June 29, 2023

Augustine Temperature Management, LLC
% Garrett Augustine
VP R&d
Augustine Temperature Management
6581 City West Parkway
Eden Prairie, Minnesota 55344

Re: K230866
Trade/Device Name: HotDog Warming Mattress + Return Electrode
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ, ODR
Dated: March 29, 2023
Received: March 29, 2023

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,

Kathleen M. Grunder -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

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)*
K230866

Device Name

HotDog Warming Mattress + Return Electrode

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 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.

The HotDog Return Electrode Mattress is intended to conduct monopolar electrosurgical energy from the target tissue of a patient back to one electrosurgical unit (ESU) or generator in monopolar surgery. The HotDog Return Electrode Mattress is restricted to use with isolated monopolar electrosurgical generators. The Hotdog Return Electrode Mattress is intended for use with adult patients only.

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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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:	03/29/2023
Trade Name	HotDog Warming Mattress + Return Electrode
Primary Code	DWJ -- Thermal Regulating System (21 CFR §870.5900)
Reference Code	GEI -- Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR § 878.4400)
Common Name	Warming Mattress + Return Electrode
Predicate Device	HotDog Temperature Management System (K220941)
Reference Device	HotDog Return Electrode Mattress (K210727)
Related Submission	Q-Submission (Q222939)
Device Description	The HotDog Warming Mattress + Return Electrode ("Mattress") is part of a thermal regulating system, indicated for controlling patient temperature in adult patients. Mattresses utilize a flexible semi-conductive polymer fabric which warms the patient effectively within safe limits (controlled temperature, low watt density, low thermal mass) from a controller and sensor feedback loop. They are RF sealed in durable urethane shells designed to eliminate uncleanable crevices. Via a blue cable, they are powered with a low voltage floating isolated DC current, designed to safely operate in the most demanding clinical settings. Mattresses contain a green cable which enables the mattress to function as a capacitive return electrode for electrosurgery.

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Premarket 510k Summary

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Indication for Use

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Technological Characteristics

Active warming of patients with semi-conductive 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:

- Heater conductor material
- Shell material
- Output voltage
- Controller
- Port
- Power supply

The subject and predicate devices are in every other respect identical in their construction, with one exception: for the subject device, a proprietary green cable enables the mattress to function as a return electrode. This functionality represents the technological difference between the subject and predicate devices.

The reference device contains the functionality of return electrode mattress. Its use is the same, and -- aside from the warming function -- the construction is identical. The reference device supports scientific methodology / standard reference values as it relates to the expanded technology of this submission (ie use of

FDA recognized consensus standards IEC 60601-2-2 [HF electrosurgical accessories]).

Performance Data

Bench testing was performed to demonstrate that the proposed Warming Mattress + Return Electrode 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 Warming Mattress + Return Electrode 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 Warming Mattress + Return Electrode 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

IEC 60601-2-2, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories edition 6.0, FDA recognition # 6-389

Risk Management & Human Factors

Risk management was applied throughout the development process of the device. Risks related to a warming mattress + return electrode were assessed, particularly in how the functions might interact with each others' safety and performance, as compared to the known risks of a standalone warming mattress or standalone return electrode. Risk mitigations were verified. Residual risks were assessed and an overall benefit-risk was established. The benefits of the warming mattress + return electrode outweigh the risks.

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

Human factors and usability engineering was applied to the HotDog Warming Mattress + Return Electrode, on the design side, and throughout risk management.

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

Further Bench Testing

Additional bench testing was completed to assess the impact on performance or safety of an integrated mattress (warming + return electrode) as compared to a standalone warming mattress or return electrode mattress. Testing shows that warming functions as intended during use as a return electrode. In addition, the warming control at the WC77 controller is unaffected by electrosurgical use. Testing also shows that cut performance/safety of electrosurgery is unaffected whether or not warming is engaged in the mattress. Testing also show that warming and return electrode functions do not have some deleterious effect on longevity or shelf life. In sum, testing shows that warming and return electrode functions do not affect the safety or performance of one another, and do not create a substantial new risk that is not inherent to the standalone pads.

Validation

HotDog Warming Mattress + Return Electrode was validated on porcine tissue in a real operating room environment at the University of Minnesota's Visible Heart Laboratory.

Summary

Bench testing was performed to demonstrate that the proposed Warming Mattress + Return Electrode is compliant with FDA recognized consensus standards related to this submission. This and further bench testing demonstrate that the device is substantially equivalent to the predicate device. Warming performance and safety is equivalent. Return electrode performance and safety is equivalent. No substantial new risks exist from the integration of the two features.

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Clinical Data Not required

Conclusion The HotDog Warming Mattress + Return Electrode was found to be substantially equivalent to the predicate HotDog Temperature Management System. Reference device HotDog Return Electrode Mattress presents clear methodology for addressing differences in technology. 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 Warming Mattress + Return Electrode this submission is as safe, as effective, and performs as well as the legally marketed predicate device.