Barkey GmbH & Co. KG
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

May 24, 2022

Re: K213191
Trade/Device Name: S-Line
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: April 24, 2022
Received: April 26, 2022

Dear Paul Dryden:

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. 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.

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,

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K213191

Device Name

Barkey S-Line

Indications for Use *(Describe)*

The Barkey S-Line blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients. It delivers the fluid via intravenous (IV) administration in hospitals and clinical settings where warmed intravenous fluids are required.

Type of Use *(Select one or both, as applicable)*

XX 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.

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510(k) Summary

Date Prepared:	24-Apr-22
Applicant	Barkey GmbH & Co. KG Gewerbestr. 8 33818 Leopoldshoehe Germany Tel - +49(0)5202-9801-0
Sponsor Contact:	Thomas Barkey, CEO
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	S-line
Common/Usual Name:	Warmer, Thermal, Infusion Fluid
Classification Name:	Warmer, Thermal, Infusion Fluid
Product Classification:	LGZ
CFR:	Unclassified
Predicate Device:	K121198
Tradename:	Biegler BW685S
Classification Name:	Warmer, Thermal, Infusion Fluid
Product Classification:	LGZ
CFR:	Unclassified

Accessory

Device Description:

The Barkey S-line is a blood and infusion fluid warmer. The infused fluid flows through a standard IV set. The IV line is inserted into a groove in a warming sleeve, referred to as the S-line. The warming sleeve is made of silicon with embedded heating wires.

There is no direct contact between the heat exchanging tube and the fluids. The fluid only contacts the off-the-shelf 510(k) I.V. extension set.

There is no software / firmware in the device.

The S-line operates on 100 – 240 VAC, 50/60 Hz powering an IEC 60601-1 compliant internal power supply.

The set temperature is set to 39 °C which is not user selectable.

The fluid is warmed to approximately 39 °C as it travels a path through the heating sleeve. The temperature is constantly monitored and adjusted. The temperature is measured at the end of the extension set, where it leaves the heated sleeve prior to delivery to the patient.

The S-line unit weighs approximately 1.3 kg and is equipped with a knob clamp at the back of the devices for attachment to an I.V. pole, the S-line may also be clamped to a bedrail.

Independent overtemperature protector monitors the temperature in the warming section.
In case of a fault, there is a second overtemperature safety feature which if a temperature of 43°C +/- 1°C is reached, the warming section's heater is switched off, the luminous ring in the display and control panel shows yellow and an acoustic alarm sounds.

Principle of Operation:
The infused fluid flows through a compatible IV extension set. This tube is inserted into a groove in a warming sleeve. The warming sleeve is made of silicon and is heated to a set temperature by an embedded heating wire. All heating is done within the warming sleeve.

Indications for Use:
The Barkey S-Line blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients. It delivers the fluid via intravenous (IV) administration in hospitals and clinical settings where warmed intravenous fluids are required.

Patient Population:
Patients where warming of fluids to be infused is necessitated.

Environments of use:
Hospitals and clinical settings where warmed IV fluids are required.

We present the proposed device vs. the predicate in **Table 1**.

As part of the comparison we will present and discuss the:

- Indications for Use
- Technology and Principle of Operation
- Performance and Specifications

