April 12, 2022

Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
Ray Wang
Gerneral Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912 Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K214088
Trade/Device Name: Disposable Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 10, 2022
Received: March 15, 2022

Dear Ray 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 and Part 809); 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
Acting 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)*
K214088

Device Name
Disposable Surgical Gown

Indications for Use *(Describe)*
Disposable Surgical Gown is 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. In addition, this surgical gown meets the requirements of AAMI Level 4 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. It is 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.

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.

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"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."

The assigned 510(k) Number: K214088

510(k) Summary

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

1. Date of Preparation: 2022/04/12

2. Sponsor Identification

Weihai Hongyu Nonwoven Fabric Products Co., Ltd.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Disposable Surgical Gown
Common Name: Gown, Surgical

Regulatory Information
Classification Name: Gown, Surgical
Classification: 2
Product Code: FYA
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital

Indication For Use Statement:
Disposable Surgical Gown is 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. In addition, this surgical gown meets the requirements of AAMI Level 4 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. It is single use, disposable medical devices, provided sterile.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K173847
Product Name: Disposable Ultra Reinforced Surgical Gown
Manufacturer: Xiantao Rayxin Medical Products Co., ltd.

6. Device Description

The subject devices 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 materials.
In addition, this surgical gown meets the requirements of AAMI Level 4 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.
The proposed device is single use, disposable medical devices and provided sterile.
The main materials of device are SMS nonwoven +TPU membrane, PP and Polyester fiber, and the main manufacturing technique are Ultrasonic welding and Sewing.

7. Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- 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.
- ISO 10993-7: 2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F2407-06, Standard Specification For Surgical Gowns Intended For Use In Healthcare Facilities.
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities.
- ISO 11135-1:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]

Test Method	Purpose	Acceptance Criteria	Results
AATCC 127	Water resistance Hydrostatic Pressure	>50 cm	Passed
AATCC 42	Water Resistance impact penetration Nonwoven and plastic Barriers	≤1.0 g	Passed
ASTM D5034-09	Tensile Strength	MD Mean≥30 lbs; CD Mean≥25 lbs	Passed
ASTM D5587-19	Tearing Strength	MD Mean≥9 lbs; CD Mean≥18 lbs	Passed
ASTM F1868-17	Evaporative Resistance of fabrics	Mean Evaporative Resistance (Ref)≥0.06(kPa·m2/W).	Passed
16 CFR 1610	Flammability testing	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements
ASTM D1683-17	Seam Strength	>50N	Passed
ASTM F1671	Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage ASTM F1671	No virus through, “None Seen”	Passed
ISO 9073-10:2003	Lint and Other particles generation in the dry state	Log 10 < 4	Passed
ISO 10993-5	Tests for In vitro cytotoxicity	Device must not be cytotoxic	Device is noncytotoxic
ISO 10993-10	Tests for irritation and skin	Device must not be irritant	Device is not an irritant

	Irritation		
ISO 10993-10	Tests for irritation and skin sensitization	Device must not be sensitizer	Device is not a sensitizer
ISO 10993-7	Ethylene Oxide Sterilization Residuals	Residual Ethylene oxide levels must be below limits	Ethylene Oxide residual levels are below limitations
USP43<85>	Bacterial Endotoxin Test	<20EU/piece	Passed

8. Summary of Clinical Testing

No clinical study is included in this submission.

9. Comparison of Technological Characteristics with the Predicate Device

ITEM	Proposed Device K214088	Predicate Device K173847	Remark
Intended Use/Indication For Use	Disposable Surgical Gown is 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. In addition, this surgical gown meets the requirements of AAMI Level 4 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. It is single use, disposable medical devices, provided sterile.	The Disposable Ultra Reinforced Surgical Gown is 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. 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. It is single use, disposable medical devices, provided sterile.	SIMILAR
Product Code	FYA	FYA	SAME
Use	Single Use; Disposable	Single Use; Disposable	SAME
Material Composition	SMS nonwoven + TPU membrane	SMS polypropylene nonwoven	SIMILAR
Prescription vs. OTC	OTC	OTC	SAME
Sterile	Sterile	Sterile	SAME
Color	Blue	Blue	SAME

Sterilization Method	EO	EO	SAME
Weight per square (g)	67g/m²	44 g/m²	SIMILAR
Tensile	MD Mean≥30 lbs; CD Mean≥25 lbs	MD Mean≥30 lbs; CD Mean≥25 lbs	SAME
Tear	MD Mean≥9 lbs; CD Mean≥18 lbs	MD Mean≥9 lbs; CD Mean≥18 lbs	SAME
Hydrostatic Pressure (cm) AATCC-127	>50 cm	>50 cm	SAME
Water Impact (g) AATCC-42	≤1.0 g	≤1.0 g	SAME
Seam Strength	>58 N	Not Known	/
Linting	Log 10<4	Not Known	/
Resistance to blood and liquid penetration	Level 4 AAMI PB70	Level 3 AAMI PB70	DIFFERENCE
Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage ASTM F1671	No virus through, "None Seen"	Not Appliable for Level 3.	/
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL	SIMILAR
16 CFR Part 1610 Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements of Flame Resistant CPSC 1610 Class 1	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
Shelf Life	1 years	2 years	DIFFERENCE
Sterilization Method & SAL	Ethylene Oxide (EO), SAL=10^{-6} The EO/ECH residues meet the requirements of ISO 10993-7	Ethylene Oxide (EO), SAL=10^{-6} The EO/ECH residues meet the requirements of ISO 10993-7	SAME

Analysis:

The proposed device is different from the predicate device in Seam Strength and Linting, because the predicate device is not known on these two testing results. But the test results meet the requirements of ASTM F2407.

The proposed device is different from the predicate device, the resistance to blood and liquid penetration of the proposed device comply with AAMI PB70 Level 4, the predicate device comply with AAMI PB70 Level 3, but this difference would not affect its safety and effectiveness. The proposed

device has one more performance advantage than the predicate device in resistance to blood and liquid penetration, this performance has been verified, the results meet the requirements of AAMI PB70 Level.

The proposed device has better performance to the predicate device. Both proposed device and predicate device are safe and effective, so we consider which is same with the predicate device.

The proposed device is different from the predicate device in shelf life, the 1 year shelf life real time aging validation has been conducted, and the results shown that the proposed device could maintain its performance at the end of 1 year shelf life claimed, so we consider this difference would not raise any safety or effectiveness concerns.

10. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Gown cleared under K173847.