



October 29, 2021

Sentinel Medical Technologies, LLC  
% Darci Diage  
Owner  
TPL Consulting  
1056 Eugenia Pl, Suite B  
Carpinteria, California 93013

Re: K210570

Trade/Device Name: TraumaGuard Intra-abdominal Pressure Sensing System  
Regulatory Class: Unclassified  
Product Code: PHU  
Dated: September 17, 2021  
Received: September 23, 2021

Dear Darci Diage:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Anjana Jain -S**

for Long Chen, Ph.D.  
Assistant Director  
DHT4A: Division of General Surgery 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

Form Approved: OMB No. 0910-0120  
Expiration Date: 06/30/2023  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)  
K210570

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 – K210570****Table 1: 510(k) Summary**

<b>Submitter:</b>	Sentinel Medical Technologies, LLC 50 N Laura Street, Suite 2500 Jacksonville, FL 32202 Phone number: (904) 704-9787
<b>Contact Person:</b>	Darci Diage Regulatory Affairs Phone: 707.953.2615 E-mail: <a href="mailto:darci@tplconsulting.net">darci@tplconsulting.net</a>
<b>Date Prepared:</b>	September 20, 2021
<b>Trade Name:</b>	TraumaGuard Intra-abdominal Pressure Sensing System
<b>Common Name:</b>	Intra-Abdominal Pressure Monitoring Device
<b>Classification:</b>	Unclassified, pre-amendment device
<b>Product Code:</b>	PHU
<b>Regulation</b>	Unclassified
<b>Predicate Device(s):</b>	The subject device is equivalent to the following device: <ul style="list-style-type: none"> <li>• Accuryn Monitoring System (K153655)</li> </ul> This predicate has not been subject to a design-related recall.
<b>Device Description:</b>	<p>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.</p> <p>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.</p> <p>Temperature can be displayed in Celsius or Fahrenheit and is accurate within <math>\pm 1^{\circ}\text{C}</math> over a range of <math>25^{\circ}\text{C}</math> to <math>40^{\circ}\text{C}</math> (<math>77^{\circ}\text{F}</math> to <math>104^{\circ}\text{F}</math>). Pressure displayed is between 0mmHg and 40mmHg.</p> <p>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. The TG Cables are reusable. TG is a single use catheter intended for short-term use (no more than 30 days).</p>

**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 ThermaGuard Intra-abdominal Pressure Sensing System is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the drainage of urine for continuous measuring of IAP and CBT. The predicate device has a container mounted on the monitor that is used to measure the amount of urine collected; the subject device does not include a urine measurement container.

	<b>TraumaGuard Intra-abdominal Pressure Catheter (Subject Device)</b>	<b>Accuryn Monitoring System (Predicate Device)</b>	<b>Comment</b>
<b>Device Overview</b>			
<b>510(k) Number</b>	K210570	K153655	
<b>Decision Date</b>	To be determined	April 5, 2016	
<b>Manufacturer</b>	Sentinel Medical Technology	Potrero Medical, Inc	
<b>Classification</b>	Unclassified	Class II	
<b>Indications for Use</b>	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 Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for short-term use (less than 30 days).	Subject device is not indicated for the monitoring of urine output.
<b>Intended Use</b>	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
<b>Principle of operation</b>	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.	The bladder is filled with saline and used as medium to transmit pressure form bladder wall to pressure sensing balloon. This constricts the sensing balloon transmitting a pressure response through the pressure lumen connected to the monitor. The pressure sensor located on the console is reading the pressure within the system.	Subject device has a dual balloon pressure sensing mechanism that can measure IAP in an empty bladder.
<b>Technical Comparison</b>	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	Single pressure sensing balloon lumen that transmits pressure changes in a full bladder because of increased IAP. System is provided with the monitor and custom drainage tubing that connects to a urine	Core body temperature monitoring is the same.

	<b>TraumaGuard Intra-abdominal Pressure Catheter (Subject Device)</b>	<b>Accuryn Monitoring System (Predicate Device)</b>	<b>Comment</b>
	monitors already located in clinical setting.	collection vessel located on the monitor.	
<b>Components</b>	Silicone catheter with silicone retention balloon and polyurethane balloons. Pressure and temperature transmitting custom cables.	Silicone catheter with silicone retention balloon and polyurethane balloon. Collection and sensing Tubing. Custom monitor with collection vessel.	Subject device does not include collection and sensing tubing or custom monitor with collection vessel.
<b>Placement</b>	In the bladder	In the bladder	Same
<b>Balloons</b>	3	2	Additional inner balloon is part of the dual balloon pressure sensing system.
<b>Catheter French Size</b>	18	16	Pressure sensing balloon system increases French size.
<b>Latex Free</b>	Yes	Yes	Same
<b>Biomonitoring</b>	Intra-abdominal pressure and core body temperature	Intra-abdominal pressure and core body temperature	Same
<b>Catheter</b>	Single Use Disposable	Single Use Disposable	Same
<b>Mode of Pressure Sensing</b>	Sensor located in cable connected to catheter hub	Sensor located in the monitor connected to catheter via tubing	Predicate has a pressure transducer inside the tubing connecting to the monitor.
<b>Custom Console Required</b>	No	Yes	Subject device plugs into a standard bedside monitor.
<b>Wear Duration</b>	30 days	30 days	Same
<b>Monitoring Duration</b>	Continuous	Non-continuous	Dual pressure sensing balloon system allows for measuring pressure in an empty bladder instead of requiring saline introduction to bladder.
<b>Sterilization Method</b>	E-beam Radiation	Ethylene Oxide	Split dose validated minimizes risk of further cross-link

	TraumaGuard Intra-abdominal Pressure Catheter (Subject Device)	Accuryn Monitoring System (Predicate Device)	Comment
			polymers; performance testing not impacted.
Minimum SAL	1 x 10 <sup>-6</sup>	1 x 10 <sup>-6</sup>	Same
MR Compatible	Yes	Yes	Same

**Functional and Safety Testing:**

Representative samples of the TraumaGuard device were tested in accordance with the company's design control procedures to ensure that the functional and performance requirements of the device were met. Finished, sterile devices underwent performance bench testing in simulated conditions. As a result of verification and validation activities and risk assessment, testing ensures the device design meets its functional and performance requirements.

Testing includes the following:

- Drainage Flow Rate
- Balloon Integrity (Resistance to Rupture)
- Inflated Balloon Response to Pullout
- Balloon Volume Maintenance
- Balloon Size and Shaft Size (Catheter Dimensional Verification)
- Deflation Reliability (Failure to Deflate)
- Temperature Measurement

Additional testing was performed for the pressure sensing function of the TraumaGuard device. To verify the functional requirement for continuous pressure monitoring the following tests were performed:

- Static Pressure
- Dynamic Pressure
- Recharge Pressure

The following standards were used in testing:

- ISO 11137-1:2006/AMD 2:2018 Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-1:2018, Biological evaluation of medical devices
- ASTM F623-19 Standard Performance Specification for Foley Catheters.
- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

**Conclusion:**

The TraumaGuard Intra-abdominal Pressure Sensing System intended use, indication for use, materials, and fundamental scientific technology is similar to the predicate device. Performance bench testing demonstrate that the differences between the subject device and the predicate device do not raise new risks of safety and effectiveness.