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.