December 21, 2022

Xuchang Zhengde Environstar Medical Products Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K213893
Trade/Device Name: Comfort Gown, Safewear Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: November 22, 2022
Received: November 30, 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,

Allan Guan -S

For 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)*
K213893

Device Name
Comfort Gown, Safewear 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, Comfort Gown met the requirements for Level 1 and Level 2 Standard Surgical Gown classifications, and Safewear Gown met the requirements for Level 3 Standard Surgical Gown, Level 3 Standard Plus Surgical Gown, Level 3 Reinforced Surgical Gown and Level 3 Reinforced Plus Surgical Gown classifications.

The gowns are provided sterile and non-sterile. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

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: K213893

1. Date of Preparation: 12/20/2022

2. Sponsor Identification

Xuchang Zhengde Environstar Medical Products Co., Ltd.
Area B, Baihua Road East, South Side of Erji river, Industry Cluster District, Yanling County, 461200 Xuchang, Henan, CHINA

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Comfort Gown, Safewear 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, Comfort Gown met the requirements for Level 1 and Level 2 Standard Surgical Gown classifications, and Safewear Gown met the requirements for Level 3 Standard Surgical Gown, Level 3 Standard Plus Surgical Gown, Level 3 Reinforced Surgical Gown and Level 3 Reinforced Plus Surgical Gown classifications. The gowns are provided sterile and non-sterile.
Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135

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 can be provided in sterile and non-sterile.

There are two types of surgical gown: Comfort Gown and Safewear Gown. And each type of surgical gown is available in five product sizes, including M, L, XL, XXL and XXXL.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Comfort Gown include Level 1 standard surgical gown which met the requirements for Level 1 classification, and Level 2 standard surgical gown which

met the requirements for Level 2 classification. It is made of the same material and is classified as Level 1 and Level 2 standard surgical gowns based on marketing reasons.

Safewear gown include Level 3 standard surgical gown, Level 3 standard plus surgical gown, Level 3 reinforced surgical gown and Level 3 reinforced plus surgical gown, which all met the requirements for AAMI Level 3. The four Level 3 surgical gowns differ in the weight of non-woven and whether there are reinforcements, which is 45g/m^2 and 50g/m^2 for Level 3 standard surgical gown, 50g/m^2 for Level 3 standard plus surgical gown, 35g/m^2 for Level 3 reinforced surgical gown with 35g/m^2 PE breathable film reinforcement and 45g/m^2 for Level 3 reinforced plus surgical gown with 35g/m^2 PE breathable film reinforcement. Detailed specifications for the proposed device are shown in the table below.

Table1 Specification of Surgical Gown

Proposed device	Type	Size	Style	AAMI Level
Comfort Gown	Level 1 Standard Surgical Gown	M, L, XL, XXL, XXXL	Non-reinforced	1
	Level 2 Standard Surgical Gown	M, L, XL, XXL, XXXL	Non-reinforced	2
Safewear Gown	Level 3 Standard Surgical Gown	M, L, XL, XXL, XXXL	Non-reinforced	3
	Level 3 Standard Plus Surgical Gown	M, L, XL, XXL, XXXL	Non-reinforced	3
	Level 3 Reinforced Surgical Gown	M, L, XL, XXL, XXXL	Reinforced	3
	Level 3 Reinforced Plus Surgical Gown	M, L, XL, XXL, XXXL	Reinforced	3

5. Identification of Predicate Devices

6. Predicate Device 1
510(k) Number: K192290
Product Name: SMS Standard Surgical Gown, SMS Surgical Gown with Reinforcement, BVB Surgical Gown, BVB Splicing Surgical Gown

Predicate Device 2
510(k) Number: K172987
Product Name: Surgical Gown (used AE series as predicate device)

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 device. 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 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;

