June 16, 2023

Hubei Woozon Healthcare Co.,Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd
RM.1801,No.161 Lujiazui East Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K222999
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: May 10, 2023
Received: May 22, 2023

Dear Boyle 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 -S

Bifeng Qian, MD, 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)*
K222999

Device Name
Surgical Gown

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 non-sterile. Before the use, the Surgical Gowns must be sterilized by EO sterilization based on ISO 11135:2014.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K222999

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: Hubei Woozon Healthcare Co.,Ltd.

Address: Nongfeng Road, Nonwoven Fabric Industrial Park, Wangzhou Avenue, Pengchang Town, Xiantao City, Hubei, China.

Contact: Li Chunlin

Phone Number: 86-728-3280667

Fax number: 86-728-3280667

Date of Preparation: June 12, 2023

Designated Submission Correspondent

Contact: Mr. Boyle Wang

Address: Shanghai Truthful Information Technology Co., Ltd.

Room 1801, No. 161 Lujiazui East Rd., Pudong Shanghai, 200120 China

Tel: +86-21-50313932

Email: Info@truthful.com.cn

2.0 Device information

Trade name:	Surgical Gown
Common name:	Surgical gown
Classification name:	Gown, Surgical
Model(s):	S, M, L, XL, XXL

3.0 Classification

Production code:	FYA - Gown, Surgical
Regulation number:	21CFR 878.4040 - Surgical apparel
Classification:	Class II
Panel:	Surgical apparel

4.0 Predicate device information

Manufacturer:	Hubei Wanli Protective Products Co. Ltd

Device: Surgical Gown

510(k) number: K211509

5.0 Intended Use/Indication for Use Statement

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 non-sterile. Before the use, the Surgical Gowns must be sterilized by EO sterilization based on ISO 11135:2014.

6.0 Device description

The Surgical Gown is composed of collar, body, sleeve and tie, in a blue color, offered in sizes S, M, L, XL and XXL. The neck and waist are laced, the sleeves are made of polyester elastic 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.

7.0 Technological Characteristic Comparison Table

Table 3 - General Comparison

Item	Proposed device (K222999)	Predicated device (K211509)	Remark
Product Code	FYA	FYA	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	Surgical Gown	Surgical Gown	Same
510(k) No.	K222999	K211509	/
Models	S,M,L,XL,XXL	S,M,L,XL,XXL	Same
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	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	Same

	use, disposable medical devices; provided non-sterile. Before the use, the Surgical Gowns must be sterilized by EO sterilization based on ISO 11135:2014.	medical devices; provided non-sterile.	
Material	SMS nonwoven fabric polyester fiber	Sleeve/body (polyethylene SMS Nonwoven)	Similar
Color	Blue	Blue	Same
Sterility	Sterile for end-user	Sterile for end user	Same
Single Use	Yes	Yes	Same
Impact Penetration	≤1.0 g	≤1.0 g	Same
Hydrostatic Resistance	>50 cm	>50 cm	Same
Tensile strength	Machine direction mean≥32.9 lbf; Cross direction mean≥26.3 lbf.	Machine direction mean≥27.8 lbf; Cross direction mean≥19.1 lbf	* Gap 1
Tear resistance	Machine direction mean≥9.3 lbf; Cross direction mean≥18.2 lbf	Machine direction mean≥10.7 lbf; Cross direction mean≥6.2 lbf	* Gap 2
Steam strength	Shoulder: 48.7N Armhole:33.9N Sleeve: 49.6N	Shoulder: 71.8N Armhole: 66.0N Sleeve: 77.0N	* Gap 3
16 CFR Part 1610 Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements of Flame Resistant CPSC 1610 Class 1	Same
Linting	Log_{10}<4	Log_{10}<4	Same
Liquid barrier performance	Level 3 AAMI PB70	Level 3 AAMI PB70	Same
Cytotoxicity	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity	Same
Irritation Sensitization	Under the condition of the test, no irritation and sensitization	Under the condition of the test, no irritation and sensitization	Same
Acute systemic toxicity	Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	/	/
Sterilization Modality	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same

* Gap analysis:
Gap 1-3, the two devices have some little deviation in product performance, but the difference in the performance test result does not raise additional questions for safety and effectiveness.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the related recognized standards and the requirements stated in the "Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes" dated August,1993.

Based on ASTM F2407-20 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities, the subject device has been conducted the test as following:

AATCC 42-2013 Water Resistance: Impact Penetration Test

AATCC 127-2014 Water Resistance: Hydrostatic Pressure Test

ASTM D5034-09(2017) Standard Test Method for Breaking Strength and Elongation of Texile Fabrics (Grab Test)

ASTM D5587-15(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

ASTM D1683-17(2018) Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics

ASTM F1868-17(2017) Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

ISO 9073-10:2003 Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state

16 CFR Part 1610(a) Standard for The Flammability of Clothing Textiles

ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Test Methodology	Purpose	Acceptance Criteria	Results
AATCC 42	Impact Penetration	Level 3, ≤1.0g	<1.0g
AATCC 127	Hydrostatic Resistance	Level 3, ≥50cm	≥50cm
ASTM D5034	Tensile strength	Machine direction mean: ≥18 lbf; Cross direction mean: ≥12 lbf.	Machine direction mean≥32.9 lbf; Cross direction mean≥26.3 lbf.
ASTM D5587	Tear resistance	Farbic direction A mean: ≥4.0 lbf; Farbic direction B mean: ≥2.5 lbf;	Machine direction mean≥9.3 lbf; Cross direction mean≥18.2 lbf.
ASTM D1683	Seam strength	Shoulder: ≥8.5 lbf; Arm opening: ≥5.5 lbf; Sleeve: ≥8.5 lbf;	Shoulder: ≥10.1 lbf; Arm opening: ≥7.2 lbf; Sleeve: ≥10.1 lbf;
ASTM F1868	Evaporative Resistance of fabrics	Mean Evaporative Resistance (Ref)≥0.06(kPa·m^2/W).	Mean Evaporative Resistance (Ref)≥0.06(kPa·m^2/W).
ISO 9073-10	Lint and Other particles generation in the dry state	Log 10 < 4	Index for Particulate Matter (IPM)< 2.89
16 CFR Pat 1610	Flammability testing	Class 1, Non Flammable	Class 1, Non Flammable
Cytotoxicity	Biocompatibility-cytotoxicity	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity
Irritation	Biocompatibility-irritation	Under the condition of the test, no irritation	Under the condition of the test, no irritation
Sensitization	Biocompatibility-sensitization	Under the condition of the test, no sensitization	Under the condition of the test, no sensitization
Acute systemic toxicity	Biocompatibility-Acute systemic toxicity	Under the condition of acute systemic toxicity test, the test article did not show acute systemic	Under the condition of acute systemic toxicity test, the test article did not show acute systemic

		toxicity in vivo.	toxicity in vivo.
Ethylene oxide residues	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/device ECH ≤ 9mg/device	EO: 3.68 mg/device ECH: 0.94 mg/device

9.0 Clinical Test Conclusion

No clinical study implemented for the Surgical Gown.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device K211509.