September 1, 2022

Trinity Guardion
Bruce Rippe
Chief Executive Officer
4 S Park Ave Ste 204
Batesville, Indiana 47006

Re: K201876
Trade/Device Name: Soteria Bed Barrier
Regulation Number: 21 CFR 880.6190
Regulation Name: Mattress Cover For Medical Purpose
Regulatory Class: Class I
Product Code: QTV
Dated: April 15, 2022
Received: April 21, 2022

Dear Bruce Rippe:

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,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K201876

Device Name
Soteria Bed Barrier

Indications for Use *(Describe)*
The Soteria Bed Barrier is a cover for compatible bed decks and mattresses to provide a protective physical barrier between the equipment and the patient. The device is intended to prevent soiling of bed decks and mattresses, helping to reduce contamination during use.

The Soteria Bed Barriers are classified as level 3 per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

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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TRINITY GUARDION

K201876 - 510(k) Summary

I. Submitter's Information

Company Name:	Trinity Guardion
Address:	4 S Park Ave Ste 204 Batesville, IN 47006
Phone Number:	812-932-2600
Contact Person:	Bruce Rippe
Phone Number:	812-932-2600
Email Address:	brippe@trinityguardion.com
Date Prepared:	August 31, 2022

II. Device

Tradename:	Soteria Bed Barrier
Common Name:	Mattress and Bed Deck Cover (Medical Purposes)
Classification Name:	Mattress cover for medical purposes
Classification:	Class 1 (21 CFR 880.6190)
Product Code:	QTV

III. Predicate Device

Predicate Device: Chase Mfg. Co Mattress Cover, K780033
Reference Devices: Welmed Surgical Drape, K070432, DAS Medical, DAS Medical Equipment Drapes, K121436

IV. Device Description

The Soteria Bed Barrier is a mattress cover that fits securely over a healthcare mattress and bed deck and attaches to the bed frame. The device is available in multiple configurations to fit specific mattresses and beds, attaching with hooks or clips on each side and the head and foot section of the mattress fit inside a pocket allowing fitted sheets to work over the mattress. Color coding of the label used by the laundry and edge ribbon correspond to compatible beds and mattresses, each barrier model has a different ribbon color. The Soteria Bed Barrier helps to reduce contamination of the underlying surfaces by preventing the penetration of fluids. The Soteria Bed Barrier is a nonsterile reusable device that is laundered in accordance with the validated procedure to remove microbes and spores between each patient use. The Soteria Bed Barrier is removed from the mattress/bed deck for laundering upon soiling or between patient uses. After laundering and inspection, the product is then folded and wrapped with appropriate labels to be used again.

V. Indications for Use / Intended Use

The Soteria Bed Barrier is a cover for compatible bed decks and mattresses to provide a protective physical barrier between the equipment and the patient. The device is intended to prevent soiling of bed decks and mattresses, helping to reduce contamination during use.

The Soteria Bed Barriers are classified as level 3 per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

VI. Substantial Equivalence Discussion

The Soteria Bed Barrier and its predicate have been evaluated to determine substantial equivalence.

Table 1: Overview of technological characteristics

	Soteria Bed Barrier (Subject Device)	**Mattress Cover (Predicate Device) K780033**	**Determination**
Product Name	Soteria Bed Barrier	Mattress Cover	N/A
510(k) Holder	Trinity Guardion	Chase Mfg. Co.	N/A
Principle of operation	The Soteria Bed Barrier is placed over the medical equipment (mattress and bed deck) in the clinical setting. The device prevents fluids and contaminants from reaching the surfaces below in order to prevent contamination of the underlying surfaces.	A mattress cover for medical purposes. Intended for medical purposes and used to protect a mattress.	Same
Components	Barrier with hooks, clips, and elastic to aid in positioning and securing the product to the equipment	Mattress cover with elastic to aid in positioning and securing the product to the mattress.	Same
Design	Various designs and sizes to fit specific mattresses and beds	Various designs and sizes to fit specific mattresses	Same
Materials	knit polyester fabric with a polyurethane coating	Unknown	Equivalent –materials used are sufficient for their intended purposes
Resistance of Penetration to Liquid	AATCC Test Method 42, AATCC Test Method 127	Unknown	Same – Resistance of Penetration to Liquid was performed in accordance with the same standard utilized as the reference device.
Tensile Testing	ASTM - D5034	Unknown	Same – Tensile testing was performed in accordance with the same standard utilized as the reference device.
Flammability	16 CFR Part 10, Class I	Unknown	Same – Flammability testing was performed in the same manner as the reference device.