Table2 Summary of Performance Testing

Test Methodology	**Test 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 Class1 requirements	Class 1
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.	Level 2 Surgical Gown: >20 cm H_2O; Level 3 Surgical Gown: >50 cm H2O; AQL 4.0	Level 2 Standard Surgical Gown: PASS; Level 3 Standard Surgical Gown: PASS; Level 3 Standard Plus Surgical Gown: PASS; Level 3 Reinforced Surgical Gown: PASS; Level 3 Reinforced Plus Surgical Gown: PASS
Water impact	The test was performed in	≤1.0 g	Level 2 Standard Surgical

	accordance with AATCC 42:2017 Water resistance: impact penetration test to determine the hydrostatic pressure of the test sample.	AQL 4.0	Gown: PASS; Level 3 Standard Surgical Gown: PASS; Level 3 Standard Plus Surgical Gown: PASS; Level 3 Reinforced Surgical Gown: PASS; Level 3 Reinforced Plus Surgical Gown: PASS;
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	Level 2 Standard Surgical Gown: MACHINE DIRECTION:101.4N CROSS DIRECTION:66.6N Level 3 Standard Surgical Gown: MACHINE DIRECTION:101.4N CROSS DIRECTION:66.6N Level 3 Standard Plus Surgical Gown: MACHINE DIRECTION:107.7N CROSS DIRECTION:61.6N Level 3 Reinforced Surgical Gown: MACHINE DIRECTION:101.4N CROSS DIRECTION:66.6N Level 3 Reinforced Plus Surgical Gown: MACHINE DIRECTION:120.0N CROSS DIRECTION:101.1N
Tearing	The test was performed in	≥10N	Level 2 Standard Surgical

strength	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.		Gown: MACHINE DIRECTION:36.0N CROSS DIRECTION:21.5N Level 3 Standard Surgical Gown: MACHINE DIRECTION:35.9N CROSS DIRECTION:22.8N Level 3 Standard Plus Surgical Gown: MACHINE DIRECTION:44.1N CROSS DIRECTION:30.8N Level 3 Reinforced Surgical Gown: MACHINE DIRECTION:36.0N CROSS DIRECTION:21.5N Level 3 Reinforced Plus Surgical Gown: MACHINE DIRECTION:45.9N CROSS DIRECTION:28.8N
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	Level 2 Standard Surgical Gown: Average 37.4N; Level 3 Standard Surgical Gown: Average 36.9N; Level 3 Standard Plus Surgical Gown: Average 111.8N; Level 3 Reinforced Surgical Gown:

			Average 37.5N; Level 3 Reinforced Plus Surgical Gown: Average 116.1N
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 2 Standard Surgical Gown: Average 2.97; Level 3 Standard Surgical Gown: Average 2.97; Level 3 Standard Plus Surgical Gown: Average 2.94; Level 3 Reinforced Surgical Gown: Average 2.97; Level 3 Reinforced Plus Surgical Gown: Average 2.99
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 $ft^3/min/ft^2$ (>15 $cm^3/s/cm^2$)	Level 2 Standard Surgical Gown: Average 40.55 $ft^3/min/ft^2$ (20.60 $cm^3/s/cm^2$); Level 3 Standard Surgical Gown: Average 33.85 $ft^3/min/ft^2$ (17.20 $cm^3/s/cm^2$); Level 3 Standard Plus Surgical Gown: Average 32.68 $ft^3/min/ft^2$ (16.60 $cm^3/s/cm^2$); Level 3 Reinforced Surgical Gown: Average 40.55 $ft^3/min/ft^2$ (20.60 $cm^3/s/cm^2$); Level 3 Reinforced Plus Surgical Gown: Average 34.84 $ft^3/min/ft^2$ (17.70 $cm^3/s/cm^2$)

Table3 Summary of Biocompatibility Testing

Test Method	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 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. Summary of Technological characteristics

