



February 1, 2024

Ammex-Weida (Hubei) Health and Safety Products Co., Ltd  
% Jarvis Wu  
Senior Consultant  
Shanghai Sungo Management Consulting Company Limited  
14th Floor, 1500# Central Avenue  
Shanghai, Shanghai 200122  
China

Re: K233183

Trade/Device Name: Surgical Gown (40083)  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FYA  
Dated: December 29, 2023  
Received: December 29, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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  
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Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K233183

Device Name

Surgical Gown (40083)

Indications for Use (Describe)

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 material. 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). The Surgical Gowns are single use, disposable medical devices, 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

**K233183**

*Document prepared date: 2024/1/30*

### A. Applicant:

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### B. Device:

Trade Name: Surgical Gown

Common Name: Surgical Gown

Model(s): 40083

#### Regulatory Information

Classification Name: Gown, Surgical

Classification: Class II

Product code: FYA Regulation

Number: 21 CFR 878.4040

Review Panel: Surgical Apparel

### C. Predicate device:

K231510

Surgical Gown

XIANTAO ZHIBO NON-WOVEN PRODUCTS CO.,LTD

### D. Intended use /Indications for Use:

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 material. 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). The Surgical Gowns are single use, disposable medical devices, provided sterile.

**E. Device Description:**

The proposed device Surgical Gown is model 40083, its body, sleeve and belt are made of SSMMS non-woven material, and cuff is made of cotton. The proposed device is available in XS, S, M, L, XL, 2XL, 3XL sizes. 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 blue color.

**F. Comparison with predicate device**

**Table 1 General Comparison**

<b>Device</b>	<b>Proposed Device</b>	<b>Predicate Device</b>	<b>Remark</b>
<b>Manufacturer</b>	Ammex-Weida (Hubei) Health and Safety Products Co., Ltd	XIANTAO ZHIBO NON-WOVEN PRODUCTS CO.,LTD.	-
<b>510K number</b>	K233183	K231510	-
<b>Product Name</b>	Surgical Gown	Surgical Gown	Same
<b>Classification</b>	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21CFR878.4040)	Same
<b>Intended use /Indications for Use</b>	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 material. 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). The Surgical Gowns are single use, disposable medical devices, provided sterile.	Surgical Gown is intended to be worn by room personnel during surgical procedures or other invasive tests to protect both the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This is single use, disposable device, provided sterile.  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
<b>Style</b>	Non-reinforced	Non-reinforced	Same
<b>Use</b>	Single Use; Disposable	Single Use; Disposable	Same
<b>Color</b>	Blue	Blue	Same
<b>Labeling</b>	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

**Table 2 Safety and Performance Comparison**

Item	Proposed Device(K233183)	Predicate Device(K231510)	Remark
<b>Size</b>	XS, S, M, L, XL, 2XL, 3XL	S, M, L, XL, XXL, XXXL	<b>Different.</b> resolved by performance testing
<b>Weight per square(g)</b>	45 g/m <sup>2</sup>	50 g/m <sup>2</sup>	<b>Different.</b> No affect on safety or efficacy
<b>Hydrostatic Pressure(cm) AATCC-127</b>	>50 cm	>50 cm	Same
<b>Water impact AATCC-42</b>	≤1.0 g	≤1.0 g	Same
<b>Breaking strength</b>	MD: 120.61N CD: 88.19N	MD: 144.87N CD: 88.89N	Similar
<b>Tearing strength</b>	MD: 60.03N CD: 39.78N	MD: 69.61N CD: 32.25N	Similar
<b>Seam Strength</b>	>30N	>30N	Same
<b>Flammability</b>	Class I	Class I	Same
<b>EO residue</b>	EO ≤ 4mg/d ECH ≤ 9mg/d	EO ≤ 4mg/d ECH ≤ 9mg/d	Same
<b>Shelf life</b>	3 years	3 years	Same
<b>Barrier protection level</b>	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
<b>Material</b>	SSMMS non-woven, Cotton, and Nylon + polyester	SMMS non-woven, Cotton, and Nylon	<b>Different</b>
<b>Biocompatibility</b>	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 weight per square (g), size and material 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.

Difference of the materials will not raise safe and effectiveness concerns. The biocompatibility and performance tests have been conducted to verify the safety and effectiveness of the material. Under the conditions of each study, the subject surgical gowns are 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. Summary of Non-Clinical Tests**

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.

<b>Test Item</b>	<b>Test standard</b>	<b>Acceptance Criteria</b>	<b>Result</b>
<b>Seam strength</b> 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(7lbf) per standard F2407-20 for level 3	<b>PASS</b>  68.46 N  (Average result from 30 samples)
<b>Breaking strength</b> 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(7lbf) per standard F2407-20 for level 3	<b>PASS</b>  MD: 120.61N CD: 88.19N  (Average result from 30 samples)
<b>Tear strength(N)</b> 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.	≥20N	<b>PASS</b>  MD: 60.03N CD: 39.78N  (Average result from 30 samples)
<b>Lint and other generation in the dry state</b> ISO 9073-10:2003(E)	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	<b>PASS</b>  1.9  (Average result from 6 samples )
<b>Flammability</b> CPSC 16 CFR	The test was performed in accordance with 16	Class I	<b>PASS</b>

Part 1610-2008, Standard for the Flammability of clothing textiles	CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.		Class I
<b>Water Penetration Resistance</b> AATCC 42-2013, 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.	≤1.0g AQL: 4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	<b>PASS</b>  ≤1.0g
<b>Static hydrostatic resistance</b> 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 cmH <sub>2</sub> O per standard ANSI/AAMI PB70:2012 for level 3	<b>PASS</b>  ≥50 cm
<b>EO and ECH sterilization residual</b> ISO 10993-7:2008 Ethylene oxide sterilization residuals	The test was performed in accordance with ISO 10993-7:2008 Ethylene oxide sterilization residuals to determine the EO and ECH residuals of the test sample.	EO ≤ 4mg/d ECH ≤ 9mg/d	<b>PASS</b>  EO ≤ 4mg/d ECH ≤ 9mg/d
<b>Cytotoxicity</b> ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	The test was performed in accordance with ISO 10993-5 to determine cytotoxicity of the test sample	Non-Cytotoxic	<b>PASS</b>  Under the conditions of the study, the device is non-cytotoxic.
<b>Irritation</b> ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation	The test was performed in accordance with ISO 10993-23 to determine Irritation of the test sample	Non-Irritating	<b>PASS</b>  Under the conditions of the study, the device is non-irritating.
<b>Sensitization</b> ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests For Sensitization	The test was performed in accordance with ISO 10993-10 to determine skin sensitization of the test sample	Non-Sensitizing	<b>PASS</b>  Under the conditions of the study, the device is non-sensitizing

#### **H. Summary of Clinical Test**

No clinical study is included in this submission.

#### **I. Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the subject device proposed in this 510(k) is safe, as effective, and performs as well as or better than the legally marketed predicate device under K231510.