June 13, 2020

STERIS Corporation
Gregory Land
Senior Regulatory Affairs Specialist
5960 Heisley Road
Mentor, Ohio 44060

Re: K200446
Trade/Device Name: STERIS Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: February 21, 2020
Received: February 24, 2020

Dear Gregory Land:

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,

Fernando Aguel
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200446

Device Name
STERIS Patient Warming System

Indications for Use *(Describe)*
Patient Warming System is a modular, electrically conductive Temperature Management System with adjustable temperature in a pre-defined range. The Patient Warming System is intended to prevent or treat hypothermia and maintain normothermia.

The Patient Warming System is intended primarily for use in hospital and surgical centers.

The Patient Warming System patient population includes adult and pediatric patients but excludes infant and neonatal patients.

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.

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510(k) Summary
For
STERIS Patient Warming System

STERIS Corporation
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Submission Date: February 21, 2020

K Number: K200446

1. Device Name

Trade Name:	**STERIS Patient Warming System**
Device Class:	Class II
Common/usual Name:	Patient Warming System
Classification Name:	System, Thermal Regulating
Classification Number:	21 CFR 870.5900
Product Code:	DWJ

2. Predicate Device

K112488 – HotDog Patient Warming System

Model Numbers: WC0X, WC5X, BXXX, UXXX

3. Device Description

Patient Warming System is a modular conductive patient warming system to be used during the pre-, intra-, and post-operative stages of surgical procedures to provide heating to patients for treatment of hypothermia, maintenance of normothermia and provide thermal comfort when conditions exist.

The STERIS Patient Warming System is a new product addition to STERIS. The STERIS Patient Warming System consists of a controller and one to three heating accessories as desired by the user such as the Heated Torso Pad and Overbody Warming Blanket. The controller uses software to control the heating elements for warming the contact surface of the accessory to the user selected temperature.

The Patient Warming System will be available in the following configurations.

- Controller, Power Supply, and Torso Pad Set (Foot Pad, Heated Torso Pad, and Head Pad)
  - Foot Pad and Head Pad are not heated and not subject to this 510(k)
- Controller and Power Supply
- Torso Pad Set (Foot Pad, Heated Torso Pad, and Head Pad)
  - Foot Pad and Head Pad are not heated and not subject to this 510(k)
- Heated Torso Pad
- Overbody Warming Blanket

4. Indications for Use

Patient Warming System is a modular, electrically conductive Temperature Management System with adjustable temperature in a pre-defined range. The Patient Warming System is intended to prevent or treat hypothermia and maintain normothermia.

The Patient Warming System is intended primarily for use in hospital and surgical centers.

The Patient Warming System patient population includes adult and pediatric patients but excludes infant and neonatal patients.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table

Feature	Proposed Device STERIS Patient Warming System	Predicate Device HotDog Patient Warming System (K112488)	Comparison
Indications for Use	Patient Warming System is a modular, electrically conductive Temperature Management System with adjustable temperature in a pre-defined range. The Patient Warming System is intended to prevent or treat hypothermia and maintain normothermia. The Patient Warming System is intended primarily for use in hospital and surgical centers. The Patient Warming System patient population includes adult and pediatric patients but excludes infant and neonatal patients.	The Hot Dog Patient Warming System is intended to prevent or treat hypothermia and to provide warmth to patients. The Hot Dog Patient Warming System should be used in circumstances in which patients may not maintain a state of normothermia. The patient warming system can be used with adult and pediatric patients. The System is intended primarily for use in hospital and surgical centers including without limitation operating, recovery and emergency rooms and on medical/surgical floors.	Similar
Operating Principles / Technology	A temperature control unit monitors and controls the temperature of a patient warming mattress and blanket	A temperature control unit monitors and controls the temperature of a patient warming blanket or mattress	Same

Feature	Proposed Device STERIS Patient Warming System	Predicate Device HotDog Patient Warming System (K112488)	Comparison
	which provides conductive heating to a patient.	which provides conductive heating to a patient.	
Where Used	Operating rooms, recovery rooms and emergency rooms	Operating rooms, recovery rooms and emergency rooms	Same
System Components	Temperature control unit, blanket, mattress	Temperature control unit, blanket, mattress	Same
Temperature Control Unit	48 Volt software driven control unit capable of regulating three warming accessories simultaneously. A LCD screen communicates information to the user. Five buttons are available to set the temperature of the system to predefined values.	48 Volt software driven control unit capable of regulating three warming accessories simultaneously. Three LED screens communicate information to the user. Three buttons, are used to set the temperature of each accessory independently.	Similar
Mattress Pad Material	Pressure relieving foam pad and conductive heater encased in a urethane coated fabric shell	Pressure relieving foam pad and conductive polymer coated fabric heater encased in a polymer shell.	Similar
Blanket Material	Insulating foam and a conductive heater encased in a urethane coated fabric shell	Conductive polymer coated fabric heater encased in a polymer shell	Similar
Specification	Conforms to IEC 80601-2-35: Particular requirements of the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use, edition 1	Conforms to IEC 60601-2-35: Particular requirements for the safety of blankets, pad and mattresses intended for heating in medical use, edition 1	Similar

6. Summary of Non-Clinical Performance Testing

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in **Table 2**.

Table 2. Performance Testing

Test	Acceptance Criteria	Result
Performance Testing	The STERIS Patient Warming System and warming accessories were tested for conformance to IEC 80601-2-35: Particular requirements of the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use	PASS
Pressure Management	The Underbody Warming Pad must not exhibit a peak pressure higher than 20% more than the existing torso pad. • For 5th Percentile female peak pressure shall be below 70 mmHg • For 95th Percentile male peak pressure shall be below 100 mmHg	PASS
Human Factors	Typical users are capable of following the written instructions for use to correctly use the STERIS Patient Warming System with simulated patients.	PASS
Electromagnetic Compatibility	IEC 60601-1-2:2014 General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	PASS
Electrical Safety Conformance	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	PASS
Software Validation	The software that controls the system was validated and determined to operate effectively and as designed.	PASS

7. Conclusion

The STERIS Patient Warming System has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device (K112488), Class II (21 CFR 870.5900), product code DWJ.