June 2, 2022

ZOLL Circulation, Inc.
Elizabeth Haines
Senior Director, Regulatory Affairs
2000 Ringwood Avenue
San Jose, California 95131

Re: K220008
Trade/Device Name: Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Thermogard HQ Start-Up Kit, Thermogard HQ Start-Up Kit EX, Thermogard HQ Console,
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: April 29, 2022
Received: May 2, 2022

Dear Elizabeth Haines:

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 and the limitations described below. 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.

The OHT5: Office of Neurological and Physical Medicine Devices has determined that there is a reasonable likelihood that the Solex 7 Intravascular Heat Exchange Catheter will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the box warning immediately following the indications for use statement of the device's labeling:

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. A randomized controlled trial of endovascular cooling in patients with fever associated with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

The OHT5: Office of Neurological and Physical Medicine Devices has determined that there is a reasonable likelihood that the Cool Line Intravascular Heat Exchange Catheter will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the box warning immediately following the indications for use statement of the device's labeling:

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results, refer to the Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Christopher M. Loftus M.D.
Acting Director
OHT5: Office of Neurological
and Physical Medicine 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)*
K220008

Device Name
Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Thermogard HQ Start-Up Kit, Thermogard HQ Start-Up Kit EX, Thermogard HQ Console

Indications for Use *(Describe)*

The Solex 7 Intravascular Heat Exchange Catheter connected to the Coolgard/Thermogard Thermal Regulation System is indicated for use:

• In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care. (Maximum use period: 4 days)

• To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care. (Maximum use period: 4 days)

• In fever reduction, as an adjunct to other antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated. (Maximum use period: 7 days)

Warning - Fever Reduction
The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. A randomized controlled trial of endovascular cooling in patients with fever associated with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

The Cool Line Catheter Model CL-2295A, when used with the ZOLL Thermal Regulation System, is indicated for use in fever reduction, as an adjunct to antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

WARNING – Fever Reduction
The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

	Cool Line			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

* Fischer's exact test
For more details on the clinical trial results, refer to the Physician's Manual – "Normothermia for the Neuro- critically Ill stroke patient".

The ZOLL ICY Intravascular Heat Exchange Catheter Model IC-3893A, connected to the ZOLL Coolgard/Thermogard Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/intensive care.

The ZOLL Quattro Catheter Model IC-4593, connected to a ZOLL Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/intensive care.

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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K220008 510(k) SUMMARY

Date Prepared:	May 31, 2022
Submitter:	ZOLL Circulation, Inc.
Address:	2000 Ringwood Avenue San Jose, CA 95131
Phone:	978-421-9291
Fax:	408-541-1030
Contact Person:	Elizabeth Haines, Senior Director Regulatory Affairs
Submission Author:	Melissa Paffenroth, Manager Regulatory Affairs
Trade Name:	Solex 7 Intravascular Heat Exchange Catheter Cool Line Intravascular Heat Exchange Catheter ICY Intravascular Heat Exchange Catheter Quattro Intravascular Heat Exchange Catheter Thermogard HQ™ Start-Up Kit Thermogard HQ™ Start-Up Kit EX Thermogard HQ™ Console
Common Name:	Central Venous Catheter (short term) and Thermal Regulating System
Classification/Name:	Class II; System, Hypothermia, Intravenous, Cooling
Regulation:	21 CFR 870.5900, Thermal Regulating System
Product Code:	NCX
Predicate Device:	K213031, Solex 7® Intravascular Heat Exchange Catheter, Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter, Quattro® Intravascular Heat Exchange Catheter, Start-Up Kit, Coolgard 3000® Console, Thermogard XP® Console

I. DEVICE DESCRIPTION

The ZOLL® Intravascular Temperature Management (IVTM™) System is comprised of an external heat exchange console (Thermogard HQ™ console) and intravascular heat exchange catheter connected via a sterile heat exchanger and tubing circuit (Thermogard HQ™ Start-Up Kit or Thermogard HQ™ Start-Up Kit EX). These components together comprise a patient temperature regulation apparatus employing feedback control. The subject devices of this submission are the Thermogard HQ™ Console, Thermogard HQ™ Start-Up Kit and Thermogard HQ™ Start-Up Kit EX. The Solex 7 Intravascular Heat Exchange Catheter, Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, and Quattro Intravascular Heat Exchange Catheter are also included as part of the system but are unchanged compared to the predicate device.

