December 15, 2021

Wuhan Zonsen Medical Products Co.,Ltd
% Ivy Wang
Consultant
Shanghai Sungo Management Consulting Company Limited
14 th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K212861
Trade/Device Name: Surgical Gown, Reinforced Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 8, 2021
Received: September 8, 2021

Dear Ivy 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,

For Clarence W. Murray, III, 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)*
K212861

Device Name
Surgical Gown, Reinforced Surgical Gown

Indications for Use *(Describe)*
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 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.

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SECTION 5

510(k) Summary

510(K) Summary

K212861

Document prepared date: 2021/12/13

A. Applicant:

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B. Device:

Trade Name: Surgical Gown, Reinforced Surgical Gown
Common Name: Surgical Gown
Model(s): ZSG1005, ZSG1006

Regulatory Information
Classification Name: Gown,
Surgical Classification: Class II
Product code: FYA
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K211422
Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown
Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

D. Intended use of the device:

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 surgical gown met the requirements for Level 3 classification.

E. Device Description:

The proposed devices Surgical Gown / Reinforced Surgical Gown have two models: ZSG1005 and ZSG1006.

The proposed device Surgical Gown is model ZSG1005, its body, sleeve and belt are made of SMMS non-woven material, and cuff is made of cotton. The proposed device is available in M, L, XL sizes. This proposed device can meet the requirements for Level 2 per ANSI/AAMI PB70:2012.

The proposed device Reinforced Surgical Gown is model ZSG1006, 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 M, L, XL 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	**Predicate Device**	**Proposed Device**	**Remark**
Manufacturer	Jiangsu Medplus Non-woven Manufacturer Co., Ltd.	Wuhan Zonsen Medical Products Co.,Ltd	-
510K number	K211422	K212861	-
Model Name	Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown	Surgical Gown, Reinforced Surgical Gown,	-
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21CFR878.4040)	Same
Intend use	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.	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.	Similar. No issues of safety or efficacy raised.
Style	Non-reinforced/Reinforced	Non-reinforced/Reinforced	Same
Use	Single Use; Disposable; Sterile	Single Use; Disposable; Sterile	Same
Color	Blue	Blue	Same

Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Safety and Performance Comparison

Item	**Predicate Device**	**Proposed Device**	**Remark**
Weight per square (g)	Level 2 Standard Surgical Gown: 35g/m^2; Level 3 Standard Surgical Gown: 43g/m2 Level 3 Reinforced Surgical Gown: 35g/m2 and 28g/m2	Surgical Gown: 45g/ m^2; Reinforced Surgical Gown: 45g/ m^2	Difference resolved by performance testing
Size	XS, S, M, L, XL, XXL, XXXL	M, L, XL	Different. No affect on safety or efficacy
Flammability	Class I	Class I	Same
Hydrostatic pressure	Level 2 Standard Surgical Gown: >20 cm; Level 3 Standard Surgical Gown: >50 cm; Level 3 ReinforcedSurgical 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
Linting	Log_{10}(particle count) <4	Log10(particle count) <4	Same
Barrier protection level	Level 2 and 3 per AAMI PB 70	Level 2 and 3 per AAMI PB 70	Same
Material	Level 2 Standard Surgical Gown and Level 3 Standard Surgical Gown: SMS nonwoven, Polyester and Polyamide; Level 3 Reinforced Surgical Gown: SMS nonwoven,	Surgical Gown: SMMS non-woven, Cotton, and Nylon Reinforced Surgical Gown: SMMS non-woven, Cotton, Nylon, Polypropylene and	Similar

	Polyester, Polyamide and Hydrophilic nonwoven	Polyethylene	
Sterility	Sterile	Sterile	Same
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			

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoint safe levels using 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
- CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;
- AATCC 127-2014, Water Resistance: Hydrostatic Pressure Test;
- AATCC 42-2013, Water Penetration Resistance: Impact Penetration Test;
- ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities.

Table 3 Performance Testing

Name of Testing Methodology	**Purpose**	**Acceptance Criteria**	**Results**
Flammability	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.	Meets Class 1 requirements	**PASS** Surgical Gown: Class 1 Reinforced Surgical Gown: Class 1
	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to	Surgical Gown (Level2): >20cm;	**PASS** Surgical Gown:

Hydrostatic pressure	determine the hydrostatic pressure of the test sample.	Reinforced Surgical Gown (Level 3): >50 cm	60cm Reinforced Surgical Gown: 95cm
Water impact	The test was performed in accordance with AATCC 42: 2017 Water Resistance: Impact Penetration Test to evaluate the water impact of the test sample.	≤1.0 g	**PASS** Surgical Gown: 0.1g Reinforced Surgical Gown:0g
Breaking strength	The test was performed In accordance with ASTM D5034: 2009(2017) Standard. Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	>20N	**PASS** Surgical Gown: 124N Reinforced Surgical Gown: 123N
Tearing strength	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.	>20N	**PASS** Surgical Gown: 52N Reinforced Surgical Gown:61N
Linting	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.	Log_{10}(particle count) < 4	**PASS** Surgical Gown: 2.11 Reinforced Surgical Gown: 1.88

Table 4 Biocompatibility Testing

Item	Purpose	Acceptance Criteria	Result

Cytotoxicity	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-Cytotoxic	**PASS** Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	**PASS** Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	**PASS** Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the comparison and analysis above, and the non-clinical tests performed, the proposed devices are determined to be as safe, as effective, and performs as well as the legally marketed predicate device under K211422.