March 7, 2023

Xiamen Probtain Medical Technology Co., Ltd
℅ Jarvis Wu
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai 200122, China

Re: K223401
Trade/Device Name: Disposable Surgical Gowns (S,M,L,XL,XXL,XXXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 1, 2023
Received: March 1, 2023

Dear Jarvis Wu:

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,

Allan Guan -S

For 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.

Submission Number *(if known)*

K223401

Device Name

Disposable Surgical Gowns (S,M,L,XL,XXL,XXXL)

Indications for Use *(Describe)*

The Disposable 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 matter. This is a single use, disposable device, 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.

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510(K) Summary

K223401

Document prepared date: 2023/03/01

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical Gowns (S,M,L,XL,XXL,XXXL)
Common Name: Surgical Gown
Model: S,M,L,XL,XXL,XXXL

Regulatory Information
Classification Name: Gown, Surgical
Classification: Class II
Product code: FYA
Regulation Number: 21 CFR 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K212591
Disposable Surgical Gown
Suzhou JaneE Medical Technology Co., Ltd.

D. Intended use of the device/ Indications for Use:

The Disposable 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 matter. This is a single use, disposable device, provided sterile.

E. Device Description:

The proposed device Disposable Surgical Gowns have body, sleeve and belt are made of SMMS non-woven material, and cuff is made of cotton. The Disposable Surgical Gowns are blue color, sterilized by ethylene oxide gas, single use and disposable medical device. The proposed device is available in S (115×140cm), M (120×150cm), L (130×160cm), XL (140×170cm), XXL (150×175cm), and XXXL (170×180cm).

This proposed device can meet the requirements for Level 3 per ANSI/AAMI PB70:2012.

F. Comparison with predicate device

Device	Predicate Device	Proposed Device	Comparison
Manufacturer	Suzhou JaneE Medical Technology Co., Ltd.	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD	
510K number	K212591	K223401	_
Product Name	Disposable Surgical Gown	Disposable Surgical Gowns	Same
Product Code	FYA	FYA	Same
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	Same
Intend use	The Disposable 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 matter. This is a single use, disposable device, provided sterile.	The Disposable 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 matter. This is a single use, disposable device, provided sterile.	Same
Material Composition	Polyolefin (Polypropylene) SMS nonwoven	Sleeve/body/belt（SMMS non-woven） Cuff（Cotton）	Similar
Sterility	Sterile	Sterile	Same
Sterilization	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same

Method			
Sterilization Residuals	EO ≤ 4mg/day ECH ≤ 9mg/day	EO ≤ 4mg/day ECH ≤ 9mg/day	Same
Color	Blue	Blue	Same
Size	M,L,XL,TL	S、M、L、XL、XXL、XXXL	Similar. No effect on safety or efficacy
Weight per square(g)	Critical Area: 87.8g/m^2 Non-Critical Area: 45.12g/m^2	44g/m^2	Similar. No effect on safety or efficacy.
Tensile (Breaking strength) D5034-09	MD: 16.18 lbs (72N) CD: 13.26 lbs (59N)	MD: 156.87N CD: 125.20N	Similar. No effect on safety or efficacy. Both passed performance tests.
Tearing Strength ASTM D5587-15	MD:22.25 lbs (99 N) CD:18.20 lbs (81N)	MD: 66.34N CD: 38.44N	Similar. No effect on safety or efficacy. Both passed performance tests.
Seam Strength ASTM D16383M-17	Sleeve Seam:68.3N Side Seam:69.7N Belt Seam:71N	77.54N	Similar. No effect on safety or efficacy. Both passed performance tests.
Hydrostatic Pressure(cm) AATCC-127	>50 cm	>50 cm	Same
Water Impact (g) AATCC-42	≤1.0 g	≤1.0 g	Same
Resistance to blood and liquid penetration	Level 3 AAMI PB70	Level 3 AAMI PB70	Same
Biocompatibility	Under the conditions of the study, the device extract was not cytotoxic.	Under the conditions of the study, the device extract was not cytotoxic	Same

	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.	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.	

Different analysis:

The proposed surgical gowns are similar to the predicate device, in terms of general intended use, performance testing, material composition, and configuration. The tearing strength, breaking strength and seam strength are slightly different from those of the predicate device. The proposed device has been tested according to ASTM D5587-15, ASTM D5034-09 (2017) and ASTM D1683/ D1683M-17(2018) respectively, and met the requirements of the standard.

Under the conditions of each study, the proposed surgical gown is non-cytotoxic, non-sensitizing and negligibly irritating per ISO-10993 and have met the requirements of ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities for AAMI Level 3 surgical gowns.

G. Summary of Non-Clinical Test Results

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
- ISO 10993-7:2008(R) 2012 Biological evaluation of medical devices –Part 7: Ethylene oxide sterilization residuals
- CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;
- ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);F
- 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.
- ISO9073-10-2003 Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state
- ASTM D1683/D1683M-17（2018）Standard Test Method for Failure in Sewn Seams of Woven Fabrics

Table 2 performance test

Test Item	Test standard	Acceptance Criteria	Result
Seam strength ASTM D1683M-17 Standard Test Method for Failure in Sewn	The test was performed In accordance with ASTM D1683M-17 Standard. Test Method	≥30N(7lbf) per standard F2407-20 for level 3	**PASS** 77.54 N

Seams of Woven Fabrics.	for Seam Strength of Textile Fabrics (Grab Test) to evaluate Failure in Sewn Seams of the test sample.		(Average result from 10 samples)
Breaking strength ASTM D5034-09 （2017）Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	The test was performed In accordance with D5034-09（2017）. Standard. Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	≥30N(7lbf) per standard F2407-20 for level 3	**PASS** MD: 156.87N CD: 125.20N (Average result from 10 samples)
Tear strength(N) ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	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.	≥10N	**PASS** MD: 66.34N CD: 38.44N (Average result from 10 samples)
Lint and other generation in the dry state ISO 9073- 10:2003(E)	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.	Log10(particle count) < 4	**PASS** 2.6 (Average result from 10 samples)
Flammability CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles	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.	Class I	**PASS** Class I
Water Penetration Resistance AATCC 42-2013, Impact Penetration Test	The test was performed in accordance with AATCC 42: 2013 Water Resistance: Impact Penetration Test to evaluate the water impact of the test sample.	≤1.0g AQL：4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	**PASS** ⩽1.0g

Static hydrostatic resistance AATCC 127-2014, Water Resistance: Hydrostatic Pressure Test;	The test was performed in accordance with AATCC 127: 2014 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≥50 cmH_2O per standard ANSI/AAMI PB70:2012 for level 3	**PASS** ⩾50 cm
EO and ECH sterilization residual ISO 10993-7:2008 Ethylene oxide sterilization residuals	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/d ECH ⩽ 9mg/d	**PASS** EO ⩽ 4mg/d ECH ⩽ 9mg/d

Table3 Biocompatibility endpoints assessment

Test Item	Proposed device	Acceptance Criteria	Result
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation ISO 10993-10	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization ISO 10993-10	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	PASS

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Disposable Surgical Gowns (S,M,L,XL,XXL,XXXL), is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Gowns cleared under K212591.