August 12, 2022

Smisson-Cartledge Biomedical LLC
% Julie Stephens
President/Consultant
Regulatory Resources Group, Inc.
111 Laurel Ridge Dr.
Alpharetta, Georgia 30004

Re: K202461
Trade/Device Name: ThermaCor® 1200 Disposable Sets for the ThermaCor® 1200 Rapid Thermal Infusion System
Regulation Number: 21 CFR 880.5725
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: LGZ, FRN, FPA
Dated: July 19, 2022
Received: July 20, 2022

Dear Julie Stephens:

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,

Mark J. Antonino, M.S.
Acting Division Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)* K202461

Device Name
ThermaCor® 1200 Disposable Sets for the ThermaCor® 1200 Rapid Thermal Infusion System

Indications for Use *(Describe)*

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is indicated for use over a full range of flow rates from slow feed to rapid, high flow infusion of: crystalloid, colloid, or blood product, including packed red blood cells [not in additive solutions and stored up to 21 days with anticoagulants], as volume replacement for patients suffering from blood loss due to trauma or surgery; warmed fluid to rewarm patients after surgery or for hypothermia; warmed fluid for irrigation in urology procedures

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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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Smisson-Cartledge Biomedical LLC
487 Cherry Street – Third Street Tower
Macon, GA 31201
Phone: (478) 744-9992

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc. - Phone: (678) 513-0693

Date Submitted: August 9, 2022

Device Name and Classification:

Trade/Proprietary Name:	ThermaCor® 1200 Disposable Sets for the ThermaCor® 1200 Rapid Thermal Infusion System
Common Name:	Rapid thermal infusion system
Regulation Number:	21 CFR 880.5725
Regulation Name:	Infusion Pump
Regulatory Class:	II
Product Code:	LGZ, FRN, FPA

Note: ThermaCor® 1200 Rapid Thermal Infusion System is the current "trade/proprietary name" for Smisson-Cartledge Biomedical TIS-1200 Thermal Infusion System, which was the name used within the prior 510(k) # K052055.

Legally Marketed Predicate Device:

Smisson-Cartledge Biomedical TIS-1200 Thermal Infusion System - 510(k) # K052055

Reason for 510(k) Submission:

To obtain clearance for a component modification within the ThermaCor® 1200 Disposable Sets. The component modification is the addition of a Parylene coating to the heat exchanger. The heat exchanger is a component of the cassette within the ThermaCor® 1200 Disposable Sets used with the ThermaCor® 1200 Rapid Thermal Infusion System.

Device Description:

The ThermaCor® 1200 Disposable Sets are intended for use only with the Smisson-Cartledge Biomedical (SCB) ThermaCor® 1200 Rapid Thermal Infusion System. The Disposable Sets consist of configurations that include cassettes with tubing connectors, various patient lines, and supply lines capable of interfacing with intravenous (IV) bags or optional-use reservoir equipment. Use of the ThermaCor® 1200 Disposable Sets ensures the intended use of the ThermaCor® 1200 Rapid Thermal Infusion System is met. The ThermaCor® 1200 Disposable Sets are provided sterile, non-pyrogenic and are single patient use only. They are sterilized by Ethylene Oxide (EO) sterilization method.

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is a portable or pole-mounted device intended for use in the hospital emergency room (ER), operating room (OR), intensive care unit (ICU), and Labor and Delivery (L&D) environments.

510(k) Summary

The system consists of an infusion device and a compatible, single patient use sterile disposable set with supply lines capable of interfacing with intravenous (IV) bags or an optional reservoir. The ThermaCor® 1200 Infuser may be used with a Footswitch (optional accessory) to allow hands-free, user-controlled delivery.

The ThermaCor® 1200 Infuser can deliver flow rates from 10 mL per Hour to 1200 mL per Minute selectable in 10mL/hr in Slow mode and 20mL/min in Rapid mode at normothermic temperatures and is intended for continuous operation. The ThermaCor® 1200 Rapid Thermal Infusion System is driven by a volumetric pump capable of variable-rate continuous infusion up to approximately 100 Liters total volume per Cassette. The system is also capable of delivering discrete bolus infusions. The user can select Bolus Mode to deliver a fixed, predetermined bolus of up to 1 Liter at a default or adjustable rate. When connected to alternating current (AC) power, the ThermaCor® 1200 Infuser can deliver fluids warmed to body temperature under most conditions. The Infuser can also run on battery power (heating capabilities will be disabled) to allow transport of the patient. A lithium-ion battery pack provides the power backup.

Indications for Use:

The Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System is indicated for use over a full range of flow rates from slow feed to rapid, high flow infusion of:

- crystalloid, colloid, or blood product, including packed red blood cells [not in additive solutions and stored up to 21 days with anticoagulants], as volume replacement for patients suffering from blood loss due to trauma or surgery
- warmed fluid to rewarm patients after surgery or for hypothermia
- warmed fluid for irrigation in urology procedures

Discussion of Indications for Use for ThermaCor® 1200 Disposable Sets:

The Indications for Use as proposed for the ThermaCor® 1200 Disposable Sets are same as the Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System. The ThermaCor® 1200 Disposable Sets are necessary to enable the ThermaCor® 1200 Rapid Thermal Infusion System to meet its Indications for Use.

The Indications for Use statement for the Smisson-Cartledge Biomedical ThermaCor® 1200 Rapid Thermal Infusion System did not change from the cleared 510(k) # K052055.

Discussion of Technological Characteristics:

The ThermaCor® 1200 Disposable Sets did not change technological characteristics from the cleared 510(k) # K052055 except for the addition of Parylene coating to the heat exchanger. The heat exchanger transfers heat to the fluids and is a component within the cassette. The cassette is then part of the Disposable Set that mounts onto the infusion pump unit. The addition of the Parylene coating did not change the performance of the Disposable Sets within the ThermaCor® 1200 Rapid Thermal Infusion System and demonstrated an improvement in the safety margin for potential aluminum ion leaching. The Disposable Sets are substantially equivalent to the Disposable Sets within the cleared 510(k) # K052055.

510(k) Summary

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993 biocompatibility requirements. Biocompatibility testing completed included Cytotoxicity, Acute Systemic Toxicity, Intracutaneous Reactivity Test, Material Mediated Pyrogenicity Test, Sensitization, and Blood Contact testing per ASTM F756 and ISO 10993-6 and additional FDA requests. Based on risk assessment, performance and safety testing was conducted on the ThermaCor® 1200 Disposable Sets with Parylene Coated Heat Exchangers for bond strength tests per ISO 8536-4, mechanical adhesion of the Parylene coating per ASTM D3359, particulate matter testing per USP <788>, and aluminum ion leaching verification testing. Performance verification testing was conducted with the ThermaCor® 1200 Rapid Thermal Infusion System to demonstrate maximum heat transfer equivalency of the Parylene Coated Heat Exchangers to previous versions of Heat Exchangers without Parylene coating.

Substantial Equivalence Conclusions:

The modification to the Smisson-Cartledge Biomedical ThermaCor® 1200 Disposable Sets [proposed] is substantially equivalent to the Disposable Cassette Sets within the cleared 510(k) # K052055 [predicate] in terms of indications for Use/Intended Use, technical characteristics, principles of performance and safety.