November 16, 2022

Xianning Marveldas Protective Articles CO.,Ltd.
℅ Salon Chen
QS Engineer
IMD Medical & Drug Technology Service Institutions
Room 308, building 11, No. 23, Jinqu Road, Wanjiang Street
Dongguan, Guangdong 523069
China

Re: K212812
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: October 12, 2022
Received: October 12, 2022

Dear Salon Chen:

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
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)*
K212812

Device Name
Surgical Gown

Indications for Use *(Describe)*
Surgical gowns are sterile, disposable, and single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. This device is sterilized using Ethylene Oxide (EO) following the Validation and routine control under ANSI/AAMI/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.

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510(k) Summary (K212812)

1. Submitter Information

- Company Name: Xianning Marveldas Protective Articles CO., Ltd.
- Address: Guishan Road #30, Hi-New Tech Industrial, Xianning, Hubei P R C
- Phone: +86-1572066625
- Contact Person (Title): Zhuxiaokang
- E-mail：sale@marveldas.com
- Date of Preparation: November 10, 2022

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Trade Name: Surgical Gown
- Common Name: Surgical Gown
- Classification Name: Surgical Apparel
- Model: S、M、L、XL、XXL
- Classification Product Code: FYA
- Regulation Number: 21 CFR 878.4040
- Classification: Class II
- Review Panel: General Hospital

3. Predicate Device Information:

- 510(k) Number: K121152
- Predicate Device Name: Surgical Gown
- Manufacturer: Jiangsu Guangda Medical Material Co., Ltd.
- This predicate has not been subject to a design-related recall
- No reference devices were used in this submission.

4. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person(Title): Salon Chen (System engineer)
- E-mail: 33999439@qq.com
- the address of application correspondent:308, Building 11, Zhongchuang Foreign Exchange Industrial Park, No. 23, Jinqu Road, Wanjiang Street, Dongguan, Guangdong, China

5. Device Description

The Sterile Level 4 Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The proposed devices are single

use and EO sterilized. The Sterile Level 4 Surgical Gowns are available in five models including S、M、L、XL and XXL.

The proposed surgical are constructed of a SMS nonwoven material (SMS+Film covering material+Velcro tape+Cuff material) and it is a kind of reinforced surgical gown and blue color.

6. Intended Use /Indications for Use

Surgical gowns are sterile, disposable, and single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. This device is sterilized using Ethylene Oxide (EO) following the Validation and routine control under ANSI/AAMI/ISO 11135 (2014).

7. Comparison of technological characteristics with the Predicate

Elements of Comparison	Predicate Device	Subject Device	Comparison
Company Name	Jiangsu Guangda Medical Material Co., Ltd.	Xianning Marveldas Protective Articles CO., Ltd.	/
510(k) number	K121152	K212812	/
Device Name	Surgical Gown	Surgical Gown	/
Classification Product Code	FYA	FYA	same
Regulation	21 CFR 878.4040	21 CFR 878.4040	same
Classification Name	Surgical Apparel	Surgical Apparel	same
Class	2	2	same
Prescription or OTC	OTC	OTC	same

Intended Use & Indications for Use	Jiangsu Guangda's Reinforced Surgical Gowns, Model Number GD-SG-01, are non-sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. This product may be sterilized using Ethylene Oxide (EO) following the validation and routine control under ANSI/AAMI/ISO	Surgical gowns are sterile, disposable, and single use devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. This device is sterilized using Ethylene Oxide (EO) following the Validation and routine control under ANSI/AAMI/ISO 11135 (2014).	same
Materials	SMS and PE+PP TWO layer compound	SMS+Film covering material+Velcro tape+Cuff	similar
Weight Per square(g)	45g/m^2	45g/m^2	same
Durability	Disposable	Disposable	same
Size	XL	S、M、L、XL、XXL	different
Color	Blue	Blue	same
Reinforced area	PE+PP two layer compound protective reinforcement with 100% white Terylene cuffs	double barrier non-woven fabric	same
Style	Reinforced	Reinforced	similar
Hydrostatic pressure: AATCC 127	>20cm	>50 cm	different
Impact penetration: AATCC 42	≤1	≤1	same
Tensile strength: ASTM D5034	Passed	Length(lbf):37.6 Width(lbf):24.2	similar
Tearing strength: ASTM D5733	Passed	Length yarns torn(lbf): 14.3 Width yarns torn(lbf): 8.1	similar

Seam strength: ASTM D1683		Pass	Arm Opening sleeves 23.5 lbf (FTS) 24.2lbf (FR) Shoulder 37.0 lbf (FR)	similar
Flammability: 16CFR Part 1610		Class 1	Class 1	same
Sterilization method		Although sold non-sterile, gown can be EO Sterilized	EO	same
Resistance to bacteriophage penetration ASTM F1671		Level 4 per AAMI PB70	Level 4 per AAMI PB70	same
Biocompatibility	**Cytotoxicity, ISO 10993-5:2009**	Passed	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic	same
	Irritation, ISO 10993-10:2002	Passed	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating	
	Sensitization, ISO 10993-10:2002	Passed	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing	

Analysis:

1) In term of key material composition, the surgical gowns are both constructed of a SMS nonwoven material. Other Secondary material is slightly different from those of the predicate device. The proposed device has been passed on the performance and biocompatibility. It is no effect on safety or efficacy.

2) Although the size is different from those of the predicate device. The proposed device has been passed on the performance testing. It is no effect on safety or efficacy.

3) In terms of general intended used, performance testing, material composition and configuration, hydrostatic pressure、tensile strength、tearing strength and seam strength are slightly different from those of the predicate device. The proposed device has been tested according to AATCC 127、ASTM D 5034、ASTM D 5733 and ASTM D 1683 respectively, and met the requirement of the standard.

8. Discussion of Non-Clinical Performance Tests Performed

Sterile Level 4 Surgical Gown

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

Test Method	Purpose	Acceptance Criteria	Result
AATCC 127	Hydrostatic pressure	>50 cm	Pass
AATCC 42	Impact penetration	≤1g	Pass
ASTM D 5034	Tensile Strength	Length(lbf): ⩾37.6 Width(lbf): ⩾24.2	Pass
ASTM D 5733	Tearing strength	Length yarns torn(lbf):14.3 Width yarns torn(lbf):8.1	Pass
ASTM D 1683	Seam strength	Arm Opening sleeves 23.5 lbf (FTS) 24.2lbf (FR) Shoulder 37.0 lbf (FR)	Pass
16 CFR Part 1610	Flammability of Textiles	Class 1	Class 1
ASTM F1671	Bacteriophage Phi-X174 penetration	No penetration	Pass
Biocompatibility	**Cytotoxicity, ISO 10993-5:2009**	ISO 10993-5	ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic
	Irritation, ISO 10993-10:2002	ISO 10993-10	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating

	Sensitization, ISO 10993-10:2002	SO 10993-10	ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing

9. Summary of Clinical Test

No clinical study is included in this submission.

10.Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k)，Surgical gowns is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K121152.