March 12, 2023

3A Medical Products Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K222456
Trade/Device Name: High Protection Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: February 6, 2023
Received: February 8, 2023

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

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)*
K222456

Device Name
High Protection Surgical Gown

Indications for Use *(Describe)*
High protection 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 high protection surgical gown met the requirements for 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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510(k) Summary K222456

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

The assigned 510(k) Number: K222456

1. Date of Preparation: 02/07/2023

2. Sponsor Identification

3A MEDICAL PRODUCTS CO., LTD
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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: High Protection 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:

High protection 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 high protection surgical gown met the requirements for Level 4 classification.

Device Description:

The proposed device 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. The proposed device is single use, disposable medical device and is provided in sterile. The proposed device is available in five product sizes, including S, M, L, XL, XXL. The barrier protection level for high protection surgical gowns meet AAMI Level 4.

5. Identification of Predicate Device

510(k) Number: K212869
Product Name: Disposable Surgical Gown ML515M45U
Disposable Surgical Gown GD524ME65 (Selected as the predicate device)
Disposable Reinforced Surgical Gown

6. Identification of Reference Device

510(k) Number: K221819

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;
BVB Surgical Gown (Sterile status was selected as the reference device)

7. Summary of Non-Clinical Test

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: 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 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 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;

Table 1 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: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≥50 cm H_2O	204.6 cm H_2O
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	0.02g
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.	≥30 N	Longitude:131.5N Latitude:75.2N
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.	≥10 N	Longitude:79.0N; Latitude:33.8N
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.	Log_{10}(particle count) < 4	Side A:3.1 Side B:3.2
Seam strength	The test was performed in accordance with ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven	≥30 N	Shoulder Seam:126.5N Sleeve Seam:76.7N Armhole Seam:75.3N

	Fabrics to evaluate the seam strength of the test sample.		
Resistance against penetration of Phi-X174 bacteriophage	The test was performed in accordance with ASTM F 2407-2020 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	No detectable transfer of the Phi-X174 Bacteriophage	No detectable transfer of the Phi-X174 Bacteriophage
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	The Method Detection Limit (MDL) of EO residue and ECH residue is 0.093mg/device. The total EO residue and ECH residue of the devices were less than the MDL.

Table 2 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 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	Non-irritating	Under the conditions of the study, the proposed device was

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

8. Summary of Clinical Test

No clinical study is included in this submission.

9. Summary of Technological characteristics

Table 3 General Comparison

Item	Proposed Device	Predicate Device K212869	Reference Device K221819	Remark
Product Name	High protection surgical gown	Disposable Surgical Gown GD524ME65	BVB Surgical Gown (Sterile)	/
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	High protection 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 high	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	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	Different

	protection surgical gown met the requirements for Level 4 classification.	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.	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.	
Style	Non-reinforced	Non-reinforced	Non-reinforced	Same
Durability	Single use, Disposable	Single use, Disposable	Single use, Disposable	Same
Color	Blue	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Different - Indication for Use

The predicate device and reference device are available in many types. The type GD524ME65 in K212869 is selected as the predicate device, and the BVB Surgical Gown (Sterile) in K221819 is

selected as the reference device. The indications for use for the proposed device, predicate device and reference device are the same.

Table 4 Safety and Effectiveness Comparison

Item	Proposed Device	Predicate Device K212869	Reference Device K221819	Remark
Product Name	High protection surgical gown	Disposable Surgical Gown GD524ME65	BVB Surgical Gown (Sterile)	/
Weight per square (g)	80 g/m²	67g/m²	64 g/m²	Different
Size	S, M, L, XL, XXL	S, M, L, XL, XXL, XXXL	M, L, LL, XL, XLL, XXL	Different
Flammability	Class I	Class I	Class I	Same
Hydrostatic pressure	≥50 cm H_2O	>50 cm H_2O	>50 cm H_2O	Same
Water impact	≤1.0 g	≤1.0 g	≤1.0 g	Same
Breaking strength	Longitude:131.5N Latitude:75.2N	Longitude:184 N Latitude:111 N	Longitude: 237.72 N Latitude:148.93N	Different
Tearing strength	Longitude:79.0N; Latitude:33.8N	Longitude:137 N Latitude: 90 N	Longitude: 53.98 N Latitude: 49.23N	Different
Linting	Log_{10}<4	Log_{10}<4	Log_{10}<4	Same
Seam Strength	Shoulder Seam:126.5N Sleeve Seam:76.7N Armhole Seam:75.3N	117N	70.35N	Different
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	Blue SFS 3-Ply Lamination Material, Blue PP Spunbond Nonwoven Fabric, Polyester Fiber and Nylon	SMS nonwoven, PE film, Polyester and blue masterbatch;	Blue BVB fabric, PP non-woven, Polyester and Mixing polyester with nylon	Different
	Biocompatibility			
Cytotoxicity	Under the conditions of the study, the device is	Under the conditions of the study, the device is	Under the conditions of the study, the device is	Same

Irritation Sensitization	non-toxic, non-irritating, and non-sensitizing.	non-toxic, non-irritating, and non-sensitizing.	non-toxic, non-irritating, and non-sensitizing.	
Sterilization	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	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 device is different from the predicate device and reference 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 device 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 and reference device. The proposed devices are available in 5 product sizes, including S, M, L, XL 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 and reference device. Although the longitude and latitude breaking strength of the proposed device are smaller than the predicate device and reference device, the longitude and latitude 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 and reference device. However, the longitude and latitude 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 and reference device. The shoulder seam strength, sleeve seam strength and armhole seam strength were conducted on the proposed device. The sleeve seam strength and armhole seam strength of the proposed device are smaller than the predicate device, while these seam strengths are similar to the reference device. And

these 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 and reference 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.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and perform as well as or better than the legally marketed predicate device K212869.