August 2, 2024

George Courey Inc
% Sarah Fitzgerald
Senior Consultant
Emergo by UL
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K233571
Trade/Device Name: GCI Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: November 3, 2023
Received: November 6, 2023

Dear Sarah Fitzgerald:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, M.D., Ph.D.
Assistant Director

DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233571

Device Name
GCI Surgical Gown

Indications for Use *(Describe)*
GCI surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns met the requirements for Level 2 barrier 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K233571 - 510(k) Summary
GCI Surgical Gown

1. Submission Sponsor

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3. Date Prepared

July 31, 2024

4. Device Identification

Trade/Proprietary Name:	GCI Surgical Gown
Common/Usual Name:	Surgical Gowns
Classification Name:	Surgical Apparel
Regulation Number:	878.4040
Product Code:	FYA
Class:	2
Classification Panel:	General Hospital

5. Legally Marketed Predicate and Reference Device(s)

Predicate Device name:	Level 2 Standard Surgical Gown[1]
510(k) number:	K211422
Manufacturer:	Jiangsu Medplus Non-woven Manufacturer Co., Ltd.
Common/Usual Name:	Surgical Gowns
Classification Name:	Surgical Apparel
Regulation Number:	878.4040
Product Code:	FYA
Class:	2
Reference Device Name:	Innerbloc LR Surgical Gowns

[1] The predicate also includes Level 3 gowns, but only the Level 2 gowns are relevant for this submission.

510(k) number:	K092344
Manufacturer:	Lac Mac, Limited
Common/Usual Name:	Surgical Gowns
Classification Name:	Surgical Apparel
Regulation Number:	878.4040
Product Code:	FYA
Class:	2

6. Indication for Use Statement

GCI surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns met the requirements for Level 2 barrier classification.

7. Device Description

GCI Surgical Gowns are intended to be used during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate materials. The gown is available in multiple sizes. They are provided non- sterile and intended to be sterilized prior to use. They are reusable up to 75 uses.

Per ANSI/AAMI PB70 Liquid barrier performance and classification of protective apparel intended for use in health care facilities, the proposed devices meet the requirements for 2, as indicated by their labeling.

8. Substantial Equivalence Discussion

The following table compares the subject device to the predicate devices with respect to intended use, indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence.

The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1 – Comparison of Intended Use and Indications for Use: GCI Surgical Gown

Attribute	SUBJECT: K233571 GCI Surgical Gown	PREDICATE: K211422 Level 2 Standard Surgical Gown	Comparison
Intended Use	To protect both patients and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.	To protect both patients and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.	Same
Indications for Use	GCI surgical gown is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns met the requirements for Level 2 barrier classification.	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. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Level 2 standard surgical gowns met the requirements for Level 2 barrier classification, the Level 3 standard surgical gowns and Level 3 reinforced surgical gowns met the requirements for Level 3 classification.	Similar Subject Device does not have Level 3 Gown. Meets barrier level requirements per PB70

Table 2 – Comparison of Characteristics: GCI Surgical Gowns

Attribute	SUBJECT: K233571 GCI Surgical Gown	PREDICATE: K211422 Level 2 Standard Surgical Gown	REFERENCE: K092344 Innerbloc LR Surgical Gowns	Comparison
Product Code	FYA	FYA	FYA	Same
Regulation Number	878.4040	878.4040	878.4040	Same
Class	II	II	II	Same
Intended Use Overview	To protect from the transfer of microorganisms, body fluids, and particulate material.	To protect from the transfer of microorganisms, body fluids, and particulate material.	To protect from the transfer of microorganisms, body fluids, and particulate material.	Same
Prescription or OTC	OTC	OTC	OTC	Same
Barrier Level	Level 2	Level 2 (See Note below table)	Unknown (See Note below table)	Same
Device Materials	Polyester and carbon	SMS nonwoven polyester and polyamide	Polyester and PTFE	Similar No differences to safety or effectiveness, as confirmed by performance and

