April 17, 2024

Sentinel Medical Technologies, LLC
Jackelyn Rodriguez
Quality Assurance/ Regulatory Affairs Director
50 N Laura Street, Suite 2500
Jacksonville, FL 32202

Re: K240057
Trade/Device Name: TraumaGuard Intra-abdominal Pressure Sensing System
Regulation Number: 21 CF§R 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL, PHU
Dated: February 28, 2024
Received: February 29, 2024

Dear Jackelyn Rodriguez:

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 and Part 809); 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,

Sharon M. Andrews -S

for Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240057

Device Name

TraumaGuard Intra-abdominal Pressure Sensing System

Indications for Use *(Describe)*

TraumaGuard Intra-abdominal Pressure Sensing System is intended for use in the drainage of urine for continuous measuring of intraabdominal pressure (IAP) and core body temperature (CBT). The measured IAP can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS).

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
Food and Drug Administration
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."

510(k) Summary

Table 1: 510(k) Summary

Submitter:	Sentinel Medical Technologies, LLC 50 N Laura St, Ste 2500 Jacksonville, FL 32202 1-800-579-4910
Contact Person:	Jackelyn Rodriguez Quality Assurance/ Regulatory Affairs Phone: 6097554559 E-mail: jrodriguez@sentinelmedtech.com
Date Prepared:	December 29, 2023
Trade Name:	TraumaGuard Intra-abdominal Pressure Sensing System
Common Name:	Intra-Abdominal Pressure Monitoring Device
Classification:	Class II
Establishment Registration Number	3021468326
Product Code:	EZL, PHU
Regulation	21 CFR 876.5130
Predicate Device(s):	The subject device is equivalent to the following device: TraumaGuard Intra-abdominal Pressure Sensing System (K210570) This predicate has not been subject to a design-related recall.
Device Description:	The TraumaGuard Intra-abdominal Pressure Sensing System is comprised of a catheter and cable used to connect to standard biometric monitors. The catheter is a Foley catheter that provides continuous biometric monitoring of intra-abdominal pressure and core body temperature. TraumaGuard (TG) is a silicone catheter with two polyurethane pressure sensing balloons used to detect changes in intra-abdominal pressure (IAP), the outer distal balloon and the inner sensing balloon. The outer balloon is filled with 2.0 - 2.5cc of sterile water to ensure contact with the bladder wall. The inner sensing balloon has a column of air that runs the entire length of the catheter from the middle of the outer sensing balloon to a connector on the hub. Temperature can be displayed in Celsius or Fahrenheit and is accurate within ±1°C over a range of 25°C to 40°C (77°F to 104°F). Pressure displayed is between 0mmHg and 40mmHg.

	The inflation, drainage and sensing ports of the catheter are color-coded and can be operated with a Luer Lock syringe tip. Each TG is sterile and individually pouched. TG Cables are reusable. TG is a single use catheter intended for short-term use (no more than 30 days).
Indication for Use:	TraumaGuard Intra-abdominal Pressure Sensing System is intended for use in the drainage of urine for continuous measuring of intraabdominal pressure (IAP) and core body temperature (CBT). The measured IAP can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS). The Indications for Use statement for the TraumaGuard Intra-abdominal Pressure Sensing System is identical to the predicate device. Both the subject and predicate devices have the same intended use for the drainage of urine for continuous measuring of IAP and CBT.
Legally Marketed Devices To Which Substantial Equivalence Is Claimed:	The TraumaGuard Intra-abdominal Pressure Sensing System is identical to the existing sizes of TraumaGuard Intra-abdominal Pressure Sensing System in intended use, materials, physical characteristics, and performance characteristics. The modifications attributed to the predicate device are the addition of MR conditional to the labeling.
Performance Data:	Performance data for the TraumaGuard Intra-abdominal Pressure Sensing System is compared to that of the predicate device (K210570) identified in these 510(K) summaries. Results of laboratory tests demonstrate the TraumaGuard Intra-abdominal Pressure Sensing System is substantially equivalent to the legally marketed device.

Table 2: 510(k) Device Comparison

	TraumaGuard Intra-abdominal Pressure Catheter (Subject Device)	**TraumaGuard Intra-abdominal Pressure Catheter (Predicate Device)**	**Comment**
Device Overview			

