September 20, 2022

Unimax Medical Products Co., Ltd.
% Jarvis Wu
Consultant
Shanghai SUNGO Management Consulting Company Limited.
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K221717
Trade/Device Name: Disposable Surgical Gown UM-148
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: August 12, 2022
Received: August 12, 2022

Dear Jarvis Wu:

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.

Submission Number *(if known)*

K221717

Device Name

Disposable Surgical Gown (UM-148)

Indications for Use *(Describe)*

The Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate matter. This is a single use, disposable device, provided sterile.

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

K221717

Document prepared date: 2022/9/15

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical Gown
Common Name: Surgical Gown
Model(s): UM-148

Regulatory Information
Classification Name: Gown, Surgical
Classification: Class II
Product code: FYA
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K212591

Disposable Surgical Gown

Suzhou JaneE Medical Technology Co., Ltd.

D. Intended use /Indications for Use:

The Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate matter. This is a single use, disposable device, provided sterile.

E. Device Description:

The proposed device Disposable Surgical Gown is model UM-148, its body, sleeve and belt are made of SMMS non-woven material, and cuff is made of polyester. The proposed device is available in sizes: S(120×135cm), M(125×140cm), L(130×145cm) and XL(135×150cm). This proposed device can meet the requirements for Level 3 per ANSI/AAMI PB70:2012.

The proposed devices are disposable medical devices and provided in sterile and a blue color.

F. Comparison with predicate device

Device	Predicate Device	Proposed Device	Comparison
Manufacturer	Suzhou JaneE Medical Technology Co., Ltd.	Unimax Medical Products Co., Ltd.	-
510K number	K212591	K221717	-
Product Name	Disposable Surgical Gown	Disposable Surgical Gown	Same
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	Same
Intend use /Indications for Use	The Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate matter. This is a single use, disposable device, provided sterile.	The Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate matter. This is a single use, disposable device, provided sterile.	Same
Material Composition	Polyolefin (Polypropylene) SMS nonwoven	Polyester SMMS non-woven	Similar. No effect on safety or efficacy. Both passed biocompatibility tests.
Sterility	Sterile	Sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same

Color	Blue	Blue	Same
Size	M,L,XL,TL	S,M,L,XL	Similar. No effect on safety or efficacy
Weight per square(g)	Critical Area: 87.8g/m^2 Non-Critical Area: 45.12g/m^2	45g/m^2	Similar. No effect on safety or efficacy. Both passed performance tests.
Tensile (Breaking strength)	MD: 16.18 lbs (72N) CD: 13.26 lbs (59N)	MD: 145.4N CD: 91.4N	Similar. No effect on safety or efficacy. Both passed performance tests.
Tearing Strength	MD:22.25 lbs (99 N) CD:18.20 lbs (81N)	MD: 45.5N CD: 28.2N	Similar. No effect on safety or efficacy. Both passed performance tests.
Seam Strength	Sleeve Seam:68.3N Side Seam:69.7N Belt Seam:71N	52.6N	Similar. No effect on safety or efficacy. Both passed performance tests.
Hydrostatic Pressure(cm) AATCC-127	>50 cm	>50 cm	Same
Water Impact (g) AATCC-42	≤1.0 g	≤1.0 g	Same
Liquid barrier performance	Level 3 AAMI PB70	Level 3 AAMI PB70	Same
Flammability	Class I	Class I	Same
Linting	Log10(particle count) < 4	Log10(particle count) < 4	Same

Evaporative Resistance	< 3 Pa.m²/W.	< 3 Pa.m²/W.	Same
Sterilization method	Ethylene oxide	Ethylene oxide	Same
Ethylene oxide residuals	EO:<4mg/d ECH:<9mg/d	EO:<4mg/d ECH:<9mg/d	Same
Biocompatibility	Under the conditions of the study, the device extract was not cytotoxic. Under the conditions of the study, the non-polar and polar device extracts were not found to be an irritant. Under conditions of the study, the non-polar and polar device extracts were not found to be a sensitizer.		Same

Analysis

The subject surgical gown is similar to the predicate device, in terms of general intended use, performance testing, material composition, and configuration. The tearing strength, breaking strength and seam strength are slightly different from those of the predicate device. The proposed device has been tested according to ASTM D5587-15, ASTM D5034-09 (2017) and ASTM D1683/D1683M-17(2018) respectively, and met the requirements of the standard.

Under the conditions of each study, the subject surgical gowns is non-cytotoxic, non-sensitizing and negligibly irritating per ISO-10993 and have met the requirements of ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities for AAMI Level 3 surgical gowns.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications.The subject surgical gown was assessed for performance using the following Standards and Test Methods. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoints.

Test Methodology	Purpose	Acceptance Criteria	Results
AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities.	The tests were performed to determine the classification of subject surgical gown product.	Level 3: When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure) and all critical zone components shall have a blotter weight gain of no more than 1.0 g and a hydrostatic	Level 3

		resistance of at least 50 cm, with an AQL of 4.0	
ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	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	**PASS** MD: 45.5N CD: 28.2N (Average result from 10 samples)
ASTM D5034-09（2017）Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	The test was performed In accordance with D5034-09（2017）. Standard. Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	≥30N	**PASS** MD: 145.4N CD: 91.4N (Average result from 10 samples)
ASTM D1683M-17 Standard Test Method for Failure in Sewn Seams of Woven Fabrics.	The test was performed In accordance with ASTM D1683M-17 Standard. Test Method for Seam Strength of Textile Fabrics (Grab Test) to evaluate Failure in Sewn Seams of the test sample.	≥30N	**PASS** 52.6N (Average result from 10 samples)
AATCC 42-2013, Water Penetration Resistance: Impact Penetration Test;	The test was performed in accordance with AATCC 42: 2013 Water Resistance: Impact Penetration Test to evaluate the water impact of the test sample.	≤1.0 g	**PASS** 0 g (Average result from 3 nonconsecutive batches)
Evaporative Resistance ASTM F1868-17	The test was performed in accordance with ASTM F1868-17 to evaluate the Evaporative Resistance of the test samples	< 3 Pa.m²/W.	**PASS** 2.36 Pa.m²/W. (Average result from 13 samples)

AATCC 127-2014, Water Resistance: Hydrostatic Pressure Test;	The test was performed in accordance with AATCC 127: 2014 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	>50 cm	**PASS** 65~72 cm (Average result from 3 nonconsecutive batches)
CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles	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 I requirements	**PASS** Class I (Average result from 5 samples)
ISO 9073- 10:2003(E) Lint and Other Particles Generation	The test was performed in accordance with ISO 9073-10: 2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State to evaluate the linting of the test sample.	Log10(particle count) < 4	**PASS** 2.0 (Average result from 13 samples)
ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-irritating, and Non-sensitizing.	**PASS** Under the conditions of the study, the device is non-irritating, and non-sensitizing.
ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-cytotoxic.	**PASS** Under the conditions of the study, the device is non-cytotoxic.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the comparison and analysis above, the subject device, Disposable Surgical Gown(model UM-148), is as safe, as effective, and performs as well as the legally marketed predicate device, Disposable Surgical Gowns cleared under K212591.