Table 1 is a comparison – Subject Device vs. the Predicate,

Table 1 – Comparison – Subject vs. Predicate

Attribute	Biegler GmbH BW685S 510(k) K121198	Barkey S-line 510(k) TBD	Equivalency to at least one or both devices
Product Classification	LGZ	LGZ	
Indications for Use	The BW685/S blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients.	The Barkey S-Line blood / fluid warming system is intended to deliver warm blood, blood products, and liquids to adult and pediatric patients. It delivers the fluid via intravenous (IV) administration in hospitals and clinical settings where warmed intravenous fluids are required.	Similar
Environments of use	Hospital	Hospitals and clinical settings where warmed IV fluids are required.	Similar
Principle of operation	Continuous flow electrically powered warmer	Continuous flow electrically powered warmer	Similar
Warm up time	45-55 seconds	62-66 seconds	Similar
Flow rates	Set at maximum temperature of 41ºC and fluid temperature of 20ºC 1.7 ml/mn , 37ºC 25 ml/mn, 37.5ºC 100 ml/mn – 36ºC	Set at fixed temperature of 39ºC and fluid temperature of 20ºC 1.7 ml/mn, 37ºC 25 ml/mn, 29ºC 100 ml/mn – N/A	
Ingress Protection	IPX4	IPX2	Barkey S-line provides adequate ingress protection
Degree of protection against electric shock	Type BF	Type BF	Similar
Dimensions	228 x 278 x 132mm	90 x 60 x 160 mm	Dimensions not critical
Prescriptive	Yes	Yes	Similar
Patient population	adult and pediatric	adult and pediatric	Similar
Single patient reusable	Used with user supplied cleared IV sets	Used with user supplied FDA cleared IV sets	Similar

Attribute	Biegler GmbH BW685S 510(k) K121198	Barkey S-line 510(k) TBD	Equivalency to at least one or both devices
Accessories	3 extension sets (K954769)	2 extension sets from Biegler (K954769) Model Length (cm) 35000 350 46000 460	K954769 and K121198 these extensions sets have been cleared for use with fluid warmers
Heating Mechanism	The system includes a main unit and then the warming tube, Autoline. The Autoline wraps around the extension set. This Autoline, also referred to as the TubeFlow is manufactured by Barkey. It uses a heat exchanger method with the Autoline / TubeFlow wrapped around the IV line to keep it warm.	The system included a main unit which attaches to a warming Tube, S-line. The S-line wraps around the extension set. The S-line has embedded heating element which heat and keep warm the fluids. The principle is a heat exchanger method.	Similar technology of heat exchanger. Instead of heating inside the unit like the predicate the subject device heats the line from the controller to the patient. This does not raise different risk concerns.
Fluid Contact materials	The controller and Autolone do not contact the patient. The accessory Extension sets does contact the fluid	No fluid contact contacting materials as the subject device does not provide the IV sets but there are recommended compatible extension sets which have been cleared for use with fluid warmers.	The subject device has no fluid contacting materials.
Temperature Control	3 sensors: 1 monitored by software, two hardware	Integrated overtemperature protector in the warming section of the S-line while there is monitoring of the temperature in the control unit	Similar in performance and safety
Alarm	Audio/ Visual	Audio/ Visual	Similar
Alarm Conditions	Audible and Visual Low temperature (<36.5C) High Temperature (>42.0C)	Audible and Visual Overtemperature Fault	Similar
Operation	110/220 VAC with AC power	100 – 240 VAC, 50/60 Hz	Similar
Electronics	Microprocessor Control	No microprocessor The temperature regulation is realized by hardware comparator circuit.	Similar
Infusion Temperature	User selectable between 37 to 41°C at increments of 0.5° Default 38.5ºC	Fixed 39ºC	Similar, within the temperature heating range of the predicate

Substantial Equivalence Discussion

The fundamental warming methodology as a heat exchanger is similar between the subject device and the predicate. The concept of heating within the controller as done in the predicate vs. heating the IV tubing within the S-line sleeve is still the of the S-line is similar to the predicate Biegler TubeFlow.

The fluid contact extension sets used with the S-line are FDA cleared IV-set which fits into the sleeve warmer (warming jacket) of the S-line.

Indications – Equivalent to the predicate

Technology – The technology is similar

Principal of Operation – The principal of operation is similar.

Operating specifications – Similar

Environment of Use – Similar

Patient Population – Similar

Non-clinical Testing
Performance testing demonstrated that the subject device met its acceptance criteria. Testing included:
Electrical / EMC

- AAMI ANSI ES 60601-1: 2005 + A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests

Performance testing to support accuracy and prevention of over heating

- ASTM F2172: 2002 (R2011): Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers Temperature management

Comparative testing against the predicate including:

- Temperature vs. flow rates

Substantial Equivalence Conclusion
We have performed a comparison of specifications in the above table and found the proposed models to be equivalent.