510(k) Number **Decision Date**	K230902 To be determined	K210570 October 29, 2021	
Manufacturer	Sentinel Medical Technology	Sentinel Medical Technology	Same
Classification	Class II	Class II	Same
Product Code	EZL, PHU	PHU	Same
Regulation	21 CFR 876.5130	Unclassified	Same
Medical Specialty	General and Plastic Surgery Gastroenterology/Urology	General and Plastic Surgery	Same
Indications for Use	The TraumaGuard Intra-abdominal Pressure Sensing Catheter is intended for the drainage of urine from the bladder, monitoring of urine output (when used with a standard collection bag), monitoring of core body temperature and continuous measuring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension, and the associated clinical syndrome of abdominal compartment syndrome. The TraumaGuard intra-abdominal pressure sensing catheter displays core body temperature in the healthcare setting in degrees Fahrenheit and degrees Celsius. TraumaGuard is a single use device intended for short-term use (less than 30 days).	The TraumaGuard Intra-abdominal Pressure Sensing Catheter is intended for the drainage of urine from the bladder, monitoring of urine output (when used with a standard collection bag), monitoring of core body temperature and continuous measuring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension, and the associated clinical syndrome of abdominal compartment syndrome. The TraumaGuard intra-abdominal pressure sensing catheter displays core body temperature in the healthcare setting in degrees Fahrenheit and degrees Celsius. TraumaGuard is a single use device intended for short-term use (less than 30 days).	Same
Intended Use	To serve as a Foley catheter and monitor of core body temperature and intra-abdominal pressure.	To serve as a Foley catheter and monitor of core body temperature and intra-abdominal pressure.	Same

Principle of operation	Outer distal balloon constricts onto inner sensing balloon when intra- abdominal pressure increases. This displaces the air in the inner pressure sensing balloon proximally which increases the tension of the connector located in the catheter hub onto the pressure sensor located in the cable.	Outer distal balloon constricts onto inner sensing balloon when intra- abdominal pressure increases. This displaces the air in the inner pressure sensing balloon proximally which increases the tension of the connector located in the catheter hub onto the pressure sensor located in the cable.	Same
Technical Comparison	Dual pressure sensing balloon system allows for continuous monitoring of IAP. Collection of urine via standard urine collection tubing and bag. TraumaGuard cable connects to standard hospital bedside monitors already located in clinical setting.	Dual pressure sensing balloon system allows for continuous monitoring of IAP. Collection of urine via standard urine collection tubing and bag. TraumaGuard cable connects to standard hospital bedside monitors already located in clinical setting.	Same
Components	Silicone catheter with silicone retention balloon and polyurethane balloons. Pressure and temperature transmitting custom cables	Silicone catheter with silicone retention balloon and polyurethane balloons. Pressure and temperature transmitting custom cables	Same
Placement	In the bladder	In the bladder	Same
Balloons	3	3	Same
Catheter French Size	18	18	Same
Not made with natural rubber latex	Yes	Yes	Same
Biomonitoring	Intra-abdominal pressure and core body temperature	Intra-abdominal pressure and core body temperature	Same
Catheter	Single Use Disposable	Single Use Disposable	Same
Mode of Pressure Sensing	Sensor located in cable connected to catheter hub	Sensor located in cable connected to catheter hub	Same
Custom Console Required	No	No	Same

Wear Duration	30 days	30 days	Same
Monitoring Duration	Continuous	Continuous	Same
Sterilization Method	E-beam Radiation	E-beam Radiation	Same
Minimum SAL	1 x 10-6	1 x 10-6	Same
MR Compatible	Conditional	MR Unsafe	See Below

Functional and Safety Testing:	Representative samples of the TraumaGuard device were tested in accordance with the company's design control procedures to ensure the functional and performance requirements of the device were met. Finished, sterile devices underwent MRI safety testing in simulated conditions. A study was performed to evaluate magnetically induced displacement force, magnetically induced torque, image artifact, RF-induced heating and RF exposure in the magnetic resonance imaging (MRI) environment for the Trauma Guard Catheter. This study established MRI safety conditions in accordance with ASTM F2503-20. The Standard used lists the MRI safety evaluations and the associated ASTM standard test methods. An additional Computational Modeling and Simulation (CM&S) study was performed to estimate in-vivo temperature rise due to RF-induced heating of the Sentinel Medical Technologies TraumaGuard catheter.

The following standards were used in testing:

- ASTM F2503-20 Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment.
- ASTM F623-19 Standard Performance Specification for Foley Catheters.
- ASTM F2052-21 Standard Test Method For Measurement Of Magnetically Induced Displacement Force On Medical Devices In The Magnetic Resonance Environment.
- ASTM F2213-17 Standard Test Method For Measurement Of Magnetically Induced Torque On Medical Devices In The Magnetic Resonance Environment.
- ASTM F2182-19e2 Standard Test Method For Measurement Of Radio Frequency Induced Heating On Or Near Passive Implants During Magnetic Resonance Imaging.
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-12:2021 Biological Evaluation of Medical Devices, Part 12: Sample Preparation and Reference Materials.

Additional testing was performed to support and demonstrate the non-pyrogenicity of the Sentinel TraumaGuard Intra-abdominal Pressure Sensing Catheter. This assessment focuses on the requirements of ISO 10993-1:2018. ISO Materials Mediated Rabbit Pyrogen (GLP) Report # 385393

The following guidance documents were used:

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment. Guidance for Industry and Food and Drug Administration Staff. Document issued on October 10, 2023.

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff Document issued on September 8, 2023

Conclusion:	The TraumaGuard Intra-abdominal Pressure Sensing System intended use, materials, and fundamental scientific technology is identical to the predicate device (K210570). Performance bench and laboratory testing demonstrate the labeling differences between the subject device and the predicate device do not raise new questions of safety and effectiveness.