II. INDICATIONS FOR USE

The Thermogard HQ™ Console and Thermogard HQ™ Start-Up Kit (EX) are not intended to be used separately from the heat exchange catheters and do not have specific indications for use. The indications for use of the Solex 7® Intravascular Heat Exchange Catheter, Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter, Quattro® Intravascular Heat Exchange Catheter are identical to the indications for use of the predicate device.

Indications for Use

Solex 7® Intravascular Heat Exchange Catheter

The Solex 7® Intravascular Heat Exchange Catheter connected to the Coolgard/Thermogard Thermal Regulation System is indicated for use:

- In cardiac surgery patients to achieve and/or maintain normothermia during surgery and recovery/intensive care. (Maximum use period: 4 days)
- To induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care. (Maximum use period: 4 days)
- In fever reduction, as an adjunct to other antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated. (Maximum use period: 7 days)

Warning - Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. A randomized controlled trial of endovascular cooling in patients with fever associated with subarachnoid hemorrhage and primary traumatic brain injury has shown increased mortality as compared to patients receiving standard of care.

Cool Line® Intravascular Heat Exchange Catheter

The Cool Line® Catheter Model CL-2295A, when used with the ZOLL® Thermal Regulation System, is indicated for use in fever reduction, as an adjunct to antipyretic therapy, in adult patients with cerebral infarction and intracerebral hemorrhage who require access to the central venous circulation and who are intubated and sedated.

Warning – Fever Reduction

The safety of this device has not been demonstrated for fever reduction in patients presenting with subarachnoid hemorrhage or primary traumatic brain injury. The safety and effectiveness of this device was examined in a randomized controlled trial of 296 patients. The mortality results reported in this trial, for the four patient cohorts enrolled, are presented in the table below (CI – cerebral infarction, ICH – intracerebral hemorrhage, PTBI – primary traumatic brain injury, SAH – subarachnoid hemorrhage).

	Cool Line®			Control			
	n	N	%	n	N	%	p*
CI	3	16	18.8	3	14	21.4	0.74
ICH	8	33	24.2	7	27	25.9	1.00
PTBI	10	44	22.7	4	38	10.5	0.24
SAH	13	61	21.3	7	63	11.1	0.15

*Fischer's exact test

For more details on the clinical trial results, refer to the Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient."

ICY® Intravascular Heat Exchange Catheter

The ZOLL® ICY® Intravascular Heat Exchange Catheter Model IC-3893A, connected to the ZOLL® Coolgard/Thermogard Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/intensive care.

Quattro® Intravascular Heat Exchange Catheter

The ZOLL® Quattro® Catheter Model IC-4593, connected to a ZOLL Thermal Regulation System, is indicated for use:

- In cardiac surgery adult patients to achieve and/or maintain normothermia during surgery and recovery/intensive care, and
- To induce, maintain and reverse mild hypothermia in neurosurgery adult patients in surgery and recovery/intensive care.

III. TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT DEVICES COMPARED TO THE PREDICATE DEVICES

There were no changes to the intravascular heat exchange catheters as shown through comparison of the technological characteristics in Table 1 and 2. The comparison with the predicate Start-Up Kit and Start-Up Kit EX shows the technological characteristics of the proposed Thermogard HQ™ Start-Up Kit and Thermogard HQ™ Start-Up Kit EX to be substantially equivalent in Table 3. The comparison with the predicate Thermogard XP® Console shows the technological characteristics of the proposed Thermogard HQ™ Console to be substantially equivalent in Table 4.

Table 1: Comparison of Subject and Predicate Catheters

Feature	**PREDICATE DEVICES**	**SUBJECT DEVICES**
Device Name	Quattro® Intravascular Heat Exchange Catheter, Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter	Quattro® Intravascular Heat Exchange Catheter, Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter
510(k) Number	K213031	K220008
Class	II	Same
Classification/Regulation Name	System, Hypothermia, Intravenous, Cooling/Thermal Regulating System	Same
Regulation Number	21 CFR 870.5900	Same
Product Code	NCX	Same

