September 23, 2022

Augustine Temperature Management
Garrett Augustine
VP R&d
7656 West 78th Street
Minneapolis, Minnesota 55439

Re: K220941
Trade/Device Name: HotDog Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: August 25, 2022
Received: August 25, 2022

Dear Garrett Augustine:

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,

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

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)*
K220941

Device Name
HotDog Temperature Management System

Indications for Use *(Describe)*
The HotDog Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients may not maintain a state of normothermia. The System can be used with adult and pediatric patients.

The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating rooms, recovery rooms, emergency rooms, burn units and on other medical/surgical floors.

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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SECTION 5
Premarket 510k Summary

Submitter Information:	Augustine Temperature Management, LLC 7656 West 78th Street Minneapolis, MN 55439 952.465.3529
Contact:	Garrett Augustine, VP R&D
Date Prepared:	08/25/2022
Trade Name	HotDog Temperature Management System
Product Code	DWJ - Thermal Regulating System (21 CFR §870.5900)
Common Name	Thermal Regulating System
Predicate Device	HotDog Temperature Management Controller - K201779
Reference Device	Altrix™ Precision Temperature Management System - K180834
Device Description	The HotDog Temperature Management System ("System") is a thermal regulating system, indicated for monitoring and controlling patient temperature in adult and pediatric patients of all ages. Unintended hypothermia can occur for many reasons, the most common clinically being the use of anesthetic drugs in surgery. Given the negative consequences of unintended hypothemia, active warming therapy is standard practice. The System can measure patient core temperature within the range of 31˚C to 43 C˚(87.8˚F to 109.4˚F). The System consists of the HotDog Temperature Management Controller (WC7X) and reusable Warming Blankets (BXXX) and Mattresses (UXXX). The Controller includes: • 7-inch touchscreen with intuitive user interface • Ability to power multiple warming devices at once • Integrated educational slide shows & positioning guides • Adjustable settings Additionally the controller monitors patient core temperature when receiving a signal from an Augustine YSI 400-compatible temperature probe. This requires at least a proprietary cable to make the connection. The Controller can also output the patient temperature to a third-party monitor (e.g., to port to the EMR).

AUTO mode is available if Warming Devices are placed on the patient and plugged-in, and a valid human temperature is measured/monitored. AUTO mode automatically adjusts the warming device temperature setting based on a user-selectable "Normothermia Zone" in increments described in the table below. The upper limit in the example below is set at 38°C and lower limit is set at 36°C for the Normothermia Zone (selectable in the *Menu – Setting – Temperature Graph;* the zone must extend 1°C or greater).

Table 1 AUTO mode -- Example					
Normothermia Zone (User Selectable)	**Example Patient Temperature**	**Devices: All High**	**Devices: All Medium**	**Devices: All Low**	**Devices: All Off**
>=Upper Limit Setting	**38.0°C**				**X**
67% of Upper Limit	**37.3°C**			**X**	
33% of Upper Limit	**36.7°C**		**X**		
<Lower Limit Setting	**36.0°C**	**X**			

Blankets and mattresses utilize a flexible semi-conductive polymer fabric which warms the patient effectively within safe limits (controlled temperature, low watt density, low thermal mass). They are RF sealed in durable urethane shells designed to eliminate uncleanable crevices. They are powered by a low voltage floating isolated DC current, designed to safely operate in the most demanding clinical settings.

Indications For Use

The HotDog Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients may not maintain a state of normothermia. The System can be used with adult and pediatric patients.
The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating rooms, recovery rooms, emergency rooms, burn units and on other medical/surgical floors.

Technological Characteristics

Active warming of patients with semi-conductive blankets and mattresses with a temperature sensor and controller is the technological principle for both the subject and predicate devices. The subject and predicate devices share the following same technological characteristics:

- Hardware
- Software
- Shell material
- Touchscreen
- Input Voltage
- Output Voltage
- Ports
- Power Supply

The subject and predicate devices are in every other respect identical in their construction.

