January 28, 2019

Life Warmer, Inc.
John Pettini
Chief Medical Officer, Founder
840 F. Avenue Suite 104
Plano, Texas 75074

Re: K181775
Trade/Device Name: Quantum Blood and IV Fluid Infusion Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: December 27, 2018
Received: December 28, 2018

Dear John Pettini:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn C. Dorgan -S

Digitally signed by Carolyn C. Dorgan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001800814, cn=Carolyn C. Dorgan -S
Date: 2019.01.28 09:50:13 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181775

Device Name
Quantum Blood and IV Fluid Infusion Warmer

Indications for Use *(Describe)*

The Quantum Blood and IV Fluid Infusion Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration in adult patients. It is intended to be used by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothenmia.

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."

LIFEWARMER

510(k) Summary
K181775

Submitted by/ Sponsor:	Life Warmer, Inc. 840 F. Avenue #104 Plano, TX 75074 USA 972-908-9808	**Contact Person:**	John Pettini, DO, FACEP 860-204-1711
Date Prepared:	January 28, 2019		
Trade Name:	Quantum Blood and IV Fluid Infusion Warmer		
Common Name:	Sterile Fluid Path in-line Blood and Fluid Warmer		
Classification Code Name & Reference:	LGZ	Warmer, Thermal, Infusion Fluid	21 CFR §880.5725
	BSB	Warmer, Blood, Non-electromagnetic radiation	
	Class II		
Predicate Device	K112902: enFlow IV Fluid Warmer by VITAL SIGNS, a GE Healthcare Company		

Device Description:
The Quantum Blood and IV Fluid Infusion Warmer is a light weight, portable, battery powered, in-line fluid warming system in which specially designed thermal IV administration tubing is integrated with a warming element.

The device is prescription only.

Indications for Use: The Quantum Blood and IV Fluid Infusion Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration in adult patients. It is intended to be used by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia.

Technological Characteristics: The Quantum Blood and IV Fluid Infusion Warmer is a light weight, portable, battery powered, in-line fluid warming system in which specially designed thermal IV administration tubing is integrated with a warming element. The Quantum is comprised of the following components: Controller, Battery, Charger, and Quantum thermal tubing available in two configurations: TIS (Thermal Infusion Set) and TTS-B (Thermal Transfusion Set for blood) with standard IV administration components. The microprocessor and algorithm in the Quantum Controller continually receive and assess temperature input from thermistors located on the proximal, medial and distal tubing segments. In response to this input, the Controller regulates the energy applied to the tubing to reach and/or maintain a pre-set temperature range of 38 °C ± 2 °C at delivery. A double-extrusion process results in tubing configuration with an inner tubing layer and an outer tubing layer. The warming element is in between but does not contact the fluid. Warming begins at the fluid source and continues the length of the tubing until near the point of patient entry. The TIS an TTS-B tubing perform the same function as standard IV tubing, however, when warming is desired, the TIS or TTS-B is simply connected to the Quantum Controller and the Controller is connected to the Battery. The TIS and TTS-B tubing sets are provided sterile (i.e., fluid path) for single patient use. The Controller, Battery and Battery Chargers are reusable.

Comparison to Predicate
The Quantum has the same intended use as the predicate device and similar technological features. The primary difference between the Quantum and the predicate device is the warming path and the integrated thermal tubing. The following table presents a comparison of the devices' technology and features.

Substantial Equivalence Comparison Table			
	Subject device	**Primary Predicate**	**Comparison**
	Quantum Blood and IV Fluid Infusion Warmer	**enFlow IV/Blood Warming System** [510(k) K112902]	
Common Name	Sterile Fluid Path in-line Blood and Fluid Warmer	Sterile Fluid Path, In-Line Blood Fluid Warmer	Same
Regulation	21 CFR Part 880.5725	21 CFR Part 880.5725	Same
Prod. Code	LGZ, BSB	LGZ, BSB	Same
Indication for Use	The Quantum™ Blood and IV Fluid Infusion Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration in adult patients. It is intended for use by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia.	The enFlow IV Fluid/Blood Warming System is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended for use by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.	Difference: Quantum specifies “adult patients” and transport environment.
Intended Use	Medical Emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid are desired or indicated.	Medical Emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid are desired or indicated.	Same
User Population	Healthcare professionals (e.g., physicians, registered nurses, mid-level practitioners, EMT/Paramedic, military medics)	Healthcare professionals (e.g., paramedic, nurse, doctor, etc.)	Difference: Quantum identifies additional specialties (mid-level practitioners, EMT/Paramedic, military medics)
Use Environment	Hospital, Clinic, Field and Transport	Hospital, Clinic and Field	Difference: Quantum adds Transport environment
User Interface	Visual (LED) and audible	Visual (LED) and audible	Same
User Feedback Provided	Over temperature, under temperature, battery low, no-flow/poor connection, system error	Over temperature, under temperature, battery low condition	Difference: Quantum includes system error
System Components	Sterile disposable thermal tubing (TIS/TTS-B), Controller (with LEDs), Battery (w/ LEDs and audible alert)	Fluid warmer with display, sterile disposable heat exchanger	Difference: Quantum contains thermal IV administration tubing and a controller which regulates warming. Predicate contains a heat exchanger cartridge.
Infusion Temperature	38 °C ± 2°C	Up to 40 °C (± 2 °C)	Difference: 36 to 40°C is typical normothermic range. To conserve battery life, the Quantum has a 38°C set point.
Fluid Path	Sterile; direct path with disposable IV administration tubing	Sterile; intercept path with aluminum extrusion cartridge	Quantum has direct fluid path; no intercept and redirect.
Flow Rate	Gravity 2 to 200 mL/min (depending on starting temperatures)	Gravity 1 to 200 ml/min	Difference: Quantum has the ability to detect a static line and initiates warming at 2mL/min.
Heating Method	Resistive heating	Resistive Heating	Same
Heating Control	Software	Software	Same
Warmer Type	In-line	In-Line	Same

