed devices can meet the barrier protection level 2 and 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 device is different from the predicate device K211422. The proposed devices are available in 6 product sizes, including M, L, LL, XL, XLL and XXL. 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 - Hydrostatic pressure

The hydrostatic pressure for the proposed device is different from the predicate device K211422. However, the hydrostatic pressure test has been conducted on the proposed device and the results demonstrate that the proposed devices can meet the barrier protection level 2 and level 3 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Water impact

The water impact for the proposed device is different from the predicate device K211422. However, the water impact test has been conducted on the proposed device and the results demonstrate that the proposed devices can meet the barrier protection level 2 and level 3 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Breaking strength

The breaking strength for the proposed device is different from the predicate device K211422. However, the breaking strength test was conducted on the proposed device and the testing results demonstrate that the breaking strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Tearing strength

The tearing strength for the proposed device is different from the predicate device K211422. However, the tearing strength test was conducted on the proposed device and the testing results demonstrate that the tearing strength of the proposed device meets ASTM F2407-20's requirement of greater than 10N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Seam strength

The seam strength for the proposed device is different from the predicate device K211422. However, the seam strength test was conducted on the proposed device and the testing results demonstrate that the seam strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The material for the proposed device is different from the predicate device K211422. 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.

Different - Sterilization

The proposed devices are available in two sterilization states, sterile and non-sterile, while the predicate device K211422 is only available in sterilized state. However, the non-sterilized surgical gown is required to be used after sterilization, and the recommended sterilization parameters for non-sterilized surgical gowns are the same as sterilized surgical gowns. The performance test report after sterilization shows that the proposed device is acceptable. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Table 4. General Comparison for BVB Surgical Gown

Item	Proposed Device K221819	Predicate Device 2 K192290	Remark
Product Name	BVB Surgical Gown	BVB Surgical Gown	/
Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indication for Use	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, BVB Surgical gown met the requirements for 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.	Same
Style	Non-reinforced	Non-reinforced	Same
Use	Single use, disposable	Single use, disposable	Same

Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 5. Safety and Effectiveness Comparison for BVB Surgical Gown

Item	Proposed Device K221819	Predicate Device 2 K192290	Remark
Product Name	BVB Surgical Gown	BVB Surgical Gown	/
Weight per square (g)	64g/m^2	68g/m^2	Different
Size	M, L, LL, XL, XLL, XXL	M, L, XL, XXL, XXXL, XXXL-XLONG	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cm	>50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same
Breaking strength	BVB Surgical Gown (Non-sterile): Latitude: 148.44N Longitude: 236.60N BVB Surgical Gown (Sterile): Latitude:148.93N Longitude: 237.72 N	Latitude: 92.3N Longitude: 177.11N	Different
Tearing strength	BVB Surgical Gown (Non-sterile): Latitude: 49.76N Longitude: 53.97N BVB Surgical Gown (Sterile): Latitude: 49.23N Longitude: 53.98 N	Latitude: 35.30N longitude: 56.46N	Different
Seam strength	BVB Surgical Gown (Non-sterile): 70.27N BVB Surgical Gown (Sterile): 70.35N	>70N	Different
Linting	Log10(particle count) <4	Log10(particle count) <4	Same
Viral barrier (resistance to bacteriophage Phi-X174)	Pass	Pass	Same
Barrier protection level	Level 4 per AAMI PB 70	Level 4 per AAMI PB 70	Same
Material	Standard SMMS Surgical Gown: Non-woven SMMS Fabric, Polyester,	SMS nonwoven, white knitted cuff, white spunbond and BVB	Different

	Mixing polyester with nylon Reinforced SMMS Surgical Gown: Non-woven SMMS Fabric, Polyester, Mixing polyester with nylon, PP and PE fabric		
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/Non-sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Different
Ethylene Oxide Residuals	EO:<4mg/device ECH:<9mg/device	EO:<4mg/device ECH:<9mg/device	Same

Different - Weight per square

The weight per square for the proposed device is different from the predicate device K192290. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrated that the proposed devices 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 device is different from the predicate device K192290. The proposed devices are available in 6 product sizes, including M, L, LL, XL, XLL and XXL. 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 breaking strength for the proposed device is different from the predicate device K192290. The breaking strength refers to the ability of the surgical gown to withstand destructive force. The greater the breaking strength value, the stronger the ability to withstand destructive force. The latitude and longitude breaking strength for the proposed device is larger than the predicate device. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Tearing strength

The tearing strength for the proposed device is similar to the predicate device K192290. And the tearing strength testing results demonstrate that the tearing strength of the proposed device meets ASTM

F2407-20's requirement of greater than 10N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Seam strength
The seam strength for the proposed device is different from the predicate device K192290. However, the seam strength was conducted on the proposed device and the testing results demonstrate that the seam strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material
The material for the proposed device is different from the predicate device K192290. 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.

