February 10, 2023

Nanning TECBOD Biological Technology Co.,Ltd.
℅ Eva Li
Consultant
Shanghai SUNGO Management Consulting Company Ltd.
Room 1401, Dongfang Building, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K223467
Trade/Device Name: Disposable Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: November 17, 2022
Received: November 17, 2022

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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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)*

K223467

Device Name

Disposable Isolation Gown

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 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 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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510(K) Summary
K223467

A. Applicant

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Date prepared: Feb 10th, 2023

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B. Device

K223467
Trade Name: Disposable Isolation Gown
Common Name: Isolation Gown

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

D. 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 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 Isolation Gowns are single use, disposable medical devices; provided non-sterile.

E. Device Description:

Disposable Isolation Gown is designed for the medical personnel using in medical environment, not intended for use in the operating room. The employed material is a polypropylene and polyethylene (PP+PE) compound non-woven fabric. The color of the gown is blue. The gown has long sleeves with cuffs and neck fasten belts. There are seam tapes above the sleeves and where the sleeves meet the body. The seam tape is ethylene-vinyl acetate (EVA). The material of cuff is polyester and it is elastic.

The body and sleeve of the Disposable Isolation Gowns are constructed from a blue PP+PE compound non-woven fabric and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a Disposable Isolation Gown. The Disposable Isolation Gown is a single use, disposable medical device.

F. Comparison with predicate device

Table 1 General Comparison

Device	Predicate Device	Subject Device	Comparison
Manufacturer	Chongqing Litai Fashion Group Company	Nanning TECBOD Biological Technology Co., Ltd.	-
510(K) number	K210785	K223467	-
Device Name	Disposable Surgical Isolation Gown	Disposable Isolation Gown	-
Classification	Class II Device, FYC (21 CFR878.4040)	Class II Device, FYC (21 CFR878.4040)	Same
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 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.	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 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 non-sterile.	Same
Material Composition	Sleeve/body (polyethylene SMS Nonwoven) Cuff (polyester)	Sleeve/body (PP+PE compound Nonwoven) Cuff (Polyester) Seam tap (Eva)	Similar

Color	Blue	Blue	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Shelf Life	Not specified	2 Years	Different
Liquid Barrier Performance Classification Properties	Level 3 AAMI PB70	Level 3 AAMI 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.	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.	Same

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications.

Table 2 performance test summary

Test Name	Purpose	Test Standard	Acceptance Criteria	Result
Seam strength (sleeve seam)	To evaluate the strength of the sleeve seam	ASTM D1683/D1683M-2017(2018) Method A	≥30N per standard F2407-20 for level 3	Pass
Tensile strength	To evaluate the tensile strength of the test sample	ASTM D 5034-2009(2017), Grab method 1) Media Direction 2) Cross Direction	≥30N per standard F2407-20 for level 3	Pass
Tear strength	To evaluate the tear resistance of the test sample	ASTM D 5587-2015(2019), trapezoid method 1) Media Direction 2) Cross Direction	≥10N	Pass
Hydrostatic pressure test (front, sleeve, sleeve seam, shoulder seam, back)	To evaluate the hydrostatic barrier property of the gown	AATCC 127-2018	≥50cmH2O AQL: 4% 32 of 32 samples pass each location	Pass
Lint and other particles generation in the dry state (material)	To evaluate the linting resistance of the test sample	ISO 9073-10:2003, Size of particles counted:3µm- 25µm	Critical area≤4.0 Less critical area≤ 4.0	Pass
Lint and other particles generation in the dry state (sleeve seam)	To evaluate the linting resistance in the dry state of the sleeve seam	ISO 9073-10:2003,	Critical area≤4.0 Less critical area≤ 4.0	Pass
2 year accelerated aging	To demonstrate performance stability throughout the shelf life	ASTM F1980 1) AAMI PB70:2012 a. AATCC 42 Water impact b. AATCC 127 Hydrostatic pressure	Meets all AAMI PB70 and ASTM F3352 performance requirements 1) AAMI PB70:2012 a. AATCC 42	Pass

		2) ASTM F3352 a. ASTM D5034 Tensile strength (Machine direction and cross direction) b. ASTM D5733 Tear strength (Machine direction and cross direction) c. ASTM D1683 Seam Strength d. ISO 9037-10 Lint generation	≤ 1.0 g b. AATCC 127 ≥ 50 cm H_2O 2) ASTM F3352 a. ASTM D5034 ≥ 30 N (Machine direction and cross direction) b. ASTM D5733 ≥ 10 N (Machine direction and cross direction) c. ASTM D1683 ≥ 30 N d. ISO 9037-10 Coef. of linting ≤ 4.0	
Flammability	To evaluate the flame resistance of the test sample	16 CFR Part 1610	Class I	Pass
Water impact resistance (front, sleeve, sleeve seam, shoulder seam, back)	To evaluate the water impact barrier property of the gown	AATCC 42-2017	≤1.0g AQL: 4% 32 of 32 samples pass each location Level 3 per standard ANSI/AAMI PB70:2012 for level 3	Pass
Cytotoxic potential	To evaluate the cytotoxic potential of the gown	ISO 10993-5	Under the conditions of the study, the device is not cytotoxic	Pass
Irritation	To evaluate the irritation property of the gown	ISO 10993-10	Under the conditions of the study, the device is not an irritant	Pass
Sensitization	To evaluate the sensitization property of the gown	ISO 10993-10	Under the conditions of the study, the device is not a sensitizer	Pass

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.
- 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
- ASTM F3352-19 Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities

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 or better than the legally marketed predicate device, Disposable Surgical Isolation Gowns, cleared under K210785.