December 13, 2021

Henan Robestain Medical Products Co., Ltd.
Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K212925
Trade/Device Name: Disposable Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: August 16, 2021
Received: September 14, 2021

Dear Diana Hong:

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,

For Clarence W. Murray III, PhD
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)*
K212925

Device Name
Disposable Surgical Gown

Indications for Use *(Describe)*
Disposable surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the disposable surgical gowns 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212925

1. Date of Preparation: 11/23/2021

2. Sponsor Identification

Henan Robestain Medical Products Co., Ltd
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Disposable Surgical Gown
Common Name: Surgical Gown

Regulatory Information

Classification Name: Gown, Surgical
Classification: II;
Product Code: FYA;
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital;

Indications for Use:

Disposable surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the disposable surgical gowns met the requirements for Level 3 classification.

Device Description:

The proposed devices are intended to be worn by operating room personnel during surgical procedure 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, disposable medical devices and are provided in sterile.

There are two types of disposable surgical gown: standard disposable surgical gown, reinforced disposable surgical gown. And each type of surgical gown is available in six product sizes, including S, M, L, XL, XXL and XXXL. The barrier protection level for standard and reinforce disposable surgical gown meet AAMI Level 3.

5. Identification of Predicate Device

510(k) Number: K211422
Product Name: Level 2 Standard Surgical Gown
Level 3 Standard Surgical Gown (used as Predicate Device)

Level 3 Reinforced Surgical Gown (used as Predicate Device)

6. Non-Clinical Test Conclusion

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

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- AATCC 127: 2018 Water Resistance: Hydrostatic Pressure Test;
- AATCC 42: 2017 Water Resistance: Impact Penetration Test;
- ISO 9073-10: 2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State;
- ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics;
- ASTM D5587: 2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D5034: 2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D737: 2018 Standard Test Method for Air Permeability of Textile Fabrics;
- ASTM F1886/F1886M: 2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection;
- ASTM F88/F88M: 2015 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929: 2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ISO 10993-7: 2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals;
- 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 10993-1: 2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 General Comparison

Item	Proposed Device	Predicate Device K211422	Remark
Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indication for Use	Disposable surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the disposable surgical gowns met the requirements for Level 3 classification.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Level 3 standard surgical gowns and Level 3 reinforced surgical gowns met the requirements for Level 3 classification.	Same
Style	Non-reinforced /Reinforced	Non-reinforced/Reinforced	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Safety and Effectiveness Comparison

Item	Proposed Device	Reference Device K211422	Remark
Weight per square (g)	45 g/m^2	Level 3 Standard Surgical Gown: 43g/m^2 Level 3 Reinforced Surgical Gown: 35g/m^2 and 28g/m^2	Different
Size	S, M, L, XL, XXL, XXXL	XS, S, M, L, XL, XXL, XXXL	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	Standard Disposable Surgical Gown: >50 cm	Level 3 Standard Surgical Gown: >50 cm;	Same

	Reinforced Disposable Surgical Gown: >50 cm	Level 3 Reinforced Surgical Gown: >50 cm	
Water impact	≤0.42 g	≤1.0 g	Different
Breaking strength	>20N	>20N	Same
Tearing strength	>20N	>20N	Same
Linting	Log_{10}<4	Log_{10}<4	Same
Air permeability	>30 $ft^3/min/ft^2$	>30 $ft^3/min/ft^2$	Same
Barrier protection level	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
Material	Standard disposable Surgical Gown: SMMS nonwoven, Polyester Reinforced disposable Surgical Gown: SMMS nonwoven, PE Breathable Film, Polyester	Level 3 Standard Surgical Gown: SMS nonwoven, Polyester and Polyamide; Level 3 Reinforced Surgical Gown: SMS nonwoven, Polyester, Polyamide and Hydrophilic nonwoven	Different
Biocompatibility			
Cytotoxicity	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
Irritation			
Sensitization			
Sterilization	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Sterile Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Same

Different - Weight per square

The weight per square for the proposed disposable surgical gowns is different from the predicate device. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrated that the proposed surgical gowns can meet the barrier protection level 3 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Size

The size for the proposed disposable surgical gowns is different from the predicate device. The proposed surgical gowns are available in 6 product sizes, including S, M, L, XL, XXL and XXXL. However, the difference in the size will not affect the device performance. Different size can be selected by surgeon's condition. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Water impact

Although the water impact for the proposed disposable surgical gowns is different from the predicate device, the water impact of the proposed device is better than the predicate device. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The material for the proposed disposable surgical gowns is different from the predicated device. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device K211422.