June 20, 2025

Hadleigh Health Technologies
% Dulciana Chan
Principal Consultant
RQM+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K242964
Trade/Device Name: Celsi Warmer
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: May 16, 2025
Received: May 19, 2025

Dear Dulciana Chan:

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,

Nicole M. Gillette -S

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

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)*
K242964

Device Name
Celsi Warmer

Indications for Use *(Describe)*
Celsi Warmer is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring and thermal treatment of neonates.

a. Maintain pre-set body temperature as determined by the physician.
b. Celsi Warmer is appropriate for neonates greater than 28 weeks gestational age who weigh between 1-4 kg.
c. Monitoring and controlling patient temperature.

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
K242964

DATE PREPARED
June 20, 2025

MANUFACTURER AND 510(k) OWNER
Hadleigh Health Technologies
200 Gate Five Road, Suite 215
Sausalito, CA 94965
Telephone: +1 (415) 454-3005
Official Contact: Molly McCabe, Managing Director, Projects

REPRESENTATIVE/CONSULTANT
Dulciana Chan, MSE
Allison C. Komiyama, PhD, RAC
RQM+
Telephone: +1 (412) 816-8253
Email: dchan@rqmplus.com
akomiyama@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Celsi Warmer
Common Name:	Thermal Regulating System
Regulation Number:	21 CFR 870.5900
Class:	Class II
Product Code:	DWJ
Premarket Review:	Division of Circulatory Support, Structural and Vascular Devices (DHT2B)
Review Panel:	Cardiovascular

PREDICATE DEVICE IDENTIFICATION
The Celsi Warmer is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*
K152266	Altrix Precision Temperature Management System / Stryker Medical

DEVICE DESCRIPTION

The Celsi Warmer is a portable, non-invasive thermal regulating system, indicated for continuous temperature monitoring and thermal treatment of neonates that require extra warmth to maintain normal body temperature. It uses a non-invasive thermometer (using direct mode) that measures the temperature of an infant's skin via a temperature probe placed on their abdomen to provide input into a physiological control loop that controls the mattress temperature. The Celsi Warmer is intended for use in hospitals under a clinician's supervision and is appropriate for neonates greater than 28 weeks gestational age who weigh between 1-4 kg. The Celsi Warmer is comprised of the following components:

- Warming Mattress
- Controller Tower
- Celsi Temperature Probe and Celsi Belt
- Power Supply and Cables

INDICATIONS FOR USE

Celsi Warmer is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring and thermal treatment of neonates.

a. Maintain pre-set body temperature as determined by the physician.

b. Celsi Warmer is appropriate for neonates greater than 28 weeks gestational age who weigh between 1-4 kg.

c. Monitoring and controlling patient temperature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Hadleigh Health believes Celsi Warmer is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and intended use as the device cleared in K152266. Both devices are used to provide thermal treatment (warm patients) and monitor patient temperature. They both use thermal transfer devices, a controller, and skin temperature probes to warm patients in a similar temperature range by heat transfer using conductive heat. Both devices are intended to continuously monitor patient skin temperature which then controls the thermal transfer device using a physiologic closed-loop controller. Both devices are intended to be used in a hospital environment by healthcare professionals. Both devices regulate can monitor skin temperature in a similar range and both devices can warm their thermal transfer devices in a similar temperature range. The main difference between the subject and predicate device is that the subject device uses a warming mattress while the primary predicate device uses a blanket or wrap filled with temperature controlled water. Though there is a small difference in technology, there are no different questions of safety and effectiveness as warming mattresses are a known technology for patient warming. The subject device has undergone testing to ensure the subject device is substantially equivalent to the predicate.

	Subject Device	***Predicate***	**Comparison**
	Celsi Warmer Hadleigh Health Technologies K242964	Altrix Precision Temperature Management System Stryker Medical K152266	N/A
Indications for Use	Celsi Warmer is intended for use in hospitals under a clinician's supervision or at their direction to assist nurses in continuous temperature monitoring and thermal treatment of neonates. a. Maintain pre-set body temperature as determined by the physician. b. Celsi Warmer is appropriate for neonates greater than 28 weeks gestational age who weigh between 1-4 kg. c. Monitoring and controlling patient temperature.	The Altrix system is intended for circulating temperature controlled warm or cold water via patient contact thermal transfer devices for the application of regulating human body temperature in situations where a physician or clinician with prescription privileges determines that temperature therapy is necessary or desirable. a. Maintain pre-set body temperature as determined by the physician b. Maintain normal body temperature during surgical procedures c. For use in all clinical settings including coronary care units, operating, recovery and emergency departments, burn units, and medical/surgical units d. Adult and pediatric patients e. Monitoring and controlling patient temperature f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients	Similar
Intended Use	To provide thermal treatment (warm patients) To monitor patient temperature	To provide thermal treatment (warm patients) To monitor patient temperature	Same
Product Codes / Regulation Number	DWJ / 21 CFR 870.5900	DWJ / 21 CFR 870.5900 FLL / 21 CFR 880.2910	Same
Regulation Description	Thermal Regulating System	Thermal Regulating System	Same

Components	Controller Tower Warming Mattress Temperature Probe (Celsi Probe) Celsi Belt	Controller Hose sets Thermal transfer devices Temperature probes (Adhesive skin temperature sensing Probe, foley catheter temperature probe, or general purpose temperature sensing probe) Adaptor Cable	Same
Closed Loop Feedback	Yes	Yes	Same
Skin Temperature Measurement Range	Resolution: 0.1 °C Range: 34°C to 42°C	Resolution: 0.1 °C Range: 25°C to 45°C	Similar
Contact Duration	12 hours	Unknown	N/A
Patient Population	Neonates	Adults Pediatrics	Similar
Modes	Prewarm (30 minute warming cycle to 36.5°C) Baby (maintain baby temperature between 36.5-37.5°C) Fall Back (maintain mattress temperature at 36.5°C)	Automatic Manual Monitor	Similar
Alarms	Audio and visual alarms when temperature is out of acceptable range	Patient Temperature deviation and normothermia deviation	Same
Use Environment	Hospital environment	Hospital environment	Same
User	Healthcare professionals	Healthcare professionals	Same
Prescription Use	Yes	Yes	Same

SUMMARY OF NON-CLINICAL TESTING

Biocompatibility

The subject device was evaluated for cytotoxicity, sensitization, and irritation according to FDA's *Guidance for Industry and Food and Drug Administration Staff – Use of International ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and* in compliance to ISO10993-5 *Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-10- *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*.

Software Verification and Cybersecurity

The software development and testing were executed with consideration to IEC 62304 *Medical device software- Software life cycle processes*. Cybersecurity was evaluated per AAMI TIR57 *Principles for medical device security - Risk management*.

Electromagnetic Compatibility and Electrical Safety

The subject device was tested in compliance with:
IEC 60601-1 *Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*
IEC 60601-1-2 *Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests*
IEC 60601-1-8 *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-10 *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 80601-2-35 *Part 2: Particular requirements for the safety of blankets, pad and mattresses intended for heating in medical use*
ISO 80601-2-56 *Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*.

Usability

Hadleigh Health conducted a usability study to determine whether Celsi Warmer operates as intended with the intended users of the system and to assess if there were any unidentified risks in accordance with IEC 60601-1-6 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*. Testing was consistent with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* issued on February 3, 2016.

CONCLUSION

Based on the testing performed including biocompatibility, software verification and validation, electromagnetic compatibility and electrical safety, usability, and performance it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The equivalent indications for use, similar technological characteristics, and equivalent performance characteristics for the proposed Celsi Warmer are assessed to be substantially equivalent to the predicate device.