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

March 24, 2016

ZOLL Circulation, Inc.
Mr. Sam Nanavati
Vice President, Quality & Regulatory Affairs
2000 Ringwood Avenue
San Jose, California 95131

Re: K153226
Trade/Device Name: Solex 7™ Intravascular Heat Exchange Catheter and Start-Up Kit
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: February 23, 2016
Received: February 25, 2016

Dear Mr. Sam Nanavati:

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 this device 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 (IFU) statement:

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 showed increased mortality as compared to patients receiving standard of care.

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); 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,

William H. Maisel -S

William H. Maisel, MD, MPH
Director (Acting)
Office of Device Evaluation
Deputy Center Director for Science
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)*
K153226

Device Name
Solex 7™ Intravascular Heat Exchange Catheter and Start-Up Kit

Indications for Use *(Describe)*
The Solex 7™ Intravascular Heat Exchange Catheter connected to the CoolGard 3000®/Thermogard XP® 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 showed increased mortality as compared to patients receiving standard of 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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PREMARKET NOTIFICATION 510(K) SUMMARY
K153226

Date Prepared:	March 9, 2016
Submitter:	ZOLL Circulation, Inc.
Address:	2000 Ringwood Avenue San Jose, CA 95131
Phone:	408-419-2950
Fax:	408-541-1030
Contact Person:	Sam Nanavati, VP, Quality and Regulatory Affairs
Trade Name/Proprietary Name:	Solex 7™ Intravascular Heat Exchange Catheter and Start-Up Kit
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
Legally marketed devices to which substantial equivalence is claimed:	Solex Intravascular Heat Exchange Catheter Kit, 510(k) K141139 Cool Line Intravascular Heat Exchange Catheter Kit, 510(k) K101987 and K150046 Start-Up Kit Model CG-500D and Model CG-500D EX, 510(k) K014241 and K150046

I. Device Description:

The Solex 7 Intravascular Heat Exchange Catheter (Solex 7 Catheter) 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 Solex 7 Catheter is connected to a single use, disposable CoolGard 3000® or Thermogard XP® Start-Up Kit (SUK) and the CoolGard 3000® or Thermogard XP® Console, all of which comprise the ZOLL Intravascular Heat Exchange System. The Start-Up Kit (SUK) and the CoolGard 3000 or Thermogard XP Console are supplied separately. The ZOLL Heat Exchange System is also designed for use with an off-the-shelf temperature probe. The Solex 7 Catheter is comprised of a polyurethane shaft and a serpentine shaped PET balloon at the distal end. The blood contact surfaces of the catheter incorporate a hydrophilic heparin coating.

The catheter has five lumens, two of which when connected to the Start-Up Kit, are used to circulate sterile saline in a closed loop circuit for heat exchange with the blood in the central venous system. Warmed or chilled saline is pumped through the heat exchange lumens, inflating the diameter of the serpentine balloon that interfaces with the patient's blood to warm or cool circulating blood. The inflow/outflow lumens form a closed-loop system through which the warmed or chilled saline circulates. The warmed or chilled saline is not infused into the patient.

Additional lumens of the Solex 7 Catheter consist of a 0.032" guidewire compatible lumen that can also be used as a primary infusion lumen, and two additional infusion lumens within the catheter shaft.

II. Indications for Use:
The intended use/indications for use of the modified Solex Catheter (Solex 7 Catheter) is as follows:

The Solex 7™ Intravascular Heat Exchange Catheter connected to the CoolGard 3000®/Thermogard XP® 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 showed increased mortality as compared to patients receiving standard of care.

III. Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device:

The Solex 7 Catheter

The modified Solex Catheter (Solex 7 Catheter) is substantially equivalent to the 510(k) cleared Solex Catheter (K141139) and the ZOLL Cool Line Catheter (K101987) with regard to intended use / indications for use, technological characteristics, and principles of operation. With the exception of the Custom Luers, the modified Solex Catheter (Solex 7 Catheter) is identical to the cleared Solex Catheter with respect to design and materials. **Table 1** provides a comparison of the similarities and differences between the modified Solex Catheter (Solex 7 Catheter), the cleared Solex Catheter, and the cleared ZOLL Cool Line Catheter (comparisons are relative to the subject device).