Substantial Equivalence Comparison Table (continued)			
Power Source	Rechargeable battery	Rechargeable battery 110-120 or 220-240 VAC	Same
Biocompatibility	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible and non-bioreactive.	Fluid path contacts biocompatible coated aluminum extrusion	Same (Fluid path is biocompatible)
Sterilization	Disposable TIS, TTS-B tubing: (ethylene oxide)	Disposable unit: Sterile (ethylene oxide)	Same (sterilization method)
Product Specific Standards	ASTM 2172: 2002 Standard specification for blood/intravenous fluid irrigation warmer	ASTM 2172:2002 Standard Specification for blood/intravenous Fluid Irrigation Fluid Warmers	Same

Substantial Equivalence: The Quantum Blood and IV Fluid Infusion Warmer is substantially equivalent to the enFlow IV Fluid Warmer. Both the subject and predicate devices are under the same product code (LGZ and BSB), conform to the same device-specific standard AASTM 2172, and have the same intended use. As can be seen from the Substantial Equivalence Comparison Table above, many of the technological characteristics of both devices are the same. The main technological differences between the Quantum and the predicate device is the warming path, the method of sensing and controlling temperature, and the materials. These differences, however, are not considered to raise different questions of safety and effectiveness. Further, the technological differences are supported by performance and other substantiating testing.

Sterilization and Shelf-Life

The Quantum TIS and TTS-B tubing assemblies are disposable with a sterile fluid path. Sterilization was achieved by exposure to ethylene oxide (EO) and validated in accordance with ANSI/AAMI/ISO 11135:2014, ANSI/AAMI/ISO 11737-1: 2006/(R) 2011; ANSI/AAMI/ISO 11737-2: 2009/(R) 2014; ANSI/AAMI/ISO 11138-1: 2006/R) 2015; ANSI/AAMI/ISO 11138-2: 2006/(R) 2015; ANSI/AAMI/ISO10993-7: 2008/(R) 2012; ISO 11607-1:2006, ANSI/AAMI/ISO 10993/(R) 2013.

The TIS and TTS-B shelf-life was supported with testing performed in accordance with ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, ISTA-2A (2011) Partial Simulation Performance Tests. Bacterial Endotoxin testing was performed using the Kinetic-Chromogenic Method.

Performance Testing Summary

The Quantum Blood and IV Fluid Infusion Warmer design requirements have been defined and successfully tested to support substantial equivalence, and validation to standards necessary to demonstrate the functionality of the device as presented below:

Device-Specific Testing**:**

Quantum conforms to the following device specific standards:

- ASTM F2172-02 (2011), Standard Specification for blood/intravenous fluid irrigation warmers;
- ISO 1135-5 (2015), Transfusion equipment for medical use- Part 5: Transfusion sets for single use with pressure infusion apparatus;
- ISO 1135-4 (2015) Transfusion equip. for medical use-Part 4: Transfusion sets for single use, gravity feed;
- ISO 8536-4: (2010): Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed;
- ISO 8536-8: (2015): Transfusion equipment for medical use- Part 8: Infusion sets for single use with pressure infusion apparatus.
- USP 788: Particulate Matter in Injections (Light Obscuration Testing)

Biocompatibility**:** The Quantum was successfully subjected to the following biocompatibility testing:

- Cytotoxicity: 1) MEM Elution Test; 2) Neutral Red Uptake (ISO 10993-5: 2009)
- Sensitization: Kligman Maximization Test (ISO 10993-10: 2010)
- Irritation/Intracutaneous Reactivity: Intracutaneous Injection Test (ISO 10993-10: 2010)

- Systemic Toxicity: 1) Systemic Injection Test, 2) Material Mediated Rabbit Pyrogen Test, 14-Day Repeat Dose Intravenous Toxicity Study; 3) Subchronic Systemic Toxicity: 14-Day Repeat Dose Intraperitoneal Toxicity Study in Rats (ISO 10993-11: 2017)
- Interactions with Blood: 1) Rabbit Blood Hemolysis Test; 2) In Vitro Hemocompatibility Test (Direct); 3) C3A and SC58-B-9 Complement Activation Test (Direct); 4) Platelet Aggregation Test (direct); (ISO 10993-4: 2017

Electrical Safety and Electromagnetic Compatibility: The Quantum system has been subjected to testing and conforms with the following electrical safety and EMC standards:

- AAMI ES 60601-1:2005 (R) 2012+ A1: 2012/CSAC22.2 No. 60601-1:14 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance'
- IEC 60601-6:2010 + A1:2013/CSAC22.2 No. 60601-1-6:11 + A1:15 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability;
- IEC 60601-1-12: 2014 – Medical electrical equipment-Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment;
- EMC: Type Ref. 63-5900 per IEC 60601-1-2: 2014; EMC: Type Ref: 63-5000 – Quantum Battery/Quantum Charger (accessory);
- Emission Test: EN 55032: 2012/AC: 2013; CISPR 32: 2012;
- Immunity Test: EN 55024: 2010; CISPR24: 2010;
- EMC: Type Ref: 63-5900, tested to the requirements of RTCA DO-160G (Section 21).

Conclusion

Based on comparison of the Quantum Blood and IV Fluid Infusion Warmer to the predicate device with regard to intended use and technological characteristics, and the results of Quantum device testing submitted, the devices are substantially equivalent.