Table4 General Comparison for Comfort Gown

Item	Proposed Device K213893	Predicate Device 2 K172987	Remark
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, the comfort gown met the requirements for Level 2 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 AE series surgical gowns met the requirements for Level 2 classification.	Same
Style	Non-reinforced	Non-reinforced/Reinforced	Different
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Weight per square (g)	35g/m^2	44g/m^2	Different
Size	M, L, XL, XXL, XXXL	XL	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	>20 cm;	AE series: >20 cm;	Same
Water impact	≤1.0 g	≤1.0 g	Same
Breaking strength	≥30N	≥20N	Different
Tearing strength	≥10N	>30N	Different
Seam	≥30N	≥30N	Same

strength			
Linting	$Log_{10} \leq 4$	$Log_{10} < 4$	Same
Air permeability	>30 $ft^3/min/ft^2$	>30 $ft^3/min/ft^2$	Same
Barrier protection level	Level 1/Level 2 per AAMI PB 70	Level 2 per AAMI PB 70	Different
Material	SMS nonwoven, Polyester, Polyamide;	SMMMS, Polypropylene, Polyethylene, Polyester	Different
Cytotoxicity	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
Irritation			
Sensitization			
Sterilization	Sterile/Non-Sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Non-sterile	Different

Different - Weight per square

The weight per square for the proposed surgical gowns is different from the predicate device K172987. 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 requirements as required by PB70. Therefore, this difference will not raise any safety issues.

Different - Size

The size for the proposed surgical gowns is different from the predicate device K172987. The proposed surgical gowns are available in 5 product sizes, including 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 breaking strength for the proposed surgical gowns is different from the predicate device K172987, however, the breaking strength of the proposed device is large than the predicate device. It can be considered that the proposed device showed a better performance to resist breaking. Therefore, this difference will not raise any safety issues.

Different – Tearing strength

The tearing strength for the proposed surgical gowns is different from the predicate device K172987, the tearing strength of the proposed device is less than the predicate device. The proposed acceptance criteria not less than 10N was sourced from ASTM F2407. In addition, the test result demonstrated the proposed device can meet the acceptance criteria. Therefore, this difference will not raise any safety issues.

Different – Barrier protection level

The barrier protection level of proposed device is not same as the predicate device K172987, the proposed Comfort Gown is available in level 1 and level 2 two protection levels. These two levels gowns are exactly same and classified as Level 1 and Level 2 standard surgical gowns based on marketing reasons. The level 2 can be covered by the predicate device K172987. Although the level 1 is not covered by the predicate device K172987, since the proposed level 1 and level 2 gowns are same, therefore, this difference will not raise any safety issues. In addition, the performance testing results demonstrated that the proposed surgical gowns can meet the barrier protection requirements as required by PB70.

Different - Material

The material for the proposed surgical gowns is different from the predicated device. However, the biocompatibility for proposed device was evaluated and the results showed no adverse effect. Therefore, this difference will not raise any safety issues.

Different – Sterilization

The product status of the proposed device is different from the predicate device. The proposed device can be provided in sterile and non-sterile, and the predicate device is non-sterilized. However, although the predicate device is non-sterile, it shall be further sterilized prior to use. In addition, sterilization process for the proposed device has been validated per ISO 11135 and the result demonstrated that sterilization method is valid. Therefore, this difference will not raise any safety issues.

Table5 General Comparison for level 3 standard surgical gown & level 3 standard plus surgical gown of Safewear Gown

Item	Proposed Device K213893	Predicate Device 1 K192290	Remark
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, the Level 3 Standard Surgical Gown and level 3 Standard Plus Surgical Gown met the requirements for Level 3 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.	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 +50 g/m^2, 50g/m^2;	50g/m^2	Different
Size	M, L, XL, XXL, XXXL	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	≥30N	cross direction: 61.17N machine direction: 107.35N	Different
Tearing	≥10N	cross direction: 19.71N,	Different

strength		machine direction: 62.28N	
Seam strength	≥30N	≥30N	Same
Linting	Log_{10}<4	Log_{10}<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 nonwoven, Polyester, Polyamide;	SMS nonwoven, Polyester, Polyamide;	Same
Cytotoxicity	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
Irritation			
Sensitization			
Sterilization	Sterile/Non-Sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Different

Different - Weight per square

The weight per square for the proposed surgical gowns 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 surgical gowns can meet the barrier protection requirements as required by PB70. Therefore, this difference will not raise any safety issues.