Table 1. Comparison of Solex 7 Catheter with Custom Luers to Predicates

Feature	ZOLL Intravascular Heat Exchange Catheters			
	SUBJECT DEVICE Solex 7 Intravascular Heat Exchange Catheter	**PRIMARY PREDICATE DEVICE Cool Line Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Solex Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Quattro Intravascular Heat Exchange Catheter**
510(k) Number	K153226	K101987 and K150046	K141139	K150046
Class	II	Same	Same	Same
Classification/ Regulation Name	System, Hypothermia, Intravenous, Cooling/Thermal Regulating System	Same	Same	Same
Regulation Number	21 CFR 870.5900	Same	Same	Same
Product Code	NCX	Same	Same	Same
Heparin Coating	SurModics Applause Heparin Coating	Same	Same	Same
Luer Designs	Inflow and Outflow Luers: ZOLL Custom Luers* Infusion Luers: Standard Luers Vent Caps: ZOLL Custom Vent Caps	Same	Inflow and Outflow Luers: Standard Luers Infusion Luers: Same Vent Caps: Standard Vent Caps	Same as Subject Device
Catheter working length (tip to manifold)	26cm	22 cm	Same as Subject Device	48 cm
Shaft diameter	9.3 Fr	Same	Same	Same
Number of lumens	5 lumens: 2 infusion	Same	Same	Same

Feature	ZOLL Intravascular Heat Exchange Catheters			
	SUBJECT DEVICE Solex 7 Intravascular Heat Exchange Catheter	**PRIMARY PREDICATE DEVICE Cool Line Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Solex Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Quattro Intravascular Heat Exchange Catheter**
	1 guidewire (also infusion) 1 inflow 1 outflow			
Guidewire Compatibility	0.032”	Same	Same	Same
Flow Rate (by lumen)	Distal – 1900 mL/hr Medial – 1300 mL/hr Proximal – 1300 mL/hr	Distal - 2100 mL/hr Medial - 1200 mL/hr Proximal - 1400 mL/hr	Distal – Same as Subject Device Medial – Same as Subject Device Proximal – Same as Subject Device	Distal - 1300 mL/hr Medial - 800 mL/hr Proximal - 1100 mL/hr
Heat exchange balloons	1 (serpentine)	2 (straight/coaxial)	Same as Subject Device	4 (straight/coaxial)
Inflated Balloon OD (Cross-sectional Area)	Balloon OD: N/A Cross-sectional Area: 54mm^2	Balloon OD: 5mm Cross-sectional area: N/A	Same as Subject Device	Balloon OD: 8mm Cross-sectional area: N/A
Cross Sectional Area (approx. inflated outer diameter)	54mm^2 (12.2 mm OD)	20mm^2 (5 mm)	Same as Subject Device	50mm^2 (8 mm)
Insertion Site	Jugular and SubclavianVeins	Femoral, Jugular, Subclavian Veins	Jugular Vein	Femoral
Max. Use Period	7 days	7 days	2 days	4 days

Feature	ZOLL Intravascular Heat Exchange Catheters			
	SUBJECT DEVICE Solex 7 Intravascular Heat Exchange Catheter	**PRIMARY PREDICATE DEVICE Cool Line Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Solex Intravascular Heat Exchange Catheter**	**REFERENCE PREDICATE DEVICE Quattro Intravascular Heat Exchange Catheter**
Materials	Shaft: Polyurethane Heat Exchange Balloon: PET	Shaft: Same 2 Heat Exchange Balloons: Polyurethane	Shaft: Same Heat Exchange Balloon: Same as Subject Device	Shaft: Same Heat Exchange Balloons: Same as Subject Device
Sterilization method and SAL	EO, SAL 10^{-6}	Same	Same	Same

*The ZOLL Custom Luers on the ZOLL Cool Line, ICY, and Quattro Catheters were cleared via K150046 on October 30, 2015

The Modified Start-Up Kit with Custom Luers

The modified Start-Up Kit (SUK) with Custom Luers is substantially equivalent to the 510(k) cleared SUK (K014241) with regard to intended use, technological characteristics, and principles of operation. **Table 2** provides a comparison of the similarities and differences between the modified SUK and the predicate SUK.

