October 18, 2021

Wuhan Dymex Healthcare Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K211809
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 6, 2021
Received: September 14, 2021

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD
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)*
K211809

Device Name
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, the surgical gown met the requirements for Level 3 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: K211809

1. Date of Preparation: 09/08/2021

2. Sponsor Identification

Wuhan Dymex Healthcare Co., Ltd.
Room 1701, Unit 2, Building 5, Jinsegangwan Phase 5,Dongfeng Avenue, Wuhan, 430000, China.

Establishment Registration Number: 3013006775

Contact Person: Lynn Wu
Position: Sales Manager
Tel: +86-27-85827780
Fax: +86-27-85827780
Email: lynn.w@medlinkindustry.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: 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:

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 surgical gown met the requirements for Level 3 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 devices and are provided in sterile. The surgical gown is available in six product sizes, including S, M, L, XL, XXL and XXXL. The barrier protection level for surgical gown met AAMI Level 3.

5. Identification of Predicate Device

510(k) Number: K172987; GMAX Industries, Inc.
Product Name: Surgical Gown (AE1001, AE2001, AE3001)

6. Technological Characteristics Comparison With The Predicate Device

Table 1. General Comparison

Item	Proposed Device	Predicate Device K172987	Comparison

Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
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, the 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, the AE series surgical gowns met the requirements for Level 2 classification, the AG series surgical gowns met the requirements for Level 3 classification.	Different
Style	Non-reinforced	Non-reinforced/ Fabric-reinforced/ Poly-reinforced	Similar
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Different - Indications for Use

The proposed device and predicate device 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, the proposed device met the requirements for Level 3 classification, while the predicate device met the requirements for Level 2 and Level 3 classification. The indications for use for the proposed device can be covered by the predicate device.

Similar – Style

The style for the proposed device is different from the predicate device. The proposed device is a non-reinforced device, while the predicate device is available in three types, non-reinforced, fabric-

reinforced and poly-reinforced. The style for the proposed device can be covered by the predicate device.

Table 2.Technological Comparison

Item	Proposed Device	Predicate Device K172987	Comparison
Weight per square (g)	43g/m^2	44g/m^2	Different
Size	S, M, L, XL, XXL, XXXL	XL	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cm	AE series: >20 cm; AG series: >50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same
Breaking strength	>20N	≥20N	Same
Tearing strength	>20N	>30N	Different
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 2/Level 3 per AAMI PB 70	Similar
Material	SMS, Polyester, Nylon	SMMMS, Polypropylene, PE(Poly Ethylene), Polyester	Different
Biocompatibility			
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 Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Non-sterile	Different

Different - Weight per square

The weight per square for the proposed device is different from the predicate device.

Different - Size

The size for the proposed device is different from the predicate device. The proposed device is available in 6 product sizes, including S, M, L, XL, XXL and XXXL.

Different - Tearing strength

The tearing strength for the proposed device is different from the predicate device,

Similar - Barrier protection level

The barrier protection level for the proposed device is different from the predicate device.

Different - Material

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

Different - Sterilization

The product status of the proposed device is different from the predicate device. The proposed device is sterilized and the predicate device is non-sterilized.

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(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;

Table 3. Performance Testing

Test Method	Purpose	Acceptance Criteria	Results

Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.	Meets Class 1 requirements	Pass
Hydrostatic pressure	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	>50 cm	Average 72.05 cm
Water impact	The test was performed in accordance with AATCC 42: 2017 Water Resistance: Impact Penetration Test to evaluate the water impact of the test sample.	≤1.0 g	Average 0.45g
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.	>20N	MD: Average 74.88 CD: Average 50.73
Tearing strength	The test was performed in accordance with ASTM D5587:2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure to evaluate the tearing strength of the test sample.	>20N	MD: Average 63.87 CD: Average 34.91
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	Average 3.4
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 $ft^3/min/ft^2$	Average 35.3

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: < 4 mg/device ECH: < 9 mg/device	EO: Average 0.95 mg/device ECH: Average 0.98 mg/device

Table 4. 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. 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 K172987.