



ZOLL Circulation, Inc  
Riki Chaudhary  
Senior Regulatory Affair Program Specialist  
2000 Ringwood Avenue  
San Jose, California 95131

Re: K250979

Trade/Device Name: Thermogard HQ™ Temperature Management System, Thermogard XP®  
Temperature Management System (VitalTemp™ Universal Pad)

Regulation Number: 21 CFR 870.5900

Regulation Name: Thermal Regulating System

Regulatory Class: Class II

Product Code: NZE

Dated: September 15, 2025

Received: September 15, 2025

Dear Riki Chaudhary:

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

Sincerely,

**Meaghan Erlewein -S**

For Nicole Gillette

Assistant Director

DHT2B: Division of Circulatory Support,  
Structural, and Vascular Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K250979

Device Name

Thermogard HQ™ Temperature Management System, Thermogard XP® Temperature Management System (VitalTemp™ Universal Pad)

Indications for Use (Describe)

When used with Thermogard XP® or Thermogard HQ™ console: Temperature reduction in patients 2 years and older where clinically indicated, e.g. in hyperthermic patients.

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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## 510(K) SUMMARY

### I. GENERAL INFORMATION

Date Prepared: March 31<sup>st</sup>, 2025

Submitter: ZOLL Circulation, Inc.  
Address: 2000 Ringwood Avenue  
San Jose, CA 95131

Contact Person: Riki Chaudhary  
Senior Regulatory Affairs Program Specialist  
Email: rchaudhary@zoll.com  
Phone: 351-500-3540

Trade Name: Thermogard HQ<sup>™</sup> Temperature Management System, Thermogard XP<sup>®</sup> Temperature Management System (VitalTemp<sup>™</sup> Universal Pad)

Common Name: Thermal Regulating System

Classification/Name: Class II; System, Thermal Regulating

Product Code: NZE

Primary Predicate Device: **K231182**: Thermogard HQ<sup>™</sup> Temperature Management System, Thermogard XP<sup>®</sup> Temperature Management System; Cleared on 11/03/2023

Reference Device: **K101589**: Blanketrol<sup>®</sup> III Hyper-Hypothermia Temperature Management System; Cleared on 09/20/2010

### Device Description

The Thermogard HQ<sup>™</sup> Temperature Management System and Thermogard XP<sup>®</sup> Temperature Management System (herein referred as Thermogard Surface System) consists of a Thermogard Console (TGXP or TGHQ), a Surface Start-Up Kit (SSUK) and a Surface Pad whose function is to provide therapeutic cooling to a patient. The Thermogard Surface System including the VitalTemp<sup>™</sup> Universal Pad as a surface pad, is designed to provide therapeutic cooling to patient's 2 years and older. The Surface System delivers treatment to the patient by recirculating cold fluid through a single-use surface pad (non-sterile) and its associated disposable tubing set, the Surface Start-Up Kit (SSUK). The fluid is the intermediate heat-transfer medium between the Thermogard Console and the surface pad.

The VitalTemp<sup>™</sup> Universal Pad is a non-sterile disposable product. It is available in one size and can either be placed under, over the patient or used as a wrap. The VitalTemp<sup>™</sup> is manufactured and processed using identical materials, internal parts, and processes as the Thermogard<sup>™</sup> Vest, with the only difference being the size and shape of the surface pad.

**Intended Use/Indications for Use**

Intended Use:

The Thermogard Surface Pad intends to lower patient temperature.

Indications for Use:

When used with Thermogard XP® and Thermogard HQ™ console: Temperature reduction in patients 2 years and older where clinically indicated, e.g. in hyperthermic patients.

**Summary of Technological Characteristics compared to the Predicate Device:**

The subject device and the predicate device have the following similarities:

Characteristics	Subject Device: Thermogard Temperature Management System	Predicate Device: Thermogard Temperature Management System (K231182)	Reference Device: Blanketrol® III system (K101589)
Thermal regulating system	Yes	Yes	Yes
Non-invasive system	Yes	Yes	Yes
Patient surface cooling	Yes	Yes	Yes
Contact to the patient's skin during cooling	Yes	Yes	Yes
Single use device/pad	Yes	Yes	Yes
Removal of thermal energy from the patient	Yes	Yes	Yes
Temperature monitoring with a temperature probe	Yes	Yes	Yes
Heating mechanism	No	No	Yes
Pediatric Surface Cooling	Yes	No	Yes

**Substantial Equivalence Discussion**

The Thermogard Temperature Management System used with the Surface Start-Up Kit and the VitalTemp™ Universal Pad is substantially equivalent to the currently marketed predicate device Thermogard Temperature Management System when used with Thermogard™ Vest (K231182) as a surface pad, based on comparisons of the device classifications, Intended use & technological characteristics. The subject device met the pre-determined requirements and raised no new safety or effectiveness concerns. The mechanism of action to achieve the intended use is same between the subject and predicate device. Thus, the subject device is substantially equivalent to the predicate device.

**Non-Clinical Testing Summary**

Testing was completed for the Thermogard Temperature Management System used with the Surface Start-Up Kit and VitalTemp™ Universal Pad which demonstrated intended, labeled device performance. Performance testing included dimensional verification, functional testing, temperature, flow, pressure, shipping and handling, and standards testing included electrical safety, biocompatibility and usability. All testing confirmed that the Thermogard Temperature Management System used with the Surface Start-Up Kit and VitalTemp™ Universal Pad operates as described and is substantially equivalent to the predicate device.



**Conclusion**

The Thermogard HQ<sup>™</sup> Temperature Management System and the Thermogard XP<sup>®</sup> Temperature Management System used with the Surface Start-Up Kit and VitalTemp<sup>™</sup> Universal Pad meet the design, performance, and safety specifications when used in accordance with their labeling. Based on the information provided in this submission, and performance testing, the subject device, the Thermogard HQ and XP Console's use with the VitalTemp Universal Pad, is substantially equivalent to the predicate device.