

Premarket 510k Summary

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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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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 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.

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

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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.