Feature	PREDICATE DEVICES	SUBJECT DEVICES
Insertion Site	Cool Line® – Femoral vein, jugular vein, subclavian vein ICY® – Femoral vein Quattro® – Femoral vein	Same
Heparin Coating	SurModics Applause Heparin Coating	Same
Luer Designs	Inflow and outflow Luers: ZOLL® Custom Luers Infusion Luers: ZOLL® Standard Luers Vent Caps: ZOLL® Custom Vent Caps	Same
Luer Materials	Base material is polyurethane (for all Luers except for vent caps) Inflow and outflow Luers: Polyurethane: Tecoplast OP-770-164 Orange Distal infusion Luer: Polyurethane: Tecoplast OP-770-477Brown (pad printing white ink) Medial Infusion Luer: Polyurethane: Tecoplast OP-770-White Proximal infusion Luer: Polyurethane: Tecoplast OP-770-541 Dark Blue (pad printing white ink) Male vent cap: ABS: Ineos Lustran (P/N 348-012002) Female vent cap: ABS: Ineos Lustran (P/N 348-012002)	Same
Catheter Working Length (tip to manifold)	Cool Line® – 22 cm ICY® – 38 cm Quattro® – 45 cm	Same
Shaft Diameter	9.3 Fr	Same
Number of Lumens	5 lumens: 2 infusion, 1 guidewire (plus infusion), 1 inflow, 1 outflow	Same
Guidewire Compatibility	0.032 in.	Same

Feature	PREDICATE DEVICES	SUBJECT DEVICES
Heat Exchange Balloons	Cool Line® – 2 (straight/coaxial) ICY® – 3 (straight/coaxial) Quattro® – 4 (straight/coaxial)	Same
Flow Rate (by lumen)	Cool Line® Distal – 2100 mL/hr Medial – 1200 mL/hr Proximal – 1400 mL/hr ICY® Distal – 1700 mL/hr Medial – 900 mL/hr Proximal – 1200 mL/hr Quattro® Distal – 1300 mL/hr Medial – 800 mL/hr Proximal – 1100 mL/hr	Same
Approx. Inflated Balloon OD (Cross-sectional Area)	Cool Line®: ~5 mm (20 mm^2) ICY® and Quattro®: ~8 mm (50 mm^2)	Same
Heat Exchange Power	Cool Line® – 65 Watts nominal ICY® – 140 Watts nominal Quattro® – 190 Watts nominal	Same
Materials: Shaft Balloon	Polyurethane PET and Polyurethane (ICY® and Quattro®) Polyurethane (Cool Line®)	Same
Sterilization Method and Sterility Assurance Level (SAL)	Ethylene Oxide (EO) and SAL 10^{-6}	Same

Table 2: Comparison of Subject Solex 7® Intravascular Heat Exchange Catheter with Predicate

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Device Name	Solex 7® Intravascular Heat Exchange Catheter	Solex 7® Intravascular Heat Exchange Catheter
510(k) Number	K213031	K220008
Class	II	Same
Classification/Regulation Name	System, Hypothermia, Intravenous, Cooling/Thermal Regulating System	Same
Regulation Number	21 CFR 870.5900	Same
Product Code	NCX	Same
Heparin Coating	SurModics Applause Heparin Coating	Same

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Luer Designs	Inflow and Outflow Luers: ZOLL® Custom Luers Infusion Luers: Standard Luers Vent Caps: ZOLL® Custom Vent Caps	Same
Luer Materials	Luer Base: Polyurethane (for all Luers except for vent caps) Inflow and outflow Luers: Polyurethane: Tecoplast Orange Distal infusion Luer: Polyurethane: Tecoplast Brown (pad printing white ink) Medial infusion Luer: Polyurethane: Tecoplast White Proximal infusion Luer: Polyurethane: Tecoplast Dark Blue (pad printing white ink) Male vent cap: ABS Female vent cap: ABS	Same
Catheter Working Length (tip to manifold)	20 cm	Same
Shaft Diameter	9.3 Fr	Same
Number of Lumens	5 lumens: 2 infusion 1 guidewire (also infusion) 1 inflow 1 outflow	Same
Guidewire Compatibility	0.032 in.	Same
Flow Rate (by lumen)	Distal – 1900 mL/hr Medial – 1300 L/hr Proximal – 1300 mL/hr	Same
Heat Exchange Balloons	1 (serpentine)	Same
Inflated Balloon OD (Cross- Sectional Area)	Balloon OD: N/A Cross-sectional Area: 54 mm^2	Same
Cross Sectional Area (approx. inflated outer diameter)	54 mm^2 (12.2 mm OD)	Same
Insertion Site	Jugular and Subclavian Veins	Same
Max. Use Period	7 Days	Same
Materials	Shaft: Polyurethane Heat Exchange Balloon: PET	Same

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Sterilization Method and SAL	EO and SAL 10^{-6}	Same

Table 3: Comparison of the subject Thermogard HQ™ Start-Up Kit with predicate Start-Up Kit