Table 2. Comparison of Modified Start-up Kit with Custom Luers to Predicate

Characteristic	SUBJECT DEVICE ZOLL Start-up Kit with ZOLL Custom Luers (modified) K150046	PREDICATE DEVICE ZOLL Start-up Kit with ZOLL Standard Luers
510(k) Number	TBD	K014241
Intended Use	To control patient core temperature using heat exchange fluid in conjunction with the CoolGard 3000 or Thermogard XP system 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, compatible with new Custom Luer locks, provided with SUK for removal of saline from catheter heat exchange balloon prior to catheter removal	Syringe not provided with SUK
Sterilization	Provided sterile (Gamma sterilization)	Same

IV. Summary of the Nonclinical Tests Performed:

Nonclinical testing was performed to ensure that the modified Solex Catheter (Solex 7 Catheter) and modified SUK meet their design performance specifications and that the product is substantially equivalent to the predicate devices (Catheters: K141139, K101987; SUK: K014241). Nonclinical testing performed includes: Bench Performance, Packaging Validation (SUK only), Biocompatibility, and Usability Testing. The nonclinical test results demonstrate that the modified devices continue to meet product design specifications.

1. 7-Day Indwell Testing

Bench Performance testing of the modified Solex Catheter (Solex 7 Catheter) was performed to support the proposed modification to the 7 day indwell time.

Where applicable, testing was performed in accordance with the following standards:

- ISO 10555-1:2013 - Sterile, single-use intravascular catheters Part 1. General requirements

- ISO 594-1:1986 - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 1: General requirements
- ISO 594-2:1998 – Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings

The modified Solex Catheter (Solex 7 Catheter) was functionally tested after being subjected to 7 days of simulated use conditions to verify that the catheter continues to perform as intended. Testing completed is shown in Table 3.

Table 3. Solex 7 Catheter Bench Performance Testing

Test Name	Test Method Summary	Results
Visual Inspection	Visual inspection to ensure catheter is smooth without major pits.	Catheter samples met the acceptance criterion for smooth appearance with no pits.
Catheter Indwell Life (7 days)	Verification that the catheter does not leak saline from the heat exchange path during simulated use for seven days.	Catheter samples met the acceptance criterion for normal function for seven days without leakage.
Dimensional Measurement	Measurement of catheter dimensional aspects	Catheter samples met the acceptance criteria for dimensional requirements per the product specification.
Toluidine Blue Staining	Dye staining of catheter and visual inspection to ensure consistent coverage of blue purple color and that stained portion covers all depth markers.	Catheter samples met the acceptance criteria for consistent blue purple color and stained portion covered all depth markers.
Particulate Testing	Determination of catheter coating integrity following simulated indwell and flow rate conditions.	Solex 7 samples and Cool Line samples tested demonstrated levels of particulate below that required in USP <788>.
Tensile Testing	Strength testing of various catheter joints. Must conform to EN ISO 10555-1:2013.	Catheter joints met the acceptance criteria for tensile strength requirements of EN ISO 10555-1:2013.
Burst/Leak Testing	Determination of catheter burst/leak resistance. Must conform to EN ISO 10555-1:2013.	Catheter samples met the acceptance criteria to withstand a minimum of 100 psi static pressure at 37ºC without embolic failure.
Flow Resistance Testing	Measurement of catheter back pressure.	Catheter samples met the acceptance criterion for a back pressure of less than 7 psi at a flow rate of 2000 ml/hr.
Flow Rate Testing	Measurement of catheter infusion lumen flow rates. Must conform to EN ISO 10555-1:2013.	Catheter samples met the acceptance criteria for flow rate requirements of EN ISO 10555-1:2013
Heat Exchange Testing	Determination of heat exchange capability of catheter.	Catheter samples met the acceptance criterion for a heat exchange power of 125 Watts minimum.
Flexural Fatigue/Tip Flex Testing	Determination of catheter tip strength and flexure.	Catheter samples met the acceptance criteria to withstand 100

