June 6, 2025

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

Re: K250321
Trade/Device Name: GCI Sterilization Wrappers
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: May 6, 2025
Received: May 6, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Division 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)*
K250321

Device Name
GCI Sterilization Wrappers

Indications for Use *(Describe)*

GCI Sterilization Wrappers are intended to be used to enclose reusable textile-based medical devices, such as surgical gowns, towels, and drapes, for sterilization by a health care provider. They are designed to allow effective steam sterilization of the enclosed textile items and to maintain sterility until use, for up to 28 days.

GCI Sterilization Wrapper sizes and validated load limitations are as follows:

SKU / Model	Size	Border Color	Maximum Validated Load Weight
P81818 KBRO	18″x18″	White	1 lbs
P82424 KBRO	24″x24″	Pink	1.82 lbs
P83030 KBRO	30″x30″	Yellow	3.45 lbs
P83636 KBRO	36″x36″	Blue	5.8 lbs
P84545 KBRO	45″x45″	Mint	10.98 lbs
P85454 KBRO	54″x54″	Red	18.5 lbs
P86060 KBRO	60″x60″	Green	25 lbs

GCI Sterilization Wrappers are reusable through 38 wash, dry, and sterilization cycles. Pack assembly should follow established folding, assembly, and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. Closure can include autoclave tape and elastomer closures.

Sterilization: A prevacuum steam sterilization cycle (4 minutes exposure at 132°C, Dry Time: 30 minutes) has been validated.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250321
510(k) Summary
GCI Sterilization Wrappers

1. Submission Sponsor

George Courey, Inc.
6620, Ernest-Cormier
Laval, Quebec, H7C 2T5
Canada
Contact: Cort Naab
Title: Director of Surgical Solutions
Telephone: 450-661-6620
E-mail: cnaab@georgecourey.com

2. Submission Correspondent

Emergo by UL
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: lst.us.EmergoFDASubmissions@ul.com
Contact: Sarah Marie Fitzgerald
Title: Senior Consultant, Quality and Regulatory Affairs

3. Date Prepared

June 6, 2025

4. Device Identification

Trade/Proprietary Name:	GCI Sterilization Wrappers
Common/Usual Name:	Sterilization Wraps
Classification Name:	Sterilization Wrap
Regulation Number:	880.6850
Product Code:	FRG
Class:	2

5. Legally Marketed Predicate Device

Predicate Device name:	Standard Supreme Sterilization Wrapper
510(k) number:	K172207
Manufacturer:	Standard Textile Co., Inc.
Common/Usual Name:	Sterilization Wraps
Classification Name:	Sterilization Wrap
Regulation Number:	880.6850
Product Code:	FRG
Class:	2

6. Indication for Use Statement

GCI Sterilization Wrappers are intended to be used to enclose reusable textile-based medical devices, such as surgical gowns, towels, and drapes, for sterilization by a health care provider. They are designed to allow effective steam sterilization of the enclosed textile items and to maintain sterility until use, for up to 28 days.

GCI Sterilization Wrapper sizes and load limitation are as follows:

SKU / Model	Size	Border Color	Maximum Validated Load Weight
P81818 KBRO	18”x18”	White	1 lbs
P82424 KBRO	24”x24”	Pink	1.82 lbs
P83030 KBRO	30”x30”	Yellow	3.45 lbs
P83636 KBRO	36”x36”	Blue	5.8 lbs
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P85454 KBRO	54”x54”	Red	18.5 lbs
P86060 KBRO	60”x60”	Green	25 lbs

GCI Sterilization Wrappers are reusable through 38 wash, dry, and sterilization cycles. Pack assembly should follow established folding, assembly, and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. Closure can include autoclave tape and elastomer closures.
Sterilization: A prevacuum steam sterilization cycle (4 minutes exposure at 132°C, Dry Time: 30 minutes) has been validated.

7. Device Description

GCI Sterilization Wrappers are intended to enclose a textile-based medical device for sterilization and maintain sterility of the enclosed device until used.
The proposed devices are medical devices that are provided non-sterile. They may be reused up to 38 times. They are available in multiple sizes to accommodate textile-based medical devices, ranging from 18”x18” to 60”x60”. The size is indicated by color coding of the wrap borders for easy identification.
Load sizes should be large enough to prevent too much overlapping of the wrapper material (such that all but one side of the wrapper should be a single layer when properly folded) to allow appropriate sterilant penetration. Load sizes should be small enough to overlap by at least 2 inches on the remaining side to ensure there are no gaps.

8. Technological Characteristics Comparison

Table 1 compares the subject wraps to the predicate device with respect to intended use, principles of operation, technological characteristics, materials, and performance. Table 2 compares the specific indications for use.
The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 1. Technological Characteristics Comparison Table

Attribute	SUBJECT: K250321 GCI Surgical Wrappers	PREDICATE: K172207 Sterilization Wrappers	Comparison
Class	II	II	Same
Product Code	FRG	FRG	Same

Attribute	SUBJECT: K250321 GCI Surgical Wrappers	PREDICATE: K172207 Sterilization Wrappers	Comparison
Regulation (21 CFR)	880.6850	880.6850	Same
Intended Use	Enclose another medical device for sterilization and maintain sterility of the enclosed device until used.	Enclose another medical device for sterilization and maintain sterility of the enclosed device until used.	Same
Method of Action	Physical barrier	Physical barrier	Same
Durability	Reusable	Reusable	Same
Use Life	38 uses	75 uses	Similar*
Colors	Green with additional colors on edging (white, pink, yellow, blue, mint, red, green)	Red, Yellow, Blue, or Green	Similar* Colors provide easy reference.
Available Sizes	- 18”x18” 24”x24” - 30”x30” 36”x36” 45”x45” 54”x54” - 60”x60” -	12”x12” 18”x18” 23”x23” 27”x27” 30”x30” 35”x35” 45”x45” 54”x54” 54”x72” - 70”x70”	Within Same Range (Similar*)
Maximum Wrapped Package Content Weights	Appropriate wrapping described in IFU	12.9 lbs	Similar* AAMI ST77 recommends maximum of 25 lbs, and both follow this.
Device Materials	99% polyester, 1% carbon	Polyester, cotton	Similar*
Fabric	Woven	Woven	Same
Cut-n-Sew	Yes	Yes	Same
Performance Testing	Conducted	Conducted	Same See Table 3.
Sterilization	Steam sterilization cycle – 4 minutes exposure at 132°C (~270°F), Dry time 30 minutes	Steam sterilization cycle – 4 minutes exposure at 270°F (~132°C), Dry time unknown	Similar*
Sterility	Provided non-sterile	Provided non-sterile	Same
Biocompatibility	Assessed per ISO 10993-1 and tested per the ISO 10993 Series	Assessed per ISO 10993-1 and tested per the ISO 10993 Series	Same

* Discussion on Similarity: In all cases of differences, one or more of the following are true:

- The subject device was assessed in alignment with relevant standards and/or guidance documents and met expectations.

- The subject device met the pre-determined acceptance criteria based on the expected use of the device.
- The characteristic is not relevant to the performance, safety, or effectiveness of the device, but rather is provided for convenience (size, border colors).
- The information for the predicate device is unknown based on publicly available information, but as the subject device meets expectations, no further comparison is needed.

Therefore, all pre-determined acceptance criteria have been met, the device performs as intended, and any differences are not relevant to the safety, effectiveness, or performance of the subject device as compared to the predicate device.

Table 2 provides a detailed comparison of the indications for use. The predicate has a significant amount of additional descriptive data.

Table 2. Indications for Use Comparison

<table>
<tr><th>Proposed Indications (K250321)</th><th>Predicate K172207 Cleared Indications</th></tr>
<tr><td>GCI Sterilization Wrappers are intended to be used to enclose reusable textile-based medical devices, such as surgical gowns, towels, and drapes, for sterilization by a health care provider. They are designed to allow effective steam sterilization of the enclosed textile items and to maintain sterility until use, for up to 28 days.

