September 11, 2020

Augustine Temperature Management
Temi Ogunse
QA/RA Representative
7656 West 78th Street
Minneapolis, Minnesota 55439

Re: K201779
Trade/Device Name: HotDog Temperature Management Controller
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 24, 2020
Received: June 30, 2020

Dear Temi Ogunse:

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,

Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201779

Device Name
HotDog Temperature Management Controller

Indications for Use *(Describe)*
The HotDog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The HotDog Temperature Management Controller should be used in circumstances in which patients may not maintain a state of normothermia. The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating, recovery, and emergency rooms and on 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
510(k) Number: K201779

Submitter Information:	Augustine Temperature Management, LLC 7656 West 78th Street Minneapolis, MN 55439 952.465.3539
Contact:	Temi Ogunse QA/RA Representative
Date Prepared:	06/19/2020
Trade Name	HotDog Temperature Management Controller Model: WC7X
Product Code	DWJ (21 CFR Part 870.5900)
Common Name	Thermal Regulating System
Predicate Device	HotDog Patient Warming System K052392 HotDog Multi-Function Controller K094056
Device Description	The HotDog Temperature Management Controller is part of a System intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients could become cold. The HotDog Temperature Management Controller is designed to provide power to the HotDog warming devices and to control the devices to set temperature.
Intended Use	The Controller 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 is intended primarily for use in hospitals and surgical centers including operating, recovery, and emergency rooms, on medical/surgical floors.
Technological Characteristics	A comparison between the new and predicate devices shows that the technological characteristics and indications for use are equivalent. The products have similar designs, materials, components, and dimensions.
Non-Clinical Data	Bench testing was performed to demonstrate that the proposed controller is substantially equivalent to the predicate devices.

Temperature characteristics and safety systems were assessed and found to be comparable.

The Controller is designed to meet the following performance standards:

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, edition: 3.0

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, edition: 3.1

IEC 60601-1-4:2000, Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, edition 1.1.

IEC 80601-2-35, Particular requirements for the safety of blankets, pads and mattresses intended for heating in medical use, edition 1

IEC 62366, Medical Device – Application of usability engineering to medical devices

IEC 62304, Medical Device Software - Software Life Cycle Processes

Clinical Data Not required

Conclusion The HotDog Temperature Management Controller was found to be equivalent to the predicate devices in technological characteristics and indications for use.