November 13, 2021

Chongqing Litai Fashion Group Limited Company
℅ Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K210785
Trade/Device Name: Disposable Surgical Isolation Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: August 11, 2021
Received: August 16, 2021

Dear Eva Li:

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 Murray, 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)*
K210785

Device Name
Disposable Surgical Isolation Gowns

Indications for Use *(Describe)*
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 protection for a surgical 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.

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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Chongqing Litai Fashion Group Limited Company
Building D7-1, Chongqing Textile & Garment City Project, Maliu Yanjiang Development Zone, Banan District, Chongqing City

510(K) Summary

K210785

A. Applicant

Chongqing Litai Fashion Group Limited Company
Address: Building D7-1, Chongqing Textile & Garment City Project, Maliu Yanjiang Development Zone, Banan District, Chongqing City
Contact Person: David Ni
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Date of prepared： Oct. 20th 2021

Submission Correspondent
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B. Device

Trade Name: Disposable Surgical Isolation Gowns
Common Name: Surgical Isolation Gown
Model: LT3

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:

K202310
Wildcat PE Surgical Isolation Gown Full Back
Wildcat PPE, LLC

D. Intended use of the device:

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 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.

E. Device Description:

Surgical Isolation Gown is designed for the medical personnel using in medical environment, not intended for use in the operating room. The employed material is SMS compound non-woven fabric. It is a kind of Non- Reinforced surgical isolation gown. Disposable Surgical Isolation Gowns are constructed from a blue PE SMS (spun-bond, melt-blown, spun-bond) and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical isolation gown. The Disposable Surgical Isolation Gown is a single use, disposable medical device that will be provided in a variety of non-sterile packaging configurations with 6 sizes, S, M, L, XL, XXL, and XXXL.

F. Comparison of technological characteristics between the subject and predicate devices

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Chongqing Litai Fashion Group Company	Wildcat PPE, LLC	__
510(K) number	K210785	K202310	__
Model Name	Disposable Surgical Isolation Gowns	Wildcat PE Surgical Isolation Gown Full Back	__
Classification	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21 CFR878.4040)	Same
Intend 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 protection for a surgical isolation gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes	Wildcat PE Surgical Isolation Gown Full Back is 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. In addition, The Wildcat PE Surgical Isolation Gown Full Back meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier and Performance	same

	intended for use in health care facilities (AAMI PB70). The Disposable Surgical Isolation Gowns are single use, disposable medical devices; provided non-sterile.	Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Wildcat PE Surgical Isolation Gown Full Back is a single use, disposable medical device provided non-sterile.	
Material Composition	Sleeve/body（polyethylene SMS Nonwoven） Cuff（Polyester）	Linear Low-Density Polyethylene (LLDPE)	Similar
Color	Blue	Blue	same
Sterility	Non-Sterile	Non-Sterile	same
Use	Single Use; Disposable	Single Use; Disposable	same
Liquid Barrier Performance Classification Properties	Level 3 AAMI PB70	Level 3 AMI PB70	same
Flammability of Clothing Textiles-16CFR Part 1610 (a)	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.	Pass: ISO 10993-1	same

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
- 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);
- 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.
- ASTM F1868-17 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate
- 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(sleeve seam)	ASTM D1683/D1683M-2017(2018)Method A	≥30N(7lbf) per standard F2407-20 for level 3	Pass
Breaking strength	ASTM D 5034-2009(2017), Grab method	≥30N(7lbf) per standard F2407-20 for level 3	Pass
Tear strength(N)	ASTM D 5587-2015(2019), trapezoid method	≥20N	Pass
Water-vapour resistance	ASTM F 1868-2017, Sweating guarded-hotplate test	≥30cmH2O (0.00294Kpa)	Pass
Lint and other	ISO 9073-10:2003,	Critical area≤4.0	
particles generation in the dry state(material)	Size of particles counted:3μm-25 μm	Less critical area≤ 4.0	Pass
Lint and other	ISO 9073-10:2003,	Critical area≤4.0	
particles	Size of particles		
generation in the dry state(sleeve seam)	counted:3μm-25 μm	Less critical area≤ 4.0	Pass
Flammability	16 CFR Part 1610	Class I	Pass
Water proof property(material, seam)	AATCC42-2017	≤1.0g AQL： 4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	Pass
Static hydrostatic resistance(material, seam)	AATCC 127-2018	≥50 cmH2o per standard ANSI/AAMI PB70:2012 for level 3	Pass

Table3 Biocompatibility endpoints assessment

Item	Proposed device	Acceptance Criteria	Result
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	PASS
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	PASS
Sensitization	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 nonclinical tests performed demonstrate that the subject device, Disposable surgical Isolation Gowns, is as safe, as effective, and performs as well as the legally marketed predicate device Wildcat PE Surgical Isolation Gown Full Back under K202310.