January 13, 2023

ZOLL Circulation, Inc.
Brian Robey
Vice President, Advanced Development and Design Quality Assurance
2000 Ringwood Avenue
San Jose, California 95131

Re: K223746
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 XP Console, Thermogard HQ Console
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: December 12, 2022
Received: December 14, 2022

Dear Brian Robey:

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,

David P. Mc Mullen -S

David McMullen, M.D.
Director
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223746

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 XP Console, 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			
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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."

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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K223746 510(k) SUMMARY

Date Prepared:	January 6, 2023
Submitter: Address:	ZOLL Circulation, Inc. 2000 Ringwood Avenue San Jose, CA 95131
Phone: Fax: Contact Person:	978-805-9015 408-541-1030 Brian Robey, Vice President, Advanced Development and Design Quality Assurance
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 XP® Console Thermogard HQ™ Console
Common Name: Classification/Name: Regulation: Product Code:	Central Venous Catheter (short term) and Thermal Regulating System Class II; System, Hypothermia, Intravenous, Cooling 21 CFR 870.5900, Thermal Regulating System NCX
Predicate Devices:	**K220008**: 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 **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 (either the Thermogard HQ™ Console or the Thermogard XP® Console) and intravascular heat exchange catheters connected via a sterile heat exchanger and tubing circuit. These components together comprise a patient temperature regulation apparatus employing feedback control. The subject devices of this submission are the Thermogard HQ™ Console (TGHQ) and the Thermogard XP® Console (TGXP) for software changes due to the addition of the TrakLo functionality to both consoles.

II. INDICATIONS FOR USE

The Thermogard HQ™ Console and Thermogard XP® Console 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, and Quattro® Intravascular Heat Exchange Catheter are identical to the indications for use of the predicate devices.

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).

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*Fischer's exact test

For more details on the clinical trial results, refer to the Physician's Manual – "Normothermia for 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. The comparison with the predicates Thermogard XP® Console and Thermogard HQ™ Console shows the technological characteristics of the proposed Thermogard XP® Console and Thermogard HQ™ Console with TrakLo functionality to be substantially equivalent in **Table 1.1**.

Table 1.1: Comparison of the subject Thermogard HQ™ Console and Thermogard XP® Console and predicate Thermogard HQ™ Console and Thermogard XP® Console

Feature	Predicate Devices	Subject Devices
Device Name	Thermogard XP® Console (K213031) Thermogard HQ™ Console (K220008)	Thermogard XP® Console Thermogard HQ™ Console
510(k) Number	K213031 K220008	K223746
Principle of Operation	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 bath heats and cools the saline in the catheter.	Same
Class	Class II	Same

Feature	Predicate Devices	Subject Devices
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 20 mm Lag: 60 ms @ 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 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 deionized water RFC 134a 190 watts	 Same
Controller and Display 1. Screen display 2. Controls 3. Temperature input 4. Articulation 5. Data interface	 6.4 in. (16.25 cm) LCD color VGA Push buttons and knob Thermistor, YSI 400 series 180° swivel, 45° tilt TGXP: Serial RS-232C, 9-pin sub-D connector TGHQ: USB, Wi-Fi, Digital EMR output (IOIOI), Patient temperature output (T1 Out)	 Same Same Same Same Same Same

Feature	Predicate Devices	Subject Devices
6. Alarms	Audible tones and displayed text messages Temperature Alarms: Hi Alarm, Lo Alarm	Same Temperature Alarms: Hi Alarm (Same), Lo Alarm (Same), **TrakLo Alarm (New)**
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 Type B for catheter connections	
3. Protection class	1	
4. Mode of operation	Continuous	

TrakLo is a software feature for the Thermogard XP and Thermogard HQ Consoles that improves the utility for warming applications where the patient is at a presenting temperature below 28 °C. When TrakLo is enabled on a patient whose temperature is < 28 ºC, the feature prevents the Lo alarm from being triggered so long as the patient temperature remains stable or continues to increase. The TrakLo alarm will trigger if the patient temperature decreases by 1 °C relative to the highest patient temperature the system has detected.

The TrakLo Alarm requires an update to the Thermogard console software only. The console hardware was not modified in this 510(k). In addition, there were no changes to the existing alarm features, control algorithm, principles of operation, or any other technological aspects of the subject devices. Furthermore, this change does not impact the Start-Up Kit or the IVTM catheters.

IV. SUMMARY OF THE NON-CLINICAL TESTS PERFORMED

Non-clinical performance testing for the Thermogard HQ™ Console and Thermogard XP® Console with TrakLo feature was conducted, to ensure that the device performs as intended, included in **Table 1.2**:

Table 1.2: Performance testing for the Thermogard HQ™ Console and Thermogard XP® Console

Test	Test Method Summary	Conclusion
Human Factors / Usability	Test methods validate the device for human factors per the intended use with the TrakLo feature.	Pass
Software Verification	Test methods verify that the software meets software requirements.	Pass

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 and Thermogard XP® Console with the TrakLo feature meet the design, performance, and safety specifications when used in accordance with the labeling. The difference between the subject and predicate devices does 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.