December 20, 2021

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

Re: K213031
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, Start-Up Kit, Coolgard 3000 Console, Thermogard XP Console
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: September 20, 2021
Received: September 21, 2021

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 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)*

K213031

Device Name

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

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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K213031 510(K) SUMMARY

Date Prepared: December 16, 2021

Submitter: ZOLL Circulation, Inc.

Address: 2000 Ringwood Avenue
San Jose, CA 95131

Phone: 408-419-2950

Fax: 408-541-1030

Contact Person: Elizabeth Haines, Senior Director 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
Start-Up Kit
Coolgard 3000 Console
Thermogard XP 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 Devices:

Device Name	510(k) Number
Alsius THERMOGARD XP and Catheter Thermal Regulation System	K072234
Alsius CoolGard 3000 and Catheter Thermal Regulation System	K060308
Cool Line Intravascular Heat Exchange Catheter, ICY Intravascular Heat Exchange Catheter, Quattro Intravascular Heat Exchange Catheter, Start-Up Kit (SUK)	K150046
Solex 7 Intravascular Heat Exchange Catheter and Start-Up Kit	K153226

I. DEVICE DESCRIPTION

The ZOLL Intravascular Heat Exchange Catheters (Quattro® Intravascular Heat Exchange Catheter Kit, Quattro® Intravascular Heat Exchange Catheter Premium Access Kit, Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter) are sterile, single use heparin coated flexible catheters designed for placement in the femoral, jugular, or subclavian veins. The

Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit is a sterile, single use 9.3F flexible catheter designed for placement in the superior vena cava from an insertion site in the jugular and subclavian veins. The Cool Line catheter contains two heat exchange balloons, the ICY catheter contains three heat exchange balloons, the Quattro catheter contains four heat exchange balloons and the Solex 7® catheter consists of a serpentine balloon. The ZOLL catheters are connected to a single use, disposable Start-Up Kit (SUK), the Coolgard 3000® Console and Thermogard XP® Console. The catheters connect to the console coolant well via tubing integral to the SUK. The catheter is connected to the SUK by connecting the male outflow Luer of the SUK to the female inflow Luer of the catheter and the female inflow Luer of the SUK to the male outflow Luer of the catheter. Both SUK Luers, in turn, are connected via tubing to a heat exchange coil through which saline circulates. The coil is placed in a coolant well located in the console. The controlled temperature saline is circulated through the closed-loop circuit of the SUK and catheter using the console pump, after which the saline is then returned within the SUK to the console heater and chiller coolant well via the catheter's outflow lumen. The catheters, SUK, the Coolgard 3000® Console and the Thermogard XP® Console are supplied separately. The ZOLL Intravascular Heat Exchange System is also designed for use with an off-the-shelf temperature probe, which is supplied separately and not manufactured by ZOLL.

II. Indications for Use

The intended use / Indications for Use of the Cool Line® Intravascular Heat Exchange Catheter, Icy® Intravascular Heat Exchange Catheter, Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit, Quattro® Intravascular Heat Exchange Catheter Kit, Quattro® Intravascular Heat Exchange Premium Access Kit, Start-Up Kit (SUK), Coolgard 3000® Console, and the Thermogard XP® Console are identical to the intended use and Indications for Use of the predicate Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter, Solex 7® Intravascular Heat Exchange Catheter, Quattro® Intravascular Heat Exchange Catheter, Start-Up Kit, Alsius THERMOGARD XP and Catheter Thermal Regulation System, and Alsius CoolGard 3000 and Catheter Thermal Regulation System.

Indications for Use

<u>The Solex 7® Intravascular Heat Exchange Catheter</u>

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 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			
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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

This Traditional 510(k) submission is an update to the Instructions for Use based on a request from the Food and Drug Administration (FDA) related to a recall.

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	K150046	K213031
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
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	Same

Feature	PREDICATE DEVICES	SUBJECT DEVICES
	Vent Caps: ZOLL Custom Vent Caps	
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-770-477 Brown (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
Heat Exchange Balloons	Cool Line® – 2 (straight/coaxial) ICY® – 3 (straight/coaxial) Quattro® – 4 (straight/coaxial)	Same

Feature	PREDICATE DEVICES	SUBJECT DEVICES
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	K153226	K213031
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
Luer Designs	Inflow and Outflow Luers: ZOLL Custom Luers Infusion Luers: Standard Luers Vent Caps: ZOLL Custom Vent Caps	Same

