October 18, 2019

Life Warmer, Inc.
John Pettini
Chief Medical Officer, Founder
4813 Keller Springs Rd
Addison, Texas 75001

Re: K192325
Trade/Device Name: Quantum Blood and Fluid Warming System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG, BSB
Dated: August 26, 2019
Received: August 27, 2019

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/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,

for Nikhil Thakur
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192325

Device Name
Quantum Blood and Fluid Warming System

Indications for Use *(Describe)*

The Quantum™ Blood and Fluid Warming System is indicated for warming blood, blood products and intravenous solutions prior to administration in adult and pediatric patients greater than 28 days old of normal birth weight. It is intended for use by healthcare professionals in hospital, clinical, field, and transport environments to help prevent hypothermia.

The Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.

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.

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Submitted by/ Sponsor:	Life Warmer, Inc. 4813 Keller Springs Rd Addison, TX 75287 USA 972-908-9808	**Contact Person:**	John Pettini, DO, FACEP 860-204-1711
Date Prepared:	October 18, 2019		
Trade Name:	Quantum Blood and Fluid Warming System		
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	
Predicate Device	K181775: Quantum Blood and IV Fluid Infusion Warmer by Life Warmer, Inc.		

Device Description:
The Quantum Blood and Fluid Warming System 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 Fluid Warming System is indicated for warming blood, blood products and intravenous solutions prior to administration in adult and pediatric patients greater than 28 days old of normal birth weight. It is intended to be used by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia.

The Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.

Technological Characteristics: The technological characteristics of the Quantum Blood and Fluid Warming System are unchanged from the 510(k)-cleared device which is also the predicate. The System 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 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 design and technological features of the Quantum Blood and Fluid Warming System that is the subject of this Special 510(k) is identical to the Quantum Blood and IV Fluid Infusion Warmer previously cleared under K181775. The only difference is the inclusion of pediatric patients. This difference does not result in any design change, new or increased risk. The following table presents a comparison of the devices' technology and features.

Substantial Equivalence Comparison Table			
Trade Name	**Subject device** **Quantum Blood and Fluid Warming System** (K192325)	**Primary Predicate** **Quantum Blood and IV Fluid Infusion Warmer** (K181775)	
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 and pediatric patients greater than 28 days old of normal birth weight. It is intended for use by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia. The Quantum is not for use with neonates (birth to 28 days old) or infants of low birth weight.	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.	Different: Pediatric patients are included in the indication for use. Labeling was modified to mitigate new and increased risks to pediatric patients.
Intended Use	Medical emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid is desired or indicated.	Medical emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid is desired or indicated.	Same
User Population	Healthcare professionals (e.g., physicians, registered nurses, mid-level practitioners, EMT/Paramedic, military medics)	Healthcare professionals (e.g., physicians, registered nurses, mid-level practitioners, EMT/Paramedic, military medics)	Same
Use Environment	Hospital, Clinic, Field and Transport	Hospital, Clinic, Field and Transport	Same
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, no-flow/poor connection, system error	Same
System Components	Sterile disposable thermal tubing (TIS/TTS-B), Controller (with LEDs), Battery (w/ LEDs and audible alert)	Sterile disposable thermal tubing (TIS/TTS-B), Controller (with LEDs), Battery (w/ LEDs and audible alert)	Same
Infusion Temperature	38 °C ± 2°C	38 °C ± 2°C	Same
Fluid Path	Sterile; direct path with disposable IV administration tubing	Sterile; direct path with disposable IV administration tubing	Same
Flow Rate	Gravity 2 to 200 mL/min (depending on starting temperatures)	Gravity 2 to 200 mL/min (depending on starting temperatures)	Same
Heating Method	Resistive heating	Resistive Heating	Same
Heating Control	Software	Software	Same
Warmer Type	In-line	In-Line	Same
Power Source	Rechargeable battery	Rechargeable battery	Same
Biocompatibility	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible and non-bioreactive.	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible and non-bioreactive	Same
Sterilization	Disposable TIS, TTS-B tubing: (ethylene oxide)	Disposable TIS, TTS-B tubing (ethylene oxide)	Same
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 Fluid Warming System subject device is identical in design and technological features as the 510(k) cleared, commercially distributed Quantum predicate device (K181775). The only difference is the inclusion of pediatric patients greater than 28 days old of normal birth weight as stated in the indications for use statement. The additional risks from this device to pediatric patients have been mitigated through labeling, by incorporating warnings and precautions specific to pediatrics. No modification to the device, different or additional equipment, set or training is required. No new questions of safety and effectiveness are raised by this modification.

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
No additional performance testing was required to support the addition of pediatric patients greater than 28 days old of normal birth weight to the patient user group for this device. The Quantum Blood and Fluid Warming System has been subjected to Design Controls and previously tested to appropriate device-specific standards to support substantial equivalence, and validation to standards necessary to demonstrate the functionality of the device as presented below:

Risk Analysis:
The risk profile has changed with the addition of the pediatric population. An updated risk analysis has been performed to support the addition of all pediatric populations, with the exception of neonates and low birth weight infants. The Table below shows of how each residual risk applies to this population.

System/ Patient	Adult	Adolescents (12-21 years) 39.5 kg to 70.3kg	Preadolescent (11-13 years) 35.6 kg to 45.3 kg	Children (2-12 years) 12.5 kg to 39.5 kg	Infants (29 days to 2 years) 4.4 kg-12.5 kg
Users	Healthcare professionals (e.g., physicians, registered nurses, midlevel practitioners, EMT/Paramedic, military medics	Healthcare professionals (e.g., physicians, registered nurses, midlevel practitioners, EMT/Paramedic, military medics	Healthcare professionals (e.g., physicians, registered nurses, midlevel practitioners, EMT/Paramedic, military medics	Healthcare professionals (e.g., physicians, registered nurses, midlevel practitioners, EMT/Paramedic, military medics	Healthcare professionals (e.g., physicians, registered nurses, midlevel practitioners, EMT/Paramedic, military medics
Tubing Set Components	Y-spike (vented an and non-vented), 3 roller clamps, drip chamber, 2 injection ports, 2 slide clamps, luer adapter	No additional components required	No additional components required	No additional components required	No additional components required

Fluids	IV Fluids, Blood, Blood components	IV Fluids, Blood, Blood components	IV Fluids, Blood, