DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DEC 13 2016

ZOLL Circulation, Inc.
Mr. Sam Nanavati
Vice President, Quality and Regulatory Affairs
650 Almanor Avenue
Sunnyvale, California 94085

Re: K101987
Trade/Device Name: Cool Line Catheter Model CL-2295A, ICY Catheter Model IC-3893A, Quattro Catheter Model IC-4593
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: July 13, 2010
Received: July 14, 2010

Dear Mr. Nanavati:

This letter corrects our substantially equivalent letter of October 12, 2010.

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. 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 Office of Device Evaluation has determined that there is a reasonable likelihood that the Cool Line Catheter Model CL-2295A 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 Warnings section of the device's labeling as a box warning immediately following the indications for use statement:

> 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).

Mortality by Diagnosis (ITT analysis)

	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 please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill stroke patient" #101416-001.

Please note that the above labeling limitation is 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. This limitation does not apply to the ICY and Quattro Catheters.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

John W. Sheets Jr., Ph.D.
Director
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K101987

Device Name
Cool Line Catheter Model CL-2295A, ICY Catheter Model IC-3893A, and Quattro Catheter Model IC-4593

Indications for Use *(Describe)*
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).

Mortality by Diagnosis (ITT analysis)

	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 please refer to Physician's Manual – "Normothermia for the Neuro- critically Ill stroke patient" #101416-001.

The ZOLL ICY Catheter Model IC-3893A, connected to the 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K101987

13 510(k) Summary

OCT 1 2 2010

510(K) SUMMARY FOR MODIFICATIONS TO ZOLL IVTM COOL LINE, ICY, AND QUATTRO CATHETERS

Submitter's Name, Address, Telephone Number, and Contact Person

ZOLL Circulation, Inc.
650 Almanor Avenue
Sunnyvale, CA 94085
Establishment Registration Number: 3003793491

Contact: Sam Nanavati
Phone: 408-541-2140
Fax: 408-541-1030
Email: snanavati@zollcirculation.com

Name of Device

ZOLL IVTM Cool Line Catheters
ZOLL IVTM ICY Catheters
ZOLL IVTM Quattro Catheters

Common or Usual Name

Central Venous Catheter (short term) and Thermal Regulating System

Classification Name

21 CFR 870.5900 System, hypothermia, intravenous, cooling

Device Class

Class II

Predicate Devices

Device Name	510(k) #	Decision Date	Decision
Cool Line Catheter Kit Model CL-2295A	K014241	08/01/2003	Substantially equivalent – with limitations (SU)
Icy Catheter Kit Model IC-3893A	K052443	10/17/2005	Substantially equivalent (SE)
Quattro Catheter Kit Model IC-4593	K070161	02/15/2007	Substantially equivalent (SE)

K10 1987

Indications for Use

The Thermogard XP can be used with any of the ZOLL IVTM Catheters. The indications for use are specific to the catheter.

Indications for Use *(ICY Catheter Model IC-3893A)*

The ZOLL ICY Catheter Model IC-3893A connected to the 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.

Indications for Use *(Quattro Catheter Model IC-4593)*

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.

K101987

Indications for Use ***(Cool Line Catheter Model CL-2295A)***

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 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.

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).

Table 1-1. Mortality by Diagnosis (ITT)

	Cool Line Control						
n		N	%	n	N	%	p-value*
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 results of this study please refer to Physician's Manual – "Normothermia for the Neuro-critically Ill Stroke Patient" #101416-001.

K101987

Device Description

This paragraph is applicable to all three (3) different catheter models included in this document. The model specific details and comparison to predicate are included model specific tables. ZOLL IVTM Cool Line, ICY and Quattro catheters are multi lumen intravascular catheters with balloons as heat exchange units. Each of these three catheter models has two lumens that are used to circulate sterile saline to exchange heat with the central venous blood supply. The inflow lumen/outflow lumen forms a closed-loop system through which the heated/chilled saline circulates. The thermal regulation system chills/warms the saline and pumps it through the inflow lumen of the catheter. The chilled/warmed saline travels to the balloons, whose surface facilitates heat exchange between the patient's circulating blood and the saline. The saline returns to the system via the outflow lumen. The chilled/warmed saline is not infused into the patient. Two additional lumens provide infusion channels. The fifth lumen serves as a guide wire lumen which can also be used as an infusion lumen. The basic difference between these three models of catheters is size and number of balloons which provides different heat exchange capacity.

The catheters are supplied sterile for single-use only.

Principles of Operation

The principle of operation remains unchanged. The ZOLL Intravascular Temperature Management System (IVTM) automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via feedback from a temperature probe in the patient that interfaces with the temperature controller. This principle of operation is identical to currently marketed devices as well as the modified devices.

Summary of the Basis for Finding of Substantial Equivalence

The indication statement and intended use is identical to the predicate device. The principle of operation is the same as the predicate device. The technical characteristics and materials used are very similar to the predicate device.

Conclusion

This submission includes only two modifications:

1. Change of antithrombotic coating and
2. Change of pyrogenicity claim made in the original 510(k) application.

The change in coating is made because the currently cleared/approved coating (Duraflo II®) has been discontinued by the manufacturer (Edwards LifeSciences). The new coating (Applause™ from Surmodics, Inc.) contains hydrophilic properties in addition to the antithrombotic properties.

The original 510(k) applications included the statement that the catheters were "Pyrogen Free". However, Alsius Corporation (the former sponsor) never made any labeling claim in

K101987

this regard. The requested change to "Non-pyrogenic" is more consistent with intravascular catheters.

No other changes are being made to the product specification, product design and/or configuration, safety features, catheter materials, kit components, indications for use or product labeling that can potentially alter the risk/safety profile of the catheters.

The new coating was verified via a combination of in vivo and in vitro biocompatibility testing per ISO 10993-1.In vitro Thrombogenicity testing verified performance of the heparin coating on this catheter in reducing platelet adhesion on the catheter surface for up to 168 hours of hypothermia treatment. Results demonstrated that the modified device is comparable to the results of the animal model testing of the predicate device(s) included in the original submissions cleared by the FDA.

The effects of coating on catheter performance in regards to intended use was verified via a battery of bench tests including Heat Exchange Efficiency test, Life Test (trouble free heat exchange for the in-dwell time), Balloon Bond and/or Catheter Burst test, Heparin Coating consistency (Toluidine Blue Staining) and Heparin Activity test.

In summary, descriptive information and performance data demonstrate that the modifications made to the ZOLL IVTM Catheter Models CL2295-A, IC3893-A and IC4593 characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The catheter models are substantially equivalent to their predicate device(s).