Different - Sterilization
The proposed devices are available in two sterilization states, sterile and non-sterile, while the predicate device K192290 is only available in sterilized state. However, the non-sterilized surgical gown is required to be used after sterilization, and the recommended sterilization parameters for non-sterilized surgical gowns are the same as sterilized surgical gowns. The performance test report after sterilization shows that the proposed device is acceptable. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate devices. 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: 2018 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 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;
- ISO 10993-1: 2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 11607-1: 2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2019 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1671/F1671M-13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System
- ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Table 6. Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria	Result
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	Class 1
Hydrostatic pressure	The test was performed in accordance with AATCC 127: 2018 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	Level 2 Surgical Gown: >20 cm H_2O; Level 3 Surgical Gown: >50 cm H_2O; Level 4 Surgical Gown: >50 cm H_2O;	35g Standard SMMS Surgical Gown (Non-sterile): Average 40.57cm; 35g Standard SMMS Surgical Gown (Sterile): Average 40.21cm; 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 83.53cm;

			35g Reinforced SMMS Surgical Gown (Sterile): Average 83.57cm; 43g Standard SMMS Surgical Gown (Non-sterile): Average 60.50 cm; 43g Standard SMMS Surgical Gown (Sterile): Average 60.48 cm; 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 99.59 cm; 43g Reinforced SMMS Surgical Gown (Sterile): Average 98.90 cm; 50g Standard SMMS Surgical Gown (Non-sterile): Average 83.19 cm; 50g Standard SMMS Surgical Gown (Sterile): Average 83.02 cm; 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 108.37 cm; 50g Reinforced SMMS Surgical Gown (Sterile): Average 108.37 cm; BVB Surgical Gown (Non-sterile): Average 161.71 cm; BVB Surgical Gown (Sterile): Average 162.11 cm
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;	35g Standard SMMS Surgical Gown (Non-sterile): Average 0.041g; 35g Standard SMMS Surgical Gown (Sterile): Average 0.03g; 35g Reinforced SMMS Surgical Gown (Non-sterile): Average

			0.03g; 35g Reinforced SMMS Surgical Gown (Sterile): Average 0.029g; 43g Standard SMMS Surgical Gown (Non-sterile): Average 0.036g; 43g Standard SMMS Surgical Gown (Sterile): Average 0.033g; 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 0.032g; 43g Reinforced SMMS Surgical Gown (Sterile): Average 0.032g; 50g Standard SMMS Surgical Gown (Non-sterile): Average 0.031g; 50g Standard SMMS Surgical Gown (Sterile): Average 0.034g; 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 0.033g 50g Reinforced SMMS Surgical Gown (Sterile): Average 0.031g; BVB Surgical Gown (Non-sterile): Average 0.078g; BVB Surgical Gown (Sterile): Average 0.079g
Breaking strength	The test was performed in 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.	≥30N	35g Standard SMMS Surgical Gown (Non-sterile): Latitude: 108.37N; Longitude: 161.87N; 35g Standard SMMS Surgical Gown (Sterile): Latitude: 108.37N Longitude: 161.87N; 35g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 108.72N Longitude: 161.19N;

			35g Reinforced SMMS Surgical Gown (Sterile): Latitude: 108.53N Longitude: 161.31N; 43g Standard SMMS Surgical Gown (Non-sterile): Latitude: 113.34N Longitude: 182.30N; 43g Standard SMMS Surgical Gown (Sterile): Latitude: 113.01N Longitude: 181.05 N; 43g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 113.72N Longitude: 181.14 N; 43g Reinforced SMMS Surgical Gown (Sterile): Latitude: 112.60N Longitude: 181.26N; 50g Standard SMMS Surgical Gown (Non-sterile): Latitude: 137.58N Longitude: 190.87 N; 50g Standard SMMS Surgical Gown (Sterile): Latitude: 137.77N Longitude: 188.30 N; 50g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 138.02N Longitude: 191.32N; 50g Reinforced SMMS Surgical Gown (Sterile): Latitude: 138.39N Longitude: 190.07 N; BVB Surgical Gown (Non-sterile): Latitude: 148.44N Longitude: 236.60N

			BVB Surgical Gown (Sterile): Latitude:148.93N Longitude: 237.72 N
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.	≥10N	35g Standard SMMS Surgical Gown (Non-sterile): Latitude: 32.49 N Longitude: 39.67 N; 35g Standard SMMS Surgical Gown (Sterile): Latitude: 32.31N Longitude: 39.81N; 35g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 32.44N Longitude: 39.67N; 35g Reinforced SMMS Surgical Gown (Sterile): Latitude: 32.55N Longitude: 39.92N; 43g Standard SMMS Surgical Gown (Non-sterile): Latitude: 33.99N Longitude: 41.40N; 43g Standard SMMS Surgical Gown (Sterile): Latitude: 33.92N Longitude: 41.75N; 43g Reinforced SMMS Surgical Gown (Non-sterile) Latitude: 34.09N Longitude: 41.51; 43g Reinforced SMMS Surgical Gown (Sterile): Latitude: 34.01N Longitude: 41.18N;50g Standard SMMS Surgical Gown (Non-sterile): Latitude: 44.02N Longitude: 54.18N; 50g Standard SMMS Surgical