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Device Name	Start-Up Kit Start-Up Kit EX	Thermogard HQ™ Start-Up Kit Thermogard HQ™ Start-Up Kit EX
510(k) number	K213031	K220008
Model	CG-500D CG-500D EX	TGHQ-500D TGHQ-500D EX
Class	II	Same
Classification/Regulation Name	System, Hypothermia, Intravenous, Cooling/Thermal Regulating System	Same
Regulation Number	21 CFR 870.5900	Same
Product Code	NCX	Same
Patient Contact	Indirect Patient Contact	Same
Luer Function	Join the SUK to the InFlow/OutFlow Lumens of the catheters, and allow saline to circulate through the catheter/start-up kit fluid path	Same
Supplied 20 ml Sterile Deflation (Slip-Fit) Syringe	Syringe provided with SUK for optional removal of saline from catheter heat exchange balloons prior to catheter removal	Same
Sterilization Method and SAL	Gamma sterilization SAL 10^{-6}	Same
Shelf Life	2 years	Same
IV Spike design	Bonded into a short section of larger tubing at the end of the tubing set.	New component with integrated pockets into which the inlet and outlet tubing are bonded. Revised spike geometry for ease of insertion.
Materials: Start-up Kit tubing Luer Spike	 Polyvinyl chloride Polyvinyl chloride Acrylonitrile butadiene styrene	 Same Same Same

Table 4: Comparison of the subject Thermogard HQ™ Console and predicate Thermogard XP® Console

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Device Name	Thermogard XP® Console	Thermogard HQ™ Console
510(k) number	K213031	K220008
Principle of Operation	It automatically adjusts the temperature of a heater/chiller glycol bath to achieve the patient target temperature that has previously	Same

Feature	PREDICATE DEVICE	SUBJECT DEVICE
	been set by the attending physician. A temperature probe is used to monitor the patient temperature, a catheter is used to exchange heat to and from the patient, and the delta between the target temperature and patient temperature defines the temperature of the saline pumped through the catheter. A heat exchanger placed within the glycol bath heats and cools the saline in the catheter.	
Class	Class II	Same
Classification/Regulation Name	System, Hypothermia, Intravenous, Cooling	Same
Regulation Number	21 CFR 870.5900	Same
Product Code	NCX	Same
Patient Contact	No direct patient contact	Same
Physical: 1. Dimensions 2. Weight	 Height: 45 in. (114 cm) Width: 17 in. (43 cm) Depth: 30 in. (76 cm) 107 lb. (49 kg)	Same
Electrical: 1. Configuration 2. Voltage 3. Fuse protection	 100-120 VAC, 50/60 Hz, 5 A 220-240 VAC, 50/60 Hz, 2.25 A 115 V - 230 V T6.3A (slow blow) 5 x 20mm Lag: 60ms@60A Breaking Capacity: 63A @ 250VAC	Same
Environmental: 1. Operating temperatures 2. Operating humidity 3. Atmospheric pressure:	 10° C – 27° C (50° F – 81° F) 30% to 75% noncondensing 70 kPa to 106 kPa	Same
Chiller and Heater: 1. Reservoir volume 2. Pump capacity 3. Temperature range 4. Coolant 5. Refrigerant	 2.0 liters (0.5 gal.) 7 lpm at 0 m head (0 ft.) 0° C – 42° C 1:1 mixture of propylene glycol and distilled water RFC 134a	 Same Same Same 1:1 mixture of propylene glycol and deionized water Same

Feature	PREDICATE DEVICE	SUBJECT DEVICE
6. Nominal Power (must be greater than)	190 watts	Same
Controller and Display 1. Screen display	6.4 in. (16.25 cm) LCD color VGA	Same
2. Controls	Pushbuttons and knob	Same
3. Temperature input	Thermistor, YSI 400 series	Same
4. Articulation	180° swivel, 45° tilt	Same
5. Data interface	Serial RS-232C, 9-pin sub-D connector	USB, Wi-Fi, Digital EMR output (IOIOI), Patient temperature output (T1 Out)
6. Alarms	Audible tones and displayed text messages	Same
7. Displayed temperature range	26° C– 42° C	Same
8. Displayed temperature accuracy	± 0.2° C	Same
Saline Coolant Circuit 1. Priming volume	200 ml	Same
2. Heat exchanger	Disposable stainless steel coil	
3. Priming source	Sterile saline solution (hospital-provided)	
4. Patient connection	Directional Luer connections on 72 in. (183 cm) lines	
5. Pump tubing	Roller pump compatible with directional fittings	
6. Sterility	Gamma sterilized	
7. Saline alarm	Reservoir level detection & alarm system	
8. Coolant circuit operating life	Replace disposable components after seven (7) days of continuous use	
Equipment Classifications: 1. Type of protection against moisture	Ordinary	Same
2. 60601 Safety Class	Type BF for temperature inputs	