Feature	PREDICATE DEVICE	SUBJECT DEVICE
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)	26 cm	20 cm
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 mL/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
Sterilization Method and SAL	EO and SAL 10^{-6}	Same

Table 3: Comparison of Subject Start-Up Kit with Predicate

Feature	PREDICATE DEVICE	SUBJECT DEVICE
Device Name	Start-Up Kit	Start-Up Kit
510(k) number	K153226	K213031
Model	CG-500D CG-500D EX	Same
Principle of Operation	To control patient core temperature using heat exchange fluid in conjunction with Coolgard 3000® or Thermogard XP® Consoles and ZOLL Heat Exchange Catheters	Same
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/SUK 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

Table 4: Comparison of Subject Coolgard® 3000 Console and Thermogard® XP Console with Predicate

Feature	PREDICATE DEVICE	PREDICATE DEVICE	SUBJECT DEVICES
Device Name	Alsius CoolGard 3000	Alsius THERMOGARD XP	Coolgard 3000® Console Thermogard XP® Console
510(k) number	K060308	K072234	K213031
Principle of Operation	It automatically adjusts the temperature of a heater/chiller glycol bath to achieve the patient target temperature that has previously 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	Same	Same

Feature	PREDICATE DEVICE	PREDICATE DEVICE	SUBJECT DEVICES
	bath heats and cools the saline in the catheter.		
Class	Class II	Same	Same
Classification/ Regulation Name	System, Hypothermia, Intravenous, Cooling	Same	Same
Regulation Number	21 CFR 870.5900	Same	Same
Product Code	NCX	Same	Same
Patient Contact	No direct patient contact	Same	Same
Physical: 1. Dimensions 2.Weight	 Height: 45 in. (114 cm) Width: 17 in. (43 cm) Depth: 30 in. (76 cm) 115 lb. (52 kg)	 Same Same	 Same 107 lb. (49 kg)
Electrical: 1. Configuration 2. Voltage selector setting 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 20 mm T6.3A (slow blow) 5 x 20 mm	 Same Same Same	 Same Same 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 Same Same	 Same Same Same
Chiller and Heater: 1.Reservoir volume 2. Pump capacity 3. Temperature range 4. Coolant 5. Refrigerant 6. Nominal Power (must be greater than)	 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 HFC 134a 115 watts	 Same Same Same Same Same 190 watts	 Same Same Same Same RFC 134a Coolgard 3000®: 115 watts Thermogard XP®: 190 watts

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

Feature	PREDICATE DEVICE	PREDICATE DEVICE	SUBJECT DEVICES
Equipment Classifications: 1. Type of protection against moisture	Ordinary	Same	Same
2. 60601 Safety Class	Type BF for temperature inputs Type B for catheter connections	Same	Same
3. Protection class	1	Same	Same
4. Mode of operation	Continuous	Same	Same
Alsius Start-up Kit: Start-up Kit Accessory	Model CG-500D Model CG-500D EX	Same	Same

IV. SUMMARY OF THE NONCLINICAL TESTS PERFORMED

This Traditional 510(k) submission is for an update to the Instructions for Use based on a recall related to an FDA request. Technological characteristics of the devices remain similar to the predicate devices. Nonclinical testing was performed to support 'MR Conditional' labelling. Tables 5-7 below summarize the nonclinical testing for the Cool Line® Intravascular Heat Exchange Catheter, Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit, Quattro® Intravascular Heat Exchange Catheter Premium Access Kit and Quattro® Intravascular Heat Exchange Catheter Kit. Nonclinical testing demonstrated that the Cool Line® Intravascular Heat Exchange Catheter, Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit, Quattro® Intravascular Heat Exchange Catheter Premium Access Kit and Quattro® Intravascular Heat Exchange Catheter Kit are MR Conditional. MR testing of the Quattro® Intravascular Heat Exchange Catheter Kit was used to support the 'MR Conditional' labeling for the ICY® Intravascular Heat Exchange Catheter.