			Gown (Sterile): Latitude: 44.36N Longitude: 54.07N; 50g Reinforced SMMS Surgical Gown (Non-sterile): Latitude: 43.93N Longitude: 53.96N; 50g Reinforced SMMS Surgical Gown (Sterile): Latitude: 44.30N Longitude: 54.25N; BVB Surgical Gown (Non-sterile): Latitude: 49.76N Longitude: 53.97N BVB Surgical Gown (Sterile): Latitude: 49.23N Longitude: 53.98 N
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	35g Standard SMMS Surgical Gown (Non-sterile): Average 2.89; 35g Standard SMMS Surgical Gown (Sterile): Average 2.89; 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 2.89; 35g Reinforced SMMS Surgical Gown (Sterile): Average 2.90; 43g Standard SMMS Surgical Gown (Non-sterile): Average 2.50; 43g Standard SMMS Surgical Gown (Sterile): Average 2.47; 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 2.47; 43g Reinforced SMMS Surgical Gown (Sterile): Average 2.54; 50g Standard SMMS Surgical Gown (Non-sterile): Average

			2.50; 50g Standard SMMS Surgical Gown (Sterile): Average 2.51; 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 2.47; 50g Reinforced SMMS Surgical Gown (Sterile): Average 2.48; BVB Surgical Gown (Non-sterile): Average 2.54; BVB Surgical Gown (Sterile): 2.52
Seam strength	The test was performed in accordance with ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics to evaluate the seam strength of the test sample.	≥30N	35g Standard SMMS Surgical Gown (Non-sterile): Average 41.90N 35g Standard SMMS Surgical Gown (Sterile): Average 42.21N 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 41.75N 35g Reinforced SMMS Surgical Gown (Sterile): Average 41.74N 43g Standard SMMS Surgical Gown (Non-sterile): Average 44.51N 43g Standard SMMS Surgical Gown (Sterile): Average 44.56N 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 44.55N 43g Reinforced SMMS Surgical Gown (Sterile): Average 44.34N 50g Standard SMMS Surgical Gown (Non-sterile): Average 50.52N 50g Standard SMMS Surgical Gown (Sterile): Average 50.45N 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 50.45N

			50g Reinforced SMMS Surgical Gown (Sterile): Average 50.57N BVB Surgical Gown (Non-sterile): 70.27N BVB Surgical Gown (Sterile): 70.35N
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 $ft^3/min/ft^2$	35g Standard SMMS Surgical Gown (Non-sterile): Average 70.65 $ft^3/min/ft^2$ 35g Standard SMMS Surgical Gown (Sterile): Average 68.89 $ft^3/min/ft^2$ 35g Reinforced SMMS Surgical Gown (Non-sterile): Average 70.67 $ft^3/min/ft^2$ 35g Reinforced SMMS Surgical Gown (Sterile): Average 69.94 $ft^3/min/ft^2$ 43g Standard SMMS Surgical Gown (Non-sterile): Average 65.05 $ft^3/min/ft^2$ 43g Standard SMMS Surgical Gown (Sterile): Average 65.51 $ft^3/min/ft^2$ 43g Reinforced SMMS Surgical Gown (Non-sterile): Average 65.76 $ft^3/min/ft^2$ 43g Reinforced SMMS Surgical Gown (Sterile): Average 66.56 $ft^3/min/ft^2$ 50g Standard SMMS Surgical Gown (Non-sterile): Average 62.03 $ft^3/min/ft^2$ 50g Standard SMMS Surgical Gown (Sterile): Average 62.15 $ft^3/min/ft^2$ 50g Reinforced SMMS Surgical Gown (Non-sterile): Average 62.12 $ft^3/min/ft^2$ 50g Reinforced SMMS Surgical

			Gown (Sterile): Average 62.06 $ft^3/min/ft^2$
Viral barrier (resistance to bacteriophage Phi-X174)	The test was performed in accordance with ASTM F1671/F1671M-13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System evaluate the resistance to bacteriophage penetration	No bacteriophage penetration	For BVB Surgical Gowns only. No bacteriophage penetration
Ethylene Oxide Residuals	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	EO Residue: 0.84 mg/device; ECH Residue: 1.18 mg/device

Table 7. Summary of Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
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	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.

	evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test sample.		
Irritation	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 irritation of the test sample.	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

8. Clinical Test Conclusion

No clinical study is included in this submission.

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 device K211422 for the level 2 and level 3 gowns and K192290 for the level 4 gowns.