August 22, 2023

Xiantao Zhibo Non-Woven Products Co., Ltd.
% Jarvis Wu
Consultant
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K231510
Trade/Device Name: Surgical Gown (S,M,L,XL,XXL,XXXL); Reinforced Surgical Gown (S,M,L,XL,XXL,XXXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: April 25, 2023
Received: May 25, 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 (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
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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)*
K231510

Device Name
Surgical Gown (S,M,L,XL,XXL,XXXL);
Reinforced Surgical Gown (S,M,L,XL,XXL,XXXL)

Indications for Use *(Describe)*
The 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.

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 and Reinforced 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.

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510(K) Summary
K231510

Document prepared date: 2023/8/22

A. Applicant:

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B. Device:

Trade Name: Surgical Gown, Reinforced Surgical Gown
Common Name: Surgical Gown
Model(s): S, M, L, XL, XXL, XXXL
Regulatory Information
Classification Name: Gown, Surgical
Classification: Class II
Product code: FYA
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K212861
Surgical Gown, Reinforced Surgical Gown
Wuhan Zonsen Medical Products Co.,Ltd

D. Intended use/Indications for use:

The 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.

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 and Reinforced Surgical Gown met the requirements for Level 3 classification.

E. Device Description:

The proposed device Surgical Gown its body, sleeve and belt are made of SMMS non-woven material, and cuff is made of cotton. The proposed device is available in S(110×130cm), M(120×140cm), L(130×150cm), XL(140×160cm), XXL(150×170cm), XXXL(155×180cm) sizes . This proposed device can meet the requirements for Level 3 per ANSI/AAMI PB70:2012.

The proposed device Reinforced Surgical Gown is its body, sleeve and belt are made of SMMS non-woven material, and cuff is made of cotton. The reinforced and critical zone is front chest and sleeves. This zone is reinforced with PP/PE composite breathable film. The proposed device is available in S(110×130cm), M(120×140cm), L(130×150cm), XL(140×160cm), XXL(150×170cm), XXXL(155×180cm) 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.

F. Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Remark
Manufacturer	XIANTAO ZHIBO NON-WOVEN PRODUCTS CO.,LTD.	Wuhan Zonsen Medical Products Co.,Ltd	-
510K number	K231510	K212861	-
Model Name	Surgical Gown, Reinforced Surgical Gown,	Surgical Gown, Reinforced Surgical Gown,	Same
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21CFR878.4040)	Same
Intend use/ Indications for use	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 and Reinforced Surgical Gown met the requirements for Level 3 classification.	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 2 classification, and the reinforced	Same

		surgical gowns met the requirements for Level 3 classification.	
Style	Non-reinforced/Reinforced	Non-reinforced/Reinforced	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Safety and Performance Comparison

Item	**Proposed Device**	**Predicate Device(K212861)**	**Remark**
Weight per square (g)	Surgical Gown: 50g/ m^2; Reinforced Surgical Gown: 50g/ m^2	Surgical Gown: 45g/ m^2; Reinforced Surgical Gown: 45g/ m^2	Difference resolved by performance testing
Size	S、M、L、XL、XXL、XXXL	M, L, XL	Different. No affect on safety or efficacy
Flammability	Class I	Class I	Same
Hydrostatic pressure	Surgical Gown: >50 cm; Reinforced Surgical Gown: >50 cm	Surgical Gown: >20 cm; Reinforced Surgical Gown: >50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same
Breaking strength	>20N	>20N	Same
Tearing strength	>20N	>20N	Same
Seam Strength	>30N	>30N	Same
EO residue	EO ≤ 4mg/d ECH ≤ 9mg/d	EO ≤ 4mg/d ECH ≤ 9mg/d	Same
Shelf life	3 years	3 years	Same
Barrier protection level	Level 3 per AAMI PB 70	Level 2 and 3 per AAMI PB 70	Similar
	Surgical Gown: SMMS non-woven, Cotton,	Surgical Gown: SMMS non-woven, Cotton, and	

Material	and Nylon Reinforced Surgical Gown: SMMS non-woven, Cotton, Polypropylene and Polyethylene	Nylon Reinforced Surgical Gown: SMMS non-woven, Cotton, Nylon, Polypropylene and Polyethylene	Different
Sterility	Sterile	Sterile	Same
Biocompatibility	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

Analysis

The subject surgical gowns are substantially equivalent to the predicate device, in terms of general in tended use, performance testing, and configuration. 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 gowns. 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 Testing

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 Item	Test standard	Acceptance Criteria	Result
Seam strength 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	**PASS** 59.21 N (Average result from 30 samples)

Breaking strength 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	**PASS** MD: 144.87N CD: 88.89N (Average result from 30 samples)
Tear strength(N) 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.	≥10N	**PASS** MD: 69.61N CD: 32.25N (Average result from 30 samples)
Lint and other generation in the dry state 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	**PASS** 1.9 (Average result from 6 samples)
Flammability 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.	Class I	**PASS** Class I
Water Penetration Resistance 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	**PASS** ⩽1.0g
Static hydrostatic resistance AATCC 127-2014,	The test was performed in accordance with AATCC 127: 2014 Water Resistance: Hydrostatic Pressure Test	≥50 cmH_2O per standard ANSI/AAMI PB70:2012 for level 3 AQL: 4%	**PASS** ⩾50 cm

Water Resistance: Hydrostatic Pressure Test;	to determine the hydrostatic pressure of the test sample.		
EO and ECH sterilization residual 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	**PASS** EO ⩽ 4mg/d ECH ⩽ 9mg/d
Cytotoxicity ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	The test was performed in accordance with ISO 10993-10 to determine cytotoxicity of the test sample	Non-Cytotoxic	**PASS** Under the conditions of the study, the device is non-cytotoxic.
Irritation ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	The test was performed in accordance with ISO 10993-5 to determine Irritation of the test sample	Non-Irritating	**PASS** Under the conditions of the study, the device is non-irritating.
Sensitization ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization	The test was performed in accordance with ISO 10993-10 to determine skin sensitization of the test sample	Non-Sensitizing	**PASS** 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 non-clinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device under K212861.