Table 5: Cool Line® Intravascular Heat Exchange Catheter

Test Name	Test Method Summary	Results
Magnetic Field Interactions	Testing for magnetic field interactions involved evaluations of translational attraction and torque for the Cool Line® Intravascular Heat Exchange Catheter using a 3 Tesla (T) MR system.	Testing showed the Cool Line® Intravascular Heat Exchange Catheter is MR Conditional in 3 T MR systems.
MRI-Related Heating	This device was tested for MRI-related heating according to recommendations in the ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Testing showed the Cool Line® Intravascular Heat Exchange Catheter is MR Conditional in 1.5 T/64 MHz

Test Name	Test Method Summary	Results
		and 3 T/128 MHz MR systems.
Artifact Test	MR imaging artifacts were assessed for the Cool Line® Intravascular Heat Exchange Catheter, emphasizing the part of the catheter that would be implanted in the patient, in association with the use of a 3 T MR system. This test was accomplished by performing MR imaging with the device placed inside of a gadolinium-doped, saline filled plastic phantom following aspects of the ASTM F2119-07 (2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.	Testing showed the Cool Line® Intravascular Heat Exchange Catheter is MR Conditional in 3 T MR systems.

Table 6: Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit

Test Name	Test Method Summary	Results
Magnetic Field Interactions	Testing for magnetic field interactions involved evaluations of translational attraction and torque for the Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit using a 3 T MR system. The Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit that was evaluated was representative of the manufactured or "finished" version of this device. A single sample of this device was tested and deemed appropriate since there are insignificant variations due to manufacturing differences.	Testing showed the Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit is MR Conditional in 3 T MR systems.
MRI- Related Heating	This device was tested for MRI-related heating according to recommendations in the ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Testing showed the Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit is MR Conditional in 1.5 T/64 MHz and 3 T/128 MHz MR Systems.
Artifact Test	MR imaging artifacts were assessed for the Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit, emphasizing the part of the catheter that would be implanted in the patient, in association with the use of a 3 T MR system. This test was accomplished by performing MR imaging with the device placed inside of a gadolinium-doped, saline filled plastic phantom following aspects of the ASTM F2119-07 (2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.	Testing showed the Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit is MR Conditional in 3 T MR systems.

Table 7: Quattro® Intravascular Heat Exchange Catheter Kit and Quattro® Intravascular Heat Exchange Catheter Premium Access Kit

Test Name	Test Method Summary	Results
Magnetic Field Interactions	Testing for magnetic field interactions involved evaluations of translational attraction and torque for the Quattro® Intravascular Heat Exchange Catheter Kit and Quattro® Intravascular Heat Exchange Catheter Premium Access Kit using a 3 T MR system. The Quattro Intravascular Heat Exchange Catheter Kit that was evaluated was representative of the manufactured or "finished" version of this device. A single sample of this device was tested and deemed appropriate since there are insignificant variations due to manufacturing differences.	Testing showed the Quattro® Intravascular Heat Exchange Catheter Kit and Quattro® Intravascular Heat Exchange Catheter Premium Access Kit are MR Conditional in 3 T MR systems.
MRI-Related Heating	The Quattro Intravascular Heat Exchange Catheter Kit was tested for MRI-related heating according to recommendations in the ASTM F2182-19e2: Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging.	Testing showed the Quattro® Intravascular Heat Exchange Catheter Kit and Quattro® Intravascular Heat Exchange Catheter Premium Access Kit are MR Conditional in 1.5 T/64 MHz and 3 T/ 128 MHz MR systems.
Artifact Test	MR imaging artifacts were assessed for the Quattro Intravascular Heat Exchange Catheter Kit, emphasizing the part of the catheter that would be implanted in the patient's vasculature, in association with the use of a 3 T MR system. This test was accomplished by performing MR imaging with the device placed inside a gadolinium-doped, saline filled plastic phantom following the ASTM F2119-07 (2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.	Testing showed the Quattro® Intravascular Heat Exchange Catheter Kit and Quattro® Intravascular Heat Exchange Catheter Premium Access Kit are MR Conditional in 3 T MR systems.

Biocompatibility: The changes in this submission do not impact biocompatibility.

V. SUMMARY OF CLINICAL TESTS PERFORMED

Clinical evaluations were not performed for this change.

VI. CONCLUSIONS

This Traditional 510(k) submission is for an update to the Instructions for Use. The difference in the Instructions for Use between the subject and predicate devices do not raise any new questions of safety and effectiveness. New warnings, precautions, and instructions were added to the Instructions for Use for the subject devices.

ZOLL Circulation, Inc., concludes that based on the above discussion the Cool Line® Intravascular Heat Exchange Catheter, ICY® Intravascular Heat Exchange Catheter, Solex 7® Intravascular Heat Exchange Catheter Premium Access Kit, Quattro® Intravascular Heat Exchange Catheter, Quattro® Intravascular Heat Exchange Premium Access Kit, Start-Up Kit, the Coolgard 3000® Console and the Thermogard XP® Console with updated Instructions for Use are substantially equivalent to the predicate devices.