	Soteria Bed Barrier (Subject Device)	Mattress Cover (Predicate Device) K780033	Determination
Biocompatibility	Biocompatible per ISO 10993-1	Unknown	Same – Biocompatibility was evaluated per the Biological Risk Assessment and found to be suitable for its intended use.
Seam Strength	ASTM D751; *Standard Test Method for Coated Fabrics: Seam Strength* (per ASTM F2407)	Unknown	NA
Tear Strength	ASTM D5587; *Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure* (per ASTM F2407)	Unknown	Equivalent – The subject and reference devices utilized differing standards for tear strength, however each met the criteria for success established in the applicable standard.

VII. Performance Testing

Performance Testing was conducted to evaluate the technological and performance characteristics. Test methods were utilized in the same manner as the reference devices, the DAS Medical Equipment Cover (K121436), and Welmed Surgical Drape (K070432). Pre-determined performance specifications were tested and verification and validation activities were conducted to demonstrate that the Soteria Bed Barrier meets the defined criteria. Testing on the subject device is described in Table 2.

Table 2: Soteria Bed Barrier Performance Testing.

Test method	Purpose	Acceptance Criteria	Result
AATCC 42; *Water Resistance: Impact Penetration Test* (per ASTM F2407)[1]	Measure the resistance of fabric to the penetration of water by impact	The average blotter weight gain for all test specimens must be less than or equal to 1 gram.	Pass
AATCC 127; *Water Resistance: Hydrostatic Pressure Test* (per ASTM F2407)[1]	Measure the resistance of fabric to the penetration of water under hydrostatic pressure	The average hydrostatic pressure for all test specimens must be greater than or equal to 50 cm of water pressure (0.71 psi). Hydrostatic pressure is recorded when water penetrates the specimen in 3 different locations.	Pass
ASTM D5034; *Standard Test Method for Breaking Strength and Elongation of Textile Fabrics* (per ASTM F2407)[1]	Measure the breaking strength and elongation of fabric	The average tensile strength in each direction must be greater than or equal to 7lbf. Tensile strength is the peak force recorded when the fabric separates.	Pass

[1] Test method utilized by Welmed Surgical Drape (Reference Device) K070432.

ASTM D5587; *Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure* (per ASTM F2407)[1]	Measure the tearing strength of textile fabric	The average tear strength in each direction must be greater than or equal to 2.3 lbf. Tear strength is the average of the five highest peak forces recorded after a total tear of 3 inches or complete tear.	Pass
ASTM D751; *Standard Test Method for Coated Fabrics: Seam Strength* (per ASTM F2407)	Measure the seam strength of coated fabric	The average seam strength in each direction and combination of directions must be greater than or equal to 7 lbf. Seam strength is the peak force recorded when the seam or fabric separates.	Pass
16 CFR Part 1610; Standard for the Flammability of Clothing Textiles (per ASTM F2407)	Measure the flammability of textiles	Class 1 (normal flammability). Class 1 rating is assigned when the average burn time is greater than or equal to 3.5 seconds. Burn time is the time recorded when 5" of fabric burns.	Pass
Cleaning Validation	Validate efficacy of the cleaning process by analyzing the test sample for residual protein and hemoglobin after soiling	The residual protein for each test replicate must be <6.4 µg/cm^2 The residual hemoglobin for each test replicate must be <2.2 µg/cm^2	Pass
Laundering Validation	Measurement of the viable microbes and bacteria after laundering	• >99.9999% reduction by wash-off of a mixed suspension containing *Escherichia coli* ATCC 11229 *Pseudomonas aeruginosa* ATCC 15442, Methicillin Resistant *Staphylococcus aureus* (MRSA) ATCC 33592, and *Klebsiella pneumoniae* ATCC 10031 • >99.9999% reduction by wash-off of *Mycobacterium terrae* ATCC 15755, • >99.9999% reduction by wash-off of *Clostridium difficile* spores ATCC 43598*di*	Pass

VIII. Conclusions

The conclusion drawn from the risk-benefit assessment and from nonclinical tests demonstrates that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.