Test Name	Test Method Summary	Results
		cycles of tip flexure.
Infusion Lumen Aspiration Rate Testing	Determination of catheter blood sampling rate	Catheter samples met the acceptance criterion of a blood sampling rate of 10cc in 15 seconds or less.
Torsional Integrity Testing	Determination of catheter (tip to manifold) ability to withstand twisting.	Catheter samples met the acceptance criterion to withstand one complete twist without failure
In Vitro Thrombogenicity Testing	Measurement of thrombogenic behavior of catheter following 7 day simulated use by radioactive platelet quantification and visual inspection.	Coated catheter samples showed statistically significant decreases ($p < 0.05$) in thrombogenicity when compared to normalized thrombogenic behavior of uncoated catheters.

2. Solex Catheter and Modified SUK with Custom Luers

Nonclinical testing was performed to ensure that the Solex Catheter and modified SUK with Custom Luers meet their design and performance specifications and that the product is substantially equivalent to the predicate devices.

a. Packaging Validation (SUK only)

Packaging performance testing of the modified SUK was performed to verify that following exposure to simulated shipping conditions, the addition of the sterile packaged 20 mL Deflation (Slip-Fit) syringe to the outside of the sterilized SUK packaging does not impact the integrity of the SUK sterile packaging. Packaging testing completed is shown in **Table 3**.

Table 3. Start-Up Kit Packaging Testing

Test Name	Test Method Summary	Results
Visual Inspection	Visual inspection to inspect shipping boxes and trays for damage.	Shipping boxes and trays met the acceptance criteria with respect to visible damage.
SUK Package Seal Visual Integrity	Visual inspection to inspect the package seal in the area where the syringe bag is attached.	Package seals and trays met the acceptance criteria with respect to visible damage.
Syringe Pouch Seal Visual Integrity & Adhesion to Tyvek	Visual inspection of the affected area to inspect the package seal area of the syringe bag.	Syringe pouch seals and the film and Tyvek portion of the pouches met the acceptance criteria with respect to visible damage.
SUK Package Seal Peel Test	Peel testing of the affected area to ensure that seal peel data is not less than specified acceptance criteria	SUK package seals met the acceptance criterion for peel strength.

In addition, testing was performed (following exposure to simulated shipping conditions and packaging testing) to verify that product design specifications were met. Bench performance testing completed is shown in **Table 4**.

Table 4. Start-Up Kit Performance Testing

Test Name	Test Method Summary	Results
SUK Flow Test	To verify that air flows through the SUK system.	C SUK systems met the acceptance criterion for air flow.
SUK High Pressure Leak Test	To verify no leaks below specified acceptance criteria.	SUK systems met the acceptance criterion for no leaks below the specified pressure.
Modified SUK Indwell Life Test	To verify that Custom Luers and SUK Tubing are able to function normally at specified temperatures for the labeled indwell period.	Custom Luers and SUK tubing met the acceptance criterion for normal fuction for 7 days at the specified temperature.
SUK Tubing to Luer Tensile	To verify that SUK Tubing and Custom Luers conform to EN ISO 10555-1:2013 and minimum specified acceptance criteria.	The SUK tubing meet the acceptance criterion for the tensile strength of all inflow and outflow tubes to Luers with respect to the requirements of ISO 10555-1:2013.

The packaging of the Solex catheter remains unchanged; therefore, re-validation of the catheter packaging was not warranted.

b. Bench Performance

Bench Performance Testing was conducted on samples of the Cool Line Intravascular Heat Exchange Catheter (as a representative model for the Solex Catheter subject to the same modifications) to verify that product design specifications were met. The Luers and Extension tubings are identical in all models. Testing completed is shown in **Table 5**.

