DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 15, 2016

Seiratherm GmbH
Mike Johnson, M.D.
Philosopher's River LLC
PO Box 106
Willow Creek, MT 59760

Re: K152946
Trade/Device Name: tempedy 5000 system
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX, LGZ
Dated: August 5, 2016
Received: August 16, 2016

Dear Dr. Mike Johnson:

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. 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.

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" (21CFR 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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
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)*
K152946

Device Name
Seiratherm GmbH tempedy 5000

Indications for Use *(Describe)*
The Seiratherm GmbH tempedy 5000 is intended to deliver cooled or warmed sterile intravenous solutions which may be used to alter the body temperature of adult patients.

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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Section 5

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 06-30-2016 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

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B. Contact Information

Philosopher's River llc

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Contact person: Mike Johnson M.D.

mike@philosophersriver.com

C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *tempedy 5000 system*
Device Common Name: Thermal regulating system
Classification Name: System, Hypothermia, Intravenous, Cooling 21 CFR 870.5900
Product Code: NCX
Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *tempedy system* uses similar technology and physical output characteristics as the following predicate devices*:*

- K080899 Artic Blast Intravenous Fluid Chiller (similar infusion of cold iv fluid to cool patient) from Medivance Inc.
  NCX Thermal regulating system
- K082217 Ranger Rapid Flow Blood/Fluid Warning System (similar infusion of warm iv fluid to warm the patient) from Arizant Healthcare Inc.
  LGZ Unclassified
- K080908 RapidBlue System (similar patient temperature control of cooling or warming of the patient) from INNERCOOL Therapies Inc.
  NCX Thermal regulating system

E. Device Description [21 CFR 807.92(a)(4)]

The Seiratherm *tempedy System* is an adjunct to normalizing the body temperature of adults. It is intended to be used in situations when the patient is hypothermic and requires warming or when the patient is hyperthermic and requires cooling.

1. It is an intravenous fluid cooling system

The *tempedy* allows the operator to control temperature (4^{o} to 42^{o}) and flow rate of a crystalloid iv solution. This function has as its predicate, the Medivance Inc. *Artic Blast Fluid Chiller*. A salient difference is that the tempedy allows precise control of the flow rate and the predicate relies on gravity.

2. It is an intravenous fluid warming system

The *tempedy* when it warms the crystalloid iv solution, functions similarly to its predicate, the Arizant Healthcare Inc. *Ranger Rapid Flow System*. However, the tempedy precisely controls flow whereas the predicate uses pressure of 300 mmHg to cause flow without monitoring flow rate.

3. It is a thermal regulating system with feedback of patient's temperature

The *tempedy* may be used in conjunction with a patient temperature sensor. The flow rate for a preset temperature of iv fluid may be feedback controlled toward a target temperature setpoint. When used in this temperature feedback mode, the *tempedy* is similar to a third predicate, the INNERCOOL Therapies, Inc. *RapidBlue System*. A difference is that the *RapidBlue System* uses a closed loop circulation and heat exchanger to cool/warm the patient. Because of this catheter, the *RapidBlue* must have a central line access. The *tempedy* may be used with a peripheral or central catheter access. Both systems use a YSI 400 compatible temperature probe.

The *tempedy System* does not deliver drugs. It is not a drug infusion device.

The *tempedy System* does not deliver colloids (blood products, plasma, lipids, etc.) It is only for delivery of crystalloids (normal saline, Ringers, etc.).

The *tempedy System* includes the following accessories: Power cord, Tubg Set, and Temperature Probe. A list of accessories is on Page 50 of the Instructions for Use Manual.

Patient contacting parts: The sterile "Tubing Set T0" is a patient contacting part of the system. The Tubing Set T0 is a single use part in the *tempedy System.*

The *GE Healthcare, K051873, M1024231 GP Temperature Probe, Adult* YSI 400 compatible temperature probe is also a patient contacting part of the system. It is a manufacturer sterilized, single use part.

F. **Principle of Operation**: The *tempedy System* has two insulated compartments ("thermal chambers") for storing iv crystalloid solutions at operator specified temperature. The 1 liter iv bags hand on a rack in each compartment. Each compartment has a Peltier device and a fan, which act as a heat pump to the ambient environment. This allows the usre to specify the temperature of each of the compartments individually. One compartment is designated "Cool" and other "Warm" by the operator. By independently controlling the flow rate of iv solution from each compartment and mixing the tow flows, a specified output temperature is obtained. This output temperature may be changed rapidly by changing the relative flow rates if the desired temperature is between the selected "Warm" and "Cool" compartments.