Different - Size

The size for the proposed surgical gowns is different from the predicate device K192290. The proposed surgical gowns are available in 5 product sizes, including 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 breaking strength for the proposed surgical gowns is different from the predicate device K192290. The proposed acceptance criteria not less than 30N was sourced from ASTM F2407. In addition, the test result demonstrated the proposed device can meet the acceptance criteria. Therefore, this difference will not raise any safety issues.

Different – Tearing strength

The tearing strength for the proposed surgical gowns is different from the predicate device K192290, the tearing strength of the proposed device is less than the predicate device. The proposed acceptance criteria not less than 10N was sourced from ASTM F2407. In addition, the test result demonstrated the proposed device can meet the acceptance criteria. Therefore, this difference will not raise any safety issues.

Different – Sterilization

The product status of the proposed device is different from the predicate device. The proposed device can be provided in sterile and non-sterile, and the predicate device is non-sterilized. However, although the predicate device is non-sterile, it shall be further sterilized prior to use. In addition, sterilization process for the proposed device has been validated per ISO 11135 and the result demonstrated that sterilization method is valid. Therefore, this difference will not raise any safety issues.

Table6 General Comparison for level 3 reinforced surgical gown & Level 3 reinforced plus surgical gown of Safewear Gown

Item	Proposed Device K213893	Predicate Device 1 K192290	Remark
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, the Level 3 Reinforced Surgical Gown and Level 3 reinforced plus surgical gown met the requirements for Level 3 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.	Same
Style	Reinforced	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)	45 g/m^2, $35g/m^2$	$45g/m^2$	Different
Size	M, L, XL, XXL, XXXL	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	≥30N	cross direction: 81.90N machine direction: 110.44N	Different
Tearing	≥10N	cross direction: 25.32N	Different

strength		machine direction: 45.3N	
Seam strength	≥30N	≥30N	Same
Linting	Log_{10}<4	Log_{10}<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 nonwoven, Polyester, Polyamide, LOCTITE LIOFOL LA 3720, PE breathable film;	SMS nonwoven, Polyester, Polyamide, LOCTITE LIOFOL LA 3720, PE breathable film;	Same
Cytotoxicity	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
Irritation			
Sensitization			
Sterilization	Sterile/Non-Sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Different

Different - Weight per square

The weight per square for the proposed surgical gowns 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 surgical gowns can meet the barrier protection requirements as required by PB70. Therefore, this difference will not raise any safety issues.

Different - Size

The size for the proposed surgical gowns is different from the predicate device K192290. The proposed surgical gowns are available in 5 product sizes, including 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 breaking strength for the proposed surgical gowns is different from the predicate device K192290. The proposed acceptance criteria not less than 30N was sourced from ASTM F2407. In addition, the test result demonstrated the proposed device can meet the acceptance criteria. Therefore, this difference will not raise any safety issues.

Different – Tearing strength

The tearing strength for the proposed surgical gowns is different from the predicate device K192290, the tearing strength of the proposed device is less than the predicate device. The proposed acceptance criteria not less than 10N was sourced from ASTM F2407. In addition, the test result demonstrated the proposed device can meet the acceptance criteria. Therefore, this difference will not raise any safety issues.

Different – Sterilization

The product status of the proposed device is different from the predicate device. The proposed device can be provided in sterile and non-sterile, and the predicate device is non-sterilized. However, although the predicate device is non-sterile, it shall be further sterilized prior to use. In addition, sterilization process for the proposed device has been validated per ISO 11135 and the result demonstrated that sterilization method is valid. Therefore, this difference will not raise any safety issues.

10. 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 K172987 and K192290.