October 20, 2022

Xiantao Topmed Nonwoven Protective Products Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Century Avenue
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China

Re: K221977
Trade/Device Name: Disposable Surgical Gown (G4003)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 19, 2022
Received: September 19, 2022

Dear Ivy Wang:

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)*
K221977

Device Name
Disposable Surgical Gown (G4003)

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.
In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/ AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). This is a single use, disposable device, provided sterile.
The surgical gown has six sizes - S, M, L, XL, XXL and XXXL.

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 (K221977)

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Prepared date: 2022-04-28

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical Gown
Common Name: Surgical Gown
Model: G4003

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

C. Predicate device:

K211809
Surgical Gown
Wuhan Dymex Healthcare Co., Ltd.

D. Indications for use of the device:

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.
In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). This is a single use, disposable device, provided sterile.

E. Device Description:

The Disposable surgical gown is composed of collar, body, sleeve and tie. The back is full opening, the neck and waist are laced, the sleeve are made of cotton closure by sewing, and the rest are made of heat sealing. It has been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown.

F. Comparison with predicate device

Table 1 General Comparison

Item	Proposed Device	Predicate Device	Result
510K number	-	K211809	-
Model name	Disposable Surgical Gown	Surgical Gown	Similar
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	Same
Intended 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. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). This is a single use, disposable device, provided sterile.	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.	Same
Style	Non-reinforced	Non-reinforced	Same
Color	Blue	Blue	Same

Use	Single Use, Disposable	Single Use, Disposable	Same

Table 2 Technological comparison

Item	**Proposed Device**	**Predicate Device (K211809)**	**Result**
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL, XXXL	Same
Material	SMMS nonwoven Polypropylene, Cotton, Nylon	SMS, Polyester, Nylon	Different
Weight per square(g)	45g/m^2	43g/m^2	Different
Impact Penetration	<1.0g	<1.0g	Same
Hydrostatic Resistance	>50cmH_2O for critical zone	>50cmH_2O for critical zone	Same
Tensile Strength	MD: average 135.83N CD: average 98.25N	MD: Average 74.88 CD: Average 50.73	Similar
Tear Strength	MD: average 52.03N CD: average 29.15N	MD: Average 63.87 CD: Average 34.91	Similar
Seam Strength	Average 45.18N	Not available	Different
Linting	$Log_{10}\leqslant 4$	$Log_{10}\leqslant 4$	Same
Evaporative Resistance	< 3 Pa.m^2/W	Not available	Different
Flammability	Class 1, Non Flammable	Class 1, Non Flammable	Same
Resistance to blood and liquid penetration	Level 3 per PB70	Level 3 per PB70	Same
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-5	Same
Irritation	Comply with ISO 10993-10	Comply with ISO 10993-10	Same
Sensitization			
Sterility	Sterile	Sterile	Same
Sterilization	EO method SAL: 10^{-6}	EO method SAL: 10^{-6}	Same

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specification as same/similar to the predicate device. The test results demonstrated that the proposed device comply with the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes and the following standards.

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ASTM F2407: 2020 Standard Specification for Surgical Gowns Intended for Use in Healthcare

Facilities

- 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 F1868: 2017 Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate;
- 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 Methodology	**Purpose**	**Acceptance Criteria**	**Result**
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	Pass MD: average 52.03N CD: average 29.15N
Tensile 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	Pass MD: average 135.83N CD: average 98.25N
Seam Strength	he test was performed in accordance with ASTM D1683M-17 Standard Test	⩾30N	Pass Average 45.18N

	Method for Failure in Sewn Seams of Woven Fabrics to evaluate the seam strength of the test sample.		
Impact Penetration	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	Pass 0.16g max
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	Pass 52~98cm
Thermal and Evaporative Resistance	The test was performed in accordance with ASTM F1868: 2017 Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate to evaluate the evaporative resistance of the test sample.	< 3 $Pa.m^2/W$.	Pass 0.00542 $Pa.m^2/W$
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} <4	Pass Average 2.2
Flammability	The test was performed in accordance with CPSC 16 CFR Part 1610-2008 standard for the Flammability of clothing textiles to evaluate the flammability of the test sample	Class 1	Pass Class 1
EO/ ECH residue	The test was performed in accordance with ISO 10993-7:2008 Biological	EO: < 10 ug/cm^2 ECH: < 9	EO: not detected ECH: Average 6.8 mg/device

	evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals to evaluate the level of sterilant residues.	mg/device	

Table 4 biocompatibility testing

Test Methodology	**Purpose**	**Acceptance Criteria**	**Result**
ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity	The purpose of the testing is to demonstrate the safety of the subject device.	Non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization		Non-irritating	Under the conditions of the study, the device is non-irritating.
		Non-sensitizing	Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K211809.