January 4, 2023

Xiamen Probtain Medical Techology Co., Ltd
Jianli Kang
Vice General Manager
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China

Re: K223411
Trade/Device Name: Disposable Isolation Gowns (S,M,L,XL,XXL,XXXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: December 12, 2022
Received: December 12, 2022

Dear Jianli Kang:

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, MD, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
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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)*

K223411

Device Name

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

Indications for Use *(Describe)*

Disposable Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. This Disposable Isolation Gown meets the requirements of AAMI Level 3 barrier protection for a surgical isolation gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Disposable Isolation Gowns are 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.

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510(K) Summary

K223411

Document prepared date: 2022/12/19

A. Applicant:

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B. Device:

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

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

C. Predicate device:

K210785
Disposable Surgical Isolation Gowns
Chongqing Litai Fashion Group Limited Company

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

Disposable Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. This Disposable Isolation Gown meets the requirements of AAMI Level 3 barrier protection for a surgical isolation gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Disposable Isolation Gowns are single use, disposable medical devices, provided sterile.

E. Device Description:

Disposable Isolation Gowns are designed for the medical personnel use in medical environment, not intended for use in the operating room. The employed material is Polypropylene(PP) non-woven with polyethylene(PE) lamination. It is a kind of Non- Reinforced isolation gown.

The Disposable Isolation Gowns are constructed from a blue PP&PE (non-woven fabric, PE lamination) and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical isolation gown. The Disposable Isolation Gowns are blue color, sterilized by ethylene oxide gas , single use, disposable medical device that will be provided in a variety of sterile packaging configurations with 6 sizes,

S,M,L,XL,XXL,and XXXL

F. Comparison with predicate device

Device	Predicate Device	Proposed Device	Comparison
Manufacturer	Chongqing Litai Fashion Group Company	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD	—
510K number	K210785	K223411	—
Product Name	Disposable Surgical Isolation Gowns	Disposable Isolation Gowns	
Product Code	FYC	FYC	Same
Classification	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21 CFR878.4040)	Same
Intend use/ Indications for use	Disposable Surgical Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. This Disposable Surgical Isolation Gowns meets the requirements of AAMI Level 3 barrier	Disposable Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. This Disposable Isolation Gowns meets the requirements of AAMI Level 3 barrier protection for a surgical	Same

	protection for a surgical isolation gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Disposable Surgical Isolation Gowns are single use, disposable medical devices; provided non-sterile.	isolation gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Disposable Isolation Gowns are single use, disposable medical devices, provided sterile.	
Material Composition	Sleeve/body (polyethylene SMS Nonwoven） Cuff（Polyester）	Sleeve/body（PP non-woven fabric & PE lamination） Cuff（Polyester）	Similar
Color	Blue	Blue	Same
Sterility	Non-Sterile	Sterile, Ethylene Oxide (EtO)	Different
Sterilization Method	Not available	Ethylene Oxide (EtO)	Different
Sterilization Residuals	Not available	EO ≤ 4mg/day ECH ≤ 9mg/day	Different
Use	Single Use; Disposable	Single Use; Disposable	Same
Liquid Barrier Performance Classification Properties	Level 3 AAMI PB70	Level 3 AMI PB70	Same
Water Penetration Resistance AATCC 42	≤1.0g AQL：4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	≤1.0g AQL：4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	Same
Static hydrostatic resistance AATCC 127	≥50 cmH_2O per standard ANSI/AAMI PB70:2012 for level 3	≥50 cmH_2O per standard ANSI/AAMI PB70:2012 for level 3	Same
Seam strength ASTM D1683M-17	≥30N(7lbf) per standard F2407-20 for level 3	≥30N(7lbf) per standard F2407-20 for level 3	Same
Breaking strength ASTM D5034-09	≥30N(7lbf) per standard F2407-20 for level 3	≥30N(7lbf) per standard F2407-20 for level 3	Same
Tear strength(N)	≥10N	≥10N	Same

ASTM D5587-15,			
Flammability of Clothing Textiles- 16CFR Part 1610	Class I	Class I	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.	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 devic extracts were not found to be a sensitizer.	Same

Different analysis:

The Proposed Device Disposable Isolation Gowns are provided sterile, which is different from Predicate Device's sterility. The EO and ECH Residuals tests were conducted on the proposed device to ensure its compliance to the ISO10993-7. The test result has shown the difference does not affect the safety and of the proposed device. There is no new risk generated from the difference of the sterility.

Under the conditions of each study, the Proposed Device Disposable Isolation Gowns are 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 Seams of Woven Fabrics.	The test was performed In accordance with ASTM D1683M-17 Standard. Test Method for Seam Strength of Textile Fabrics (Grab Test) to evaluate Failure in Sewn Seams of the test sample.	≥30N(7lbf) per standard F2407-20 for level 3	**PASS** 89.86 N (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: 90.92 N CD: 77.06 N (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: 31.89 N CD: 19.2 N (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** 1.8 (Average result from 10 samples)
Flammability CPSC 16 CFR Part	The test was performed in accordance with 16	Class I	**PASS**

1610-2008, Standard for the Flammability of clothing textiles	CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.		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 cmH_2O
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 Isolation Gown (model: 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 Isolation Gowns cleared under K210785.