Table 5. Custom Luer Catheter Bench Performance Testing

Test Name	Test Method Summary	Results
Visual Inspection	Visual inspection to inspect for Luers, caps, and extension tubes for correct colors.	Luers colors met the acceptance criteria based on the requirements of associated drawings.
Dimensional Measurement of Extension Tube Lengths	Verify dimensions of extension tube lengths.	Extension tubes met the acceptance criteria for specific dimensional specifications.
Guidewire Passage	Verify ability to frontload, backload, and remove J-tip 0.032" guidewire from catheter.	Catheters met the acceptance criterion for the J-tip 0.032" guidewire to be frontloaded, backloaded, and removed from the catheters.
Ink Stability	Verify that pad printed ink does not smudge or come off when tested in accordance with specified acceptance criteria.	The pad printed ink on all infusion Luers met the acceptance criterion of remaining legible after rubbing with alcohol.
Alcohol Resistance	Verify that Luers do not craze or crack when tested in accordance with specified acceptance criteria.	Luers met the acceptance criterion of no evidence of crazing or cracking after being soaked in alcohol.
Balloon Deflation Using Deflation Syringe (20 mL Slip-Fit)	Verify that balloons collapse upon aspiration at specified temperature using supplied slip-fit syringe.	Catheter balloons met the acceptance criterion of collapse upon aspiration using the supplied slip fit syringe.
Balloons Leakage Upon Aspiration	To verify that catheter balloons	Catheters met the acceptance

Test Name	Test Method Summary	Results
@ 37˚C Using the Supplied Deflation (20 mL Slip-Fit) Syringe	conform to EN ISO 10555-1:2013 (must not show air leakage during aspiration).	criterion for no air leakage from the catheter balloons during aspiration using the supplied slip fit syringe
Heat Exchange Power	To verify that the modified catheters meet specified acceptance criteria.	Catheters met the acceptance criterion for heat transfer performance.
Ultimate Burst/Leak (All Luers – Custom and Infusion Luers) - Embolic Failure	To verify that catheter Luers conform to EN ISO 10555-1:2013 (must meet minimum static pressure at specified temperature without embolic failure).	Catheters met the acceptance criterion to withstand 100-110 psi static pressure at 37ºC without embolic failure.
Catheter Inflow/Outflow Custom Luers connected to SUK Custom Inflow/Outflow Pressure Test	To verify that catheter inflow/outflow Luers and extensions withstand minimum static pressure for specified period of time.	Luers and extension tubes met the acceptance criterion to withstand a minimum static pressure while connected to an SUK for a specified period of time.
Catheter with Modified Luers - Indwell Life	To verify that catheters Luers and extensions are able to function normally for the labeled indwell period.	Luers and extension tubes met the acceptance criterion to be able to function normally for seven days.
Extension Tubing to Luer Tensile.	To verify that extensiuon tubing to Luer joints conform to EN ISO 10555-1:2013 (must meet minimum strength).	Catheter joints met the acceptance criteria for minimum tensile strength in accordance with the requirements of EN ISO 10555-1:2013.

Where applicable, testing was performed in accordance with the following standards:

- ISO 10555-1:2013 - Sterile, single-use intravascular catheters Part 1. General requirements

The results of design verification testing performed demonstrate that the modified Catheter and SUK with Custom Luers meet their design performance specifications at T=0.

c. Testing to Luer Standards

Additional testing was conducted as part of Testing to Luer Standards on the injection molded components used to manufacture the modified SUK and Catheter with Custom Luers. Results of testing verifies compliance to the following applicable standards:

- ISO 594-1:1986 - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 1: General requirements
- ISO 594-2:1998 – Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment Part 2: Lock fittings