GCI Sterilization Wrapper sizes and load limitation are as follows:
<table>
<tr><th>SKU / Model</th><th>Size</th><th>Border Color</th><th>Maximum Validated Load Weight</th></tr>
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GCI Sterilization Wrappers are reusable through 38 wash, dry, and sterilization cycles. Pack assembly should follow established folding, assembly, and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. Closure can include autoclave tape and elastomer closures.
Sterilization: A prevacuum steam sterilization cycle (4 minutes exposure at 132°C, Dry Time: 30 minutes) has been validated.</td><td>Standard Supreme Sterilization Wrappers are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
Standard Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Standard Supreme Sterilization Wrappers are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile sterilization wraps that are intended to be sterilized and processed by health care facilities and/or contract sterilization / laundry companies.
Pack Assembly:
Pack assembly should follow established folding, assembly and wrapping procedures as defined by the clinical staff for aseptic presentation of the pack and its contents. The oblong and envelope folds have been validated for use on textile packs. Closure can include autoclave tape and elastomer closures.
Sterilization:
A prevacuum sterilization cycle (4-minute exposure at 270°F) has been validated for use on textile packs. The maximum pack size validated for use was 0.58 cubic feet with a pack weight of 12.9 pounds – pack density of 22.4 lbs./cu.ft. The maximum chamber loading</td></tr>
</table>

Proposed Indications (K250321)	Predicate K172207 Cleared Indications
	configuration including 85.6 pounds of packs in a 9.1 cubic foot chamber – load density of 10.4 lbs./cu.ft. **Table 1:** **Standard Supreme Sterilization Wrappers Color and Model #'s**

Sizes	Misty	Jade	Ceil
12"x12"	21520502	-	-
18"x18"	21521502	21531502	21541502
23"x23"	21522002	21532002	21542002
27"x27"	-	21532302	-
30"x30"	21522802	21532802	21542802
35"x35"	21523002	21533002	21543002
45"x45"	21525002	21535002	21545002
54"x54"	21526002	21536002	21546002
54"x72"	21528202	21538202	21548202
70"x70"	21528802	21538802	21548802

9. Non-Clinical Performance Data

Performance testing was conducted in alignment with FDA guidance "Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities" and "Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities." Testing was conducted to relevant standards including ASTM D5587, 16 CFR 1610, AATCC 127, AATCC 42, ISO 10993-5, ISO 10993-10, ISO 9073, ASTM D5034, AAMI TIR 12, and AAMI TIR 30. All testing results passed pre-determined acceptance criteria. In alignment with requirements, supporting the performance of the subject device.

Table 3. Summary of Non-Clinical Testing (Averages)

Attribute	Acceptance Criteria	SUBJECT: K250321 GCI Surgical Wrappers	PREDICATE: K172207 Sterilization Wrappers	Comparison
Tearing Strength (ASTM D5587)	>20 PSI Standard fabric direction	> 21 PSI Standard fabric direction	Unknown	Similar*
Breaking Strength (ASTM D5034)	>20 PSI	> 163 PSI	>20 PSI	Similar*
Flammability (16 CFR 1610)	Class 1	Class 1	Unknown	Similar*
Water Resistance: Hydrostatic Pressure (AATCC 127)	Water Resistant, >20 cm H_2O	Water Resistant, >27 cm H_2O	Unknown	Similar*
Water Resistance: Impact Penetration (AATCC 42)	< 4.5 g	< 0.3 g	Unknown	Similar*
Linting	< 5 log IPM	< 5 log IPM	< 5 log IPM	Same

Attribute	Acceptance Criteria	SUBJECT: K250321 GCI Surgical Wrappers	PREDICATE: K172207 Sterilization Wrappers	Comparison
Sterility Maintenance (ANSI/AAMI/ISO 17665-1)	Sterility maintained for labeled time	28 Days	Unknown	Similar*
Cytotoxicity (ISO 10993-5)	Non-Cytotoxic	Non-Cytotoxic	Non-Cytotoxic	Same
Irritation (ISO 10993-10)	Non-Irritating	Non-Irritating	Unknown	Similar*
Sensitization (ISO 10993-10)	Non-Sensitizing	Non-Sensitizing	Unknown	Similar*
Use Life and Reprocessing Effectiveness (AAMI TIR12 and TIR30)	Reprocessing effectiveness confirmed for labeled use life	Use life 38 cycles Reprocessing effectiveness confirmed	Use life 75 cycles Reprocessing effectiveness unknown	Similar*
Sterilization Validation (ANSI/AAMI/ISO 17665-1)	SAL of 10-6 shall be demonstrated.	pass	pass	Same

Note: PSI is equivalent to lbf/in^2

10. Clinical Performance Data

N/A

11. Conclusion Statement

The conclusion drawn from the testing demonstrates that the subject device is at least as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K172207, Class II (21 CFR 880.6850, Product Code FRG).