For the subject device, the use of a proprietary cable and Augustine YSI-400 temperature probe unlocks functionality for temperature monitoring and AUTO mode closed-loop warming. This functionality represents the technological difference between the subject and predicate devices.

The reference device contains the functionality of active warming, temperature probes and closed-loop warming. Its warming is achieved via warmed water mattress which is different from the subject and predicate devices, however its broadest use is similar and supports scientific methodology / standard reference values as it relates to the expanded technology of this submission (ie use of FDA recognized consensus standards IEC 60601-1-10 [closed-loop system], ISO 80601-2-56 [temperature monitoring]).

Performance Data

Bench testing was performed to demonstrate that the proposed controller is compliant with FDA recognized consensus standards related to this submission. These tests were underwritten by Intertek, using pass/fail criteria.

Electrical safety and electromagnetic compatibility (EMC)

The HotDog Temperature Management System is designed and verified to meet the following performance standards:

ANSI AAMI ES60601-1, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 FDA recognition #19-4

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic

Compatibility - Requirements and Tests, edition: 4.0 FDA recognition # 19-8

Particular Standards

The HotDog Temperature Management System is designed and verified to meet the following particular standards:

IEC 80601-2-35, Particular requirements for the safety of blankets, pad and mattresses intended for heating in medical use, edition: 2.1 FDA recognition # 6-390

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, second edition FDA recognition # 6-421

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, edition 1.1 FDA recognition # 19-9

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, edition 2.1 FDA recognition # 5-76

Software Verification

Software was verified according to a test protocol, as well as being underwritten as compliant with the software lifecycle standard:

IEC 62304, Medical Device – Software Life Cycle Processes Edition 1.1 FDA recognition # 13-79

Usability

A Formative usability engineering study was completed on the subject device. A Summative validation was completed that showed the subject device is usable and that the theory of operation of AUTO mode is consistent with the otherwise manual operation of a typical user in a typical use-case.

IEC 62366-1, Medical Device - Application of usability engineering to medical devices, Edition: 1.0 FDA recognition # 5-114

Risk Management

Risk management was applied throughout the development process of the device. Risk mitigations were verified. Residual risks were assessed and an overall benefit-risk was established. The benefits of the subject device far outweigh the risks.

ISO 14971, Medical Device - Application of Risk Analysis to Medical Devices, third edition FDA recognition # 5-125

Further Bench Testing

Additional bench testing showed that authorized temperature probes are compatible with the system. The YSI-400 specification sheet states that single patient use probe models are interchangeable within 0.2 ºC for a temperature range of 34 to 41 ºC and are otherwise interchangeable within 0.5 ºC for ranges of 20 to 34 ºC and 41 to 45 ºC. In other words, the temperature from the controller readout must be within 0.2 ºC or 0.5 ºC of the converted YSI-400 temperature to be compatible with the probe, depending on the case. Furthermore, the temperature readout of the Multiport controller has a resolution of 0.1 ºC. The combination of these tolerances gives an acceptance criteria. For each temperature entry, the criteria passed, demonstrating that the device is compatible with the Augustine YSI-400 probes, and can therefore adequately integrate to monitor the patient temperature. Other probes were not considered in this test, as the device is only intended for use in tandem with the Augustine probe. Only Augustine temperature probes or esophageal stethoscopes using this tested connector and YSI-400 thermistor are compatible with this device. Other testing showed that AUTO mode functions according its own theory of operation.

Summary

Bench testing demonstrates that the device is substantially equivalent to the predicate device. Temperature characteristics and safety systems were assessed and found to be comparable. Summative validation shows the expanded technology of this submission (temperature monitoring and AUTO mode) are usable and essentially mimic what a user would be doing manually normally.

Clinical Data Not required

Conclusion The HotDog Temperature Management System was found to be equivalent to the predicate HotDog Temperature Management Controller in warming function. The expanded technology of this submission, when considering the reference device capabilities and tested to FDA recognized consensus standards, demonstrate

substantial equivalence to the predicate. The overall intended use of the device, achieving normothermia, is identical to the predicate. In sum, the HotDog Temperature Management System of this submission is as safe, as effective, and performs as well as the legally marketed predicate device.