The testing completed are shown in **Table 6.**

Table 6. Luer Standards Performance Testing

Test Name	Test Method Summary	Results
Critical Dimensions Inspection	Critical dimensions must meet the dimensional tolerances for the Critical dimensions, of the respective drawing	Samples met the acceptance criteria for dimensional tolerances for the critical dimensions.
Gauging	Tested using test method similar to test specified in ISO594-1&2 (§4.1)	All samples met the requirements of the test method used.
Water/Liquid Leakage	Tested using test method similar to test specified in ISO594-1&2 (§4.2.1)	All samples met the requirements of the test method used.
Air Leakage	Tested using test method similar to test specified in ISO594-2 (§4.2.2)	All samples met the requirements of the test method used.
Separation Force	Tested using test method similar to that specified in ISO594-2 (§4.3)	All samples met the requirements of the test method used.
Unscrewing Torque	Tested using test method similar to that specified in ISO594-2 (§4.4)	All samples met the requirements of the test method used.
Ease of Assembly	Tested using test method similar to that specified in ISO594-2 (§4.5 b)	All samples met the requirements of the test method used.
Resistance to Overriding	Tested using test method similar to that specified in ISO594-2 (§4.6)	All samples met the requirements of the test method used.
Stress Cracking	Tested using test method similar to that specified in ISO594-2 (§4.7)	All samples met the requirements of the test method used.

Based on the test results obtained, it can be concluded that all of the standard and custom catheter Luers, custom SUK Luers, and custom catheter vented caps are qualified for use in the assemblies used to manufacture the modified SUK and Solex Catheter with Custom Luers.

d. Biocompatibility

The only material change for the Solex Catheter and SUK has been to the Custom Luers. To verify the biocompatibility of the new materials of the Custom Luers for the Solex Catheter, ZOLL conducted biocompatibility testing on the proximal (modified) portion of the catheter only. Similarly, to verify the biocompatibility of the modified SUK, ZOLL conducted biocompatibility testing on the SUK Custom Luers only. Biocompatibility testing was conducted in accordance with GLP regulations.

Because the Custom Luer components located on the SUK and on the proximal end of the catheter have indirect blood contact and prolonged exposure, ZOLL conducted testing based on the classification of an externally communicating device, blood path indirect for prolonged exposure (>24hrs and ≤30 days). Based on this classification, the following categories of biocompatibility tests were performed: Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity and Hemocompatibility.

The biocompatibility test results are shown in **Table 7**.

Table 7. Biocompatibility Testing

Test Category	Test Method Summary	Results
Cytotoxicity	MEM Elution Test	The reactivity grade of all test article extract samples was "0".
Sensitization	ISO 10993 Part 10 Guinea Pig Maximization Sensitization Test (GLP)	The test article extracts did not cause sensitization reactions under the conditions of the assay.
Irritation	ISO/USP Intracutaneous Reactivity Irritation Test in Rabbits (GLP)	The data indicated that the test article extracts did not cause a skin irritation reaction.
Acute Systemic Toxicity	ISO/USP Medical Device Acute Systemic Toxicity Test in Mice (GLP)	Based on the clinical observations and body weight evaluations, the test article (device) extracts did not show significantly greater biological reaction than the control article extracts.
Material Mediated Pyrogen	ISO/USP Materials Mediated Pyrogen Test in Rabbits (GLP)	None of the animals in the study showed abnormal clinical signs prior to dose administration and during the observation period. No animals showed a temperature increase of 0.5°C or greater during the study period.
Hemocompatibility	ASTM Hemolysis (Extract Method) Test (GLP)	The difference between the hemolytic indexes of the test article and the negative control equals 0.00 percent. This places the test article in the non-hemolytic range. All test method acceptance criteria were met.
Hemocompatibility	Complement Activation Test (GLP)	**C3a:** The P value was >0.050 when the test article was compared to the predicate at the 30, 60, and 90 minute time points; the test article and predicate are statistically similar at these time points. The P value was >0.050 when the test article was compared to the negative control at the 30, 60, and 90 minute time points; the test article and predicate are statistically similar at these time points. **SC5b-9:** The P value was >0.050 when the test article was compared to the predicate at the 30, 60, and 90 minute time points; the test article and predicate are statistically similar at these time points. The P value was >0.050 when the test article was compared to the negative control at the 30 and 60