Attribute	SUBJECT: K233571 GCI Surgical Gown	PREDICATE: K211422 Level 2 Standard Surgical Gown	REFERENCE: K092344 Innerbloc LR Surgical Gowns	Comparison
				biocompatibility testing.
Sizes	S, M, L, XL, XXL / 2XL, XXXL / 3XL, XXXXL / 4XL, XL Tall	XS, S, M, L, XL, XXL, XXXL	Multiple sizes	Different Provides a range of sizes to fit a wide range of users. No differences to safety or effectiveness, as confirmed by performance testing.
Color	Blue	Blue	Blue	Same
Reinforcement	Non-reinforced	Non-reinforced (See Note below table)	Non-reinforced	Same
Method of Action	Physical barrier	Physical barrier	Physical barrier	Same
Durability	Reusable	Single-Use (Disposable)	Reusable	Different Same as reference device. No differences to safety or effectiveness, as confirmed by performance testing.
Flammability	Class 1	Class 1	Unknown	Same
Water Resistance: Hydrostatic Pressure	Water Resistant ≥20 cm	Water Resistant ≥20 cm (See Note below table)	Unknown	Same
Water Resistance: Impact Penetration	≤1.0 g water	≤1.0 g water	Unknown	Same
Breaking / Bursting Strength	>20 N	>20 N	Unknown	Same
Tearing Strength	>20 N	>20 N	Unknown	Same
Seam Strength	>20 N	Unknown	Unknown	Equivalent Meets expectations per standard for appropriate barrier protection level.
Linting	$Log_{10} < 4$	$Log_{10} < 4$	Unknown	Same

Attribute	SUBJECT: K233571 GCI Surgical Gown	PREDICATE: K211422 Level 2 Standard Surgical Gown	REFERENCE: K092344 Innerbloc LR Surgical Gowns	Comparison
Sterility	Non-Sterile (for use Sterile, SAL 10^{-6})	Sterile, SAL 10^{-6}	Unknown	Provided Different Same for Use No differences to safety or effectiveness, as confirmed by sterilization validation aligned with the provided instructions.
Biocompatibility				
- Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Under the conditions of the study, the device is non-cytotoxic.	Unknown	Same
- Irritation	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Unknown	Same
- Sensitization	Under the conditions of study, not a sensitizer.	Under the conditions of study, not a sensitizer.	Unknown	Same
Note: K211422 also includes additional gowns (including Level 3 gowns) and styles (including reinforced) but equivalence only claimed to these gowns.				

9. Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The subject surgical gowns were assessed for performance using the following standards and test methods, as also described in Table 2, and in alignment with FDA guidance "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" and "Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes." All testing results passed pre-determined acceptance criteria.

Table 3 – Summary of Performance Data

Attribute	Purpose: To ensure compliance with the following standard	Acceptance Criteria	Results
Flammability	16 CFR §1610: Standard for the Flammability of Clothing Textile	Meets Class 1 Requirements	Meets Class 1 Requirements
Water Resistance: Hydrostatic Pressure	AATCC 127:2017 Water Resistance: Hydrostatic Pressure Test	Water Resistant ≥20 cm	Water Resistant ≥20 cm
Water Resistance: Impact Penetration	AATCC 42:2017 Water Resistance: Impact Penetration Test	≤1.0 g water	≤1.0 g water
Breaking / Bursting Strength	ASTM D5034:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	≥20 N	>20 N
Tearing Strength	ASTM D5587:2019 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	≥20 N	>20 N
Seam Strength	ASTM D1683/D1683M:2017/(R)2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics	≥20 N	>20 N
Linting	ISO 9073-10:2003 Textiles – Test Methods for Nonwovens – Part 10: Lint and Other Particles Generation in the Dry State	$Log_{10} < 4$	$Log_{10} < 4$
Biocompatibility	ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Biocompatible in alignment with ISO 10993-1	Biocompatible in alignment with ISO 10993-1
- Cytotoxicity	ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic.
- Irritation	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization	Non-irritating	Under the conditions of the study, the device is not an irritant
- Sensitization	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization	Non-sensitizing	Under the conditions of the study, the device is not a sensitizer

10. Clinical Performance Data

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the testing demonstrates that the proposed subject device is as safe, as effective, and perform as well as or better than the legally marketed predicate device K211422.