G. Device Specifications and Comparison to Predicates [21 CFR 807.92(a)(6)]

The predicate devices used to argue substantial equivalence are the K080899 Medivance, Inc. *Arctic Blast Intravenous Fluid Chiller,* K082217 Arizant Healthcare Inc. *Ranger Rapid Flow blood/fluid warming system,* and INNERCOOL therapies Inc. *RapidBlue System*. Below is a comparison table.

Characteristic	Seiratherm GmbH *tempedy*	Medivance, Inc. *Arctic Blast Intravenous Fluid Chiller*	Arizant Healthcare Inc. *Ranger Rapid Flow blood/fluid warming system*. Now owned by 3M.	INNERCOOL therapies Inc. RapidBlue System
Applicable 510(k)s	NA	K080899	K082217	K080908 K033623
Common/Usual Name **Classification Name**	Thermal Regulating System Blood/Fluid Warmer System, hypothermia, intravenous cooling	Thermal regulating system System, hypothermia, intravenous cooling	Blood/Fluid Warmer with Pressure Infusor	Thermal regulating system System, hypothermia, intravenous cooling
Panel **Product Code** **Regulation Number**	General and Plastic Surgery NCX / LGZ 21 CFR 870.5900 / Unclassified	General and Plastic Surgery NCX 21 CFR 870.5900	General Hospital LGZ Unclassified	General and Plastic Surgery NCX 21 CFR 870.5900
Indications for Use Statement	The Seiratherm GmbH tempedy is intended to deliver cooled sterile solutions and warmed sterile solutions to adult patients.	The Artic Blast Intravenous Fluid Chiller is intended to cool sterile solutions during intravenous administration where clinically indicated for reduction of patient temperature.	The Ranger Rapid Flow Blood/Fluid Warming System is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.	The RapidBlue System is a thermal regulating system intended to induce, maintain, and reverse mild hypothermia in neurosurgical patients in surgery and in recovery/intensive care, to achieve and/or maintain normothermia in cardiac surgery patients in surgery and in recovery/intensive care, and for the use in fever reduction, as an adjunct to other antipyretic therapy, in patients with cerebral infarction and intracerebral hemorrhage who required access to the central venous circulation and who are intubated and sedated.

Classification	Class II	Class II	Class II	Class II
Infusion Pump	Flow rate control 1-250 ml/min	Gravity infusion	Pressure of 300 mmHg flow rates up to 30,000 mL per hour	Flow rate control of closed loop system.
Safety Features	Air bubble detection, pressure & temperature sensors	NA	Air bubble detection Fluid level detection	Air trap, temperature sensors
Cooling Mechanism	Two chamber heating and cooling chambers with controlled mixing	Heat exchanger assembly and adsorption cooling module	NA	Refrigeration and hating elements with heat exchanger.
Heating Mechanism	Two chamber heating and cooling chambers with controlled mixing	NA	Warming plates	Refrigeration and hating elements with heat exchanger.
Temperature Range	$4^{o}C – 42^{o}C$	4°C – 6°C	$42^{o}C$	$4^{o}C – 42^{o}C$
Feedback of Patient Temperature	Yes	No	No	Yes
Patient Temperature Sensor	Off the shelf temperature probes such as YSI-400 esophageal, bladder or rectal probes	NA	NA	Off the shelf temperature probes such as YSI-400 esophageal probes or probe integrated into the central venous catheter.
Operator Controls and Displays	Graphical User Interface (Touchscreen Monitor)	NA	Display of temperature and warming unit status.	Graphical User Interface (Touchscreen Monitor)
Alarms	Audible and visual alarms.	None	Audible and visual under and over temperature. Alarms activate at $25^{o}C$, $45.5^{o}C$, and $46^{o}C$	Audible and visual alarms.
Closed-Loop Circulation vs. Infusion	Infusion	Infusion	Infusion	Closed-loop fluid circulation with heat exchange at distal end of endovascular catheter.
Infusion Fluid	Crystalloid Fluids	Crystalloid Fluids	Crystalloid or Blood Products Fluids	No infusion
Fluid Contacting Pathway	Disposable sterile tubing set	Disposable sterile tubing set	Disposable sterile tubing set	Disposable sterile tubing set
Sterilization Method	100% EO	100% EO	100% EO, reference Isomedix Soft Cycle	100% EO

Disposable Packaging	Box and pouch. Packaging validated	Box and pouch	Box and pouch. Made of polyethelene and tyvek header. Packaging validated	Box and pouch.
Equivalence determined by Performance / Clinical Trial	Performance	Performance	Performance	Performance

H. Indications for Use [21 CFR 807.92(a)(5)]

The Seiratherm *tempedy 5000* is intended to deliver cooled or warmed sterile intravenous solutions which may be used to alter the body temperature of adult patients.

