April 18, 2024

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

Re: K232627
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, GEI
Dated: March 19, 2024
Received: March 19, 2024

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 (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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232627

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 or two electrosurgical units (ESU) or generators 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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SECTION 5
Premarket 510k Summary

Submitter Information:	Augustine Temperature Management, LLC 15305 Minnetonka Blvd Minnetonka, MN 55345 952.465.3529
Contact:	Garrett Augustine, VP R&D
Date Prepared:	03/19/2024
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 Warming Mattress + Return Electrode (K230866)
Reference Device	Mega 2000 Soft Dual Cord Patient Return Electrode Pad (K031285)
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.

SECTION 5
Premarket 510k Summary

Indication 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 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 or two electrosurgical units (ESU) or generators 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.

Technological Characteristics

The subject and predicate devices are identical in every respect but one. While the predicate device can function as a return electrode for a single ESU, the subject device can function as a return electrode for one or two ESUs, using a "Y" version of the predicate's cable.

This technological characteristic – one or two ESU's -- is well established in the FDA-cleared devices in the capacitive-style return electrode category going back to May of 2003. Megadyne (K031285), which functions in a substantially equivalent manner to the submission device, indicates for one or two ESU's.

The reference Megadyne device, from their 510(k) summary, supports scientific methodology / standard reference values as it relates to the expanded technology of this Special 510(k) submission. Their summary defines temperature rise with two ESUs and impedance performance as bench testing to establish substantial equivalence. For Megadyne, in K031285 both of these values were found to be within acceptable limits to the standard, and substantially equivalent to their predicate (ie. use with one ESU).

SECTION 5
Premarket 510k Summary

Performance Data

Bench testing was performed to demonstrate that the proposed Warming Mattress + Return Electrode is compliant with FDA recognized consensus standards for use with one ESU. 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 use with two ESUs compared to one were analyzed. 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.

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 use of two generators vs one. Utilizing the reference device to support well established methodology, the temperature rise performance of the HotDog Warming Mattress + Return Electrode is substantially equivalent to the predicate device when utilizing two or one electrosurgical generators. Impedance results are theoretically unaffected by one or two generators, and therefore additional bench testing on impedance was not necessary. Patient Leakage testing was conducted under worst case conditions, demonstrating safety in dual generator use.

Summary

Bench testing was performed to demonstrate that the proposed HotDog 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. No substantial new risks exist from the ability to use one or two generators in electrosurgery with this device.

Clinical Data Not required

Conclusion The HotDog Warming Mattress + Return Electrode was found to be substantially equivalent to the predicate HotDog Warming Mattress + Return Electrode. Reference device Mega 2000 Soft Dual Cord Patient Return Electrode Pad presents clear methodology for addressing differences in technology. The expanded technology of this submission, when considering the reference device capabilities and testing to FDA recognized consensus standards, demonstrate substantial equivalence to the predicate. The overall intended use of the device 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.