February 1, 2022

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

Re: K210727
Trade/Device Name: HotDog Return Electrode Mattress
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 5, 2021
Received: December 27, 2021

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K210727

Device Name
HotDog Return Electrode Mattress

Indications for Use *(Describe)*
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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SECTION 5
Premarket 510k Summary

Submitter Information:	Augustine Temperature Management, LLC 7656 West 78th Street Minneapolis, MN 55439 952.465.3539
Contact:	Temi Ogunse RA/QA Representative
Date Prepared:	01/25/2022
Trade Name	Return Electrode Mattress Model: U501, U502
Classification	21 CFR Part 878.4400 / Class II
Product Code	GEI
Common Name	Patient Return Electrode
Predicate Device	MegaSoft Universal Patient Return Electrode - K133726
Device Description	The HotDog Return Electrode Mattress is sold with a Return Electrode Cable, 4m (A136) that enables connection to one electrosurgical generator. The HotDog Return Electrode Mattress completes the circuit required for electrosurgery through Capacitive method. A capacitor is created when two conductive plates are separated by an insulator. The separation of two conductive plates by an insulator creates a capacitor. The insulator prevents current from flowing directly between the two plates, thereby avoiding the resistance which creates heat. With capacitive grounding, current from the active electrode produces a charge on the first conductive plate. This causes an equal (but opposite) charge to form on the second conductive plate. Current produced by the charge on the second plate produces electrical returns to the generator and completes the circuit.
Indication for Use	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.

SECTION 5
Premarket 510k Summary

Technological Characteristics

The proposed subject device is found to possess similar technological characteristics under the premise of sharing the same intended use, warning, contraindications, area of use, frequency, cut power, COAG power, electrical safety standards, and conductor. Further detailed information is listed in the Substantial Equivalence Comparison table.

The proposed subject device uses foam for pressure relief under the patient, while the predicate device uses a gel for pressure relief under the patient. The proposed subject device has a polyurethane layer that serves as a dielectric material, whereas the predicate device has a gel layer the serves as a dielectric material in separating the two conductive layers. The analysis of the differences between the subject and predicate device does not raise questions regarding safety and effectiveness.

Non-Clinical Data

Designed bench and functional use testing in a porcine model as recommended by the FDA guidance Premarket Notification 510(k) Submission for Electrosurgical Devices for General Surgery to support substantial equivalence to the Predicate. The results demonstrated the subject device can perform the intended use as safely and effectively as the predicate device.

HotDog Return Electrode Mattress has conducted extensive testing to ensure conformance to the following standards:

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, edition: 3.1

IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, edition: 4.0

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

ISO 14971 Medical Device - Application of Risk Analysis to Medical Devices

SECTION 5
Premarket 510k Summary

Sterilization	The HotDog Return Electrode Mattress are not sterile, delivered sterile or intended to be sterilized by the end user.
Biocompatibility	The device is not intended to contact the patient. The IFU calls out a thin barrier between the patient and the shell material.
Clinical Data	Not required
Conclusion	The HotDog Patient Return Electrode Mattress was found to be as safe and effective as the predicate device as intended for use.