I. Nonclinical Tests [21 CFR 807.92(b)(1)]

Test	Test Method Summary	Results
Infusion Essential Function and Safety Testing Third Party Testing to EN 60601-2-24: 2012-10	Safety and infusion accuracy tests performed by Third Party. Subsets of this testing is described below. Acceptance Criterion = "a.c."	Pass on all clauses.
Spillage testing IEC 60529 – IPX2 Clause 201.11.6.3 and 5	Test per IEC 60529. IPX2	Pass
Unintended bolus testing Clause 201.12.4.4.104	For Min/max occlusion pressure, time to occlusion alarm (a.c. < 2.5 s), measurement of surplus bolus (a.c. <5ms)	Time to occlusion alarm < 2.5s. No measureable unintended bolus. Pass.
Reverse delivery testing Clause 201.12.4.4.105	Visual inspection	No instance of reverse flow. Pass.
Fitting of tubing, alarms Clause 201.15.101 and 102	Alarm at incorrect positioning of tubing, bubble detection, traction to patient. (a.c. 100% function)	Pass
Use errors / alarms Clause 201.15.103	2 actions required before flow after alarm or a start up	Pass
Infusion Accuracy – Bolus Accuracy Clause 201.12.1.106	Minimum and maximal boluses were delivered and measured by weight.	All boluses (n=25) were delivered with acceptance criterion of <6%. Pass
Infusion Accuracy – Flow Accuracy Clause 201.12.1.107	Start Up Diagrams and Trumpet Diagrams Flow Pump 1 Pump 2 3500 4000 4000 4000	All Flow Rates within acceptance criterion of <6%. Pass

	7500 7500 ml/h	
Temperature Sensing Accuracy DIN EN ISO 80601-2-56	Temperature Management Mode	Tprobe=Tdisplay=Tservice connection (+/- 0.2°C). Pass
038_20160725_performance cooling	Cooling infusion in Temperature Management Mode	Appropriate responses to cooling.
039_20160727_performance warming	Warming infusion in Temperature Management Mode	Appropriate responses to warming

Performance tests: The EN 60601-2-24 guided bench testing of the *tempedy*. The ISO 80601-2-56 guided testing of the *GE Healthcare, K051873, M1024231 GP Temperature Probe, Adult* YSI 400 compatible temperature sensor.

Safety tests: The tempedy was tested to the 60601-1 and 60601-1-2 consensus standards. Third party testing reports were submitted.

Biocompatibility tests (Tubing Set T0): See table below:

Test	**Results**	**Conclusions**
iso 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing		
Hemocompatibility iso 10993-4 Hemolysis	Test material does not release substances in hemolytic conentrations during 24 h contact of 4.5 cm^2 surface area to 1 ml of physiological fluid.	Tubing set does not cause hemolysis.
Cytotoxicity, L929-Proliferation iso 10993-5, -12	Test material does not release substances in cytotoxic concentrations during 24 h contact of 4.5 cm^2 surface area to 1 ml physiological fluid.	Tubing set is not cytotoxic.
Chemical analysis, characterization of organic leachables / extractables iso 10993-12, -18	Extraction tests on the test materials were performed with organic and aqueous solutions at 37°C.	The extractable substances are not released in toxicologically relevant concentrations during clinical application.

J. Conclusion [21 CFR 807.92(b)(3)]

The Seiratherm GmbH *tempedy 5000* was found to be substantially equivalent to the predicate devices, in terms of technology, function and intended use. The indications for use are similar to the previously cleared devices INNERCOOL Therapies Inc. *RapidBlue System* (K080908), Arizant Healthcare Inc. *Ranger Rapid Flow* (K082217), and Medivance, Inc. *Arctic Blast* (K080899). We believe that there are no new questions of safety or efficacy raised by the introduction of the *tempedy 5000* System.