Feature	PREDICATE DEVICE	SUBJECT DEVICE
3. Protection class	Type B for catheter connections 1	
4. Mode of operation	Continuous	
Start-Up Kit Accessory	Model CG-500D Model CG-500D EX	TGHQ-500D TGHQ-500D EX

IV. SUMMARY OF THE NONCLINICAL TESTS PERFORMED

Non-clinical performance testing was conducted to verify the performance of the Thermogard HQ™ Console, Thermogard HQ™ Start-Up Kit and Thermogard HQ™ Start-Up Kit EX. The following performance data were provided in support of substantial equivalence determination between the subject and predicate devices.

Table 5: Performance testing for the Thermogard HQ™ Console and Thermogard HQ™ Start-Up Kits

Test	Test Method Summary	Conclusion
Air Trap Insertion / Removal	Test method verifies that the Thermogard HQ™ Start-Up Kit Air Trap may be inserted into and removed from the Thermogard HQ™ Console as intended.	Pass
Console Warming and Cooling	Test method verifies that the system cools and warms as intended.	Pass
Electrical Safety	Test methods verify that the system meets electrical safety standards.	Pass
Electromagnetic Compatibility	Test method verifies that the system meets electrical immunity and emissions standards.	Pass
Human Factors / Usability	Test methods validate the device for human factors per the intended use.	Pass
Software Verification	Test methods verify that the software meets software requirements.	Pass

Table 6: Performance testing specific only to the Thermogard HQ™ Console

Test	Test Method Summary	Conclusion
Data Module Functionality	Test methods verify that the Data Module meets applicable requirements.	Pass
Reliability	Test methods verify that the system meets the service life requirements.	Pass

Test	Test Method Summary	Conclusion
Transit Testing	Test methods verify that the system meets the shipping and transit requirements.	Pass

Table 7: Performance testing specific only to the Thermogard HQ™ Start-Up Kits

Test	Test Method Summary	Conclusion
Use Duration (Life) and Durability Testing	Test methods verify that the Thermogard HQ™ Start-Up Kits meet the duration of use requirements.	Pass
Leak Testing	Test methods verify that the Thermogard HQ™ Start-Up Kits meet the leak requirements.	Pass
Tensile Testing	Test methods verify that the Thermogard HQ™ Start-Up Kits meet the tensile strength requirements.	Pass
Transit and Environmental	Test methods verify that the Thermogard HQ™ Start-Up Kits meet the shipping and transit requirements.	Pass

Safety testing per the international recognized standards

The proposed Thermogard HQ™ Console, Thermogard HQ™ Start-Up Kit, and Thermogard HQ™ Start-Up Kit EX were tested and all requirements were met from each applicable FDA recognized consensus standard.

Table 8: Thermogard HQ™ Console, Thermogard HQ™ Start-Up Kit, Thermogard HQ™ Start-Up Kit EX Standards

FDA Consensus Number	Standard	Year
5-125	ISO 14971	2019
5-117	ISO 15223	2016
19-8	IEC 60601-1-2	2014
19-4	IEC 60601-1	2005/A1:2012
5-89	IEC 60601-1-6	2010+ A1:2013
5-76	IEC 60601-1-8	2006+ A1:2012
19-9	IEC 60601-1-10	2007+A1:2013
6-421	ISO 80601-2-56	2017
13-79	IEC 62304:2006/Amd1	2015
5-129	IEC 62366-1	2015/Cor1:2016
5-57	ANSI/AAMI HE 75	2009/(R)2013
5-89	EN 60601-1-6 Edition 3.1	2013-10
14-499	ASTM D4169	2016
2-245	ISO 10993-5	1999
2-191	ISO 10993-12	2002
14-514	ISO 11737-1	2018

FDA Consensus Number	Standard	Year
14-540	ISO 11737-2	2019

V. SUMMARY OF THE CLINICAL TESTS PERFORMED

No clinical performance data were determined to be necessary to demonstrate substantial equivalence.

VI. CONCLUSION

The Thermogard HQ™ Console, Thermogard HQ™ Start-Up Kit and Thermogard HQ™ Start-Up Kit EX meet their design, performance, and safety specifications when used in accordance with the labeling. The differences between the subject and predicate devices do not raise new questions of safety and effectiveness. It was demonstrated through performance testing, and comparison of design features that the proposed devices are substantially equivalent to the predicate devices.