Test Category	Test Method Summary	Results
		minute time points; the test article and negative control are statistically similar at these time points. The P value was ≤0.050 when the test article was compared to the negative control at the 90 minute time point; the test article is statistically lower than the negative control at this time point

The results of the testing demonstrate that the modified SUK and the modified Solex Catheter with Custom Luers are biocompatible for their intended use and the modifications made to the subject devices do not adversely affect the established biocompatibility of the predicate devices.

e. Usability/Human Factors

Pursuant to FDA's guidance document entitled, "Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design" Human Factors testing was conducted as follows:

1. Summary of Formative Testing

Human factors formative testing was performed to determine if users trained according to the IFU can properly perform the following:

- Identify infusion lumens, (proximal, medial, and distal)
- Properly connect the IN and OUT Luers to the Start-Up Kit (SUK)
- Identify the saline IN and OUT Luers
- Identify any lumen that is appropriate for pharmacological infusate.
- Disconnect the Saline IN and OUT track (SUK Luers) including evacuating the saline from the catheter using a syringe.

User tasks were based on identifying and (or) making proper connections as documented in the Formative Human Factors Protocol for ZOLL Custom Luers. The test session ran over the course of two days.

Four scenarios were presented, and participants were evaluated based on 14 predefined success metrics. All participants correctly executed each scenario, with no failures. All participants who received representative level of training and had access to the IFU successfully completed all of the tasks. This indicates that the device design, training content and the IFU adequately mitigate the risk of misconnections. No device design, training or IFU modifications were indicated based on this formative test.

2. Summary of Summative Testing

Human factors summative testing was performed to evaluate if users trained according to the ZOLL Custom Luer Training Program and IFU can properly perform the following:

- Match the new catheter and new Start-Up Kit (SUK) with Custom Luers
- Place 20 cc syringe on saline hook on Thermogard XP (TGXP) console
- Connect the IN and OUT Luers on the catheter to its counterpart on the SUK
- Select an infusion lumen for an IV infusion
- Use 20 cc syringe for aspiration of saline after a catheter is used as a CVC after temperature management therapy ends
- Aspirate saline prior to catheter removal

A total of five scenarios were presented, and each participant had to correctly answer questions 9-13 to achieve a passing score. All other questions (1-8, 14-15) required a minimum of an 80% passing score. The acceptance criteria were met with 100% of the users passing the critical tests (9-13). All of the non-critical items (1-8 and 14-15) were passed with at least 12 participants passing (80%).

All participants who received training and followed the IFU successfully met the acceptance criteria. This testing confirms that the custom Luer design, training, and IFU facilitate appropriate catheter and SUK connections. No device design, training or IFU modifications were indicated based on the summative evaluation.

V. Summary of Clinical Tests Performed:

Clinical evaluations were not necessary to evaluate the modifications incorporated in the Solex Catheter and SUK to demonstrate substantial equivalence to the predicate devices.

VI. Substantial Equivalence:

Based on the results of the Bench Performance, Packaging Validation (SUK only), Biocompatibility, and Usability testing, the modified Solex Catheter (Solex 7 Catheter) and modified SUK are substantially equivalent to the currently cleared Solex Catheter (K141139), Cool Line Catheter (K101987), and SUK (K014241) with respect to intended use/indication for use, technological characteristics, and principles of operation and that the modifications do not affect the performance or function of the devices. The minor differences in the design between the modified and cleared devices, do not raise any new types of safety or effectiveness questions as confirmed by design verification testing. Therefore, the modified Solex Catheter (Solex 7 Catheter) and modified SUK are substantially equivalent to the previously cleared predicate devices.

VII. Conclusions:

ZOLL concludes that based on the results of the Bench Performance, Packaging Validation (SUK only), Biocompatibility, and Usability testing, that the modified Solex Catheter (Solex 7 Catheter) and modified SUK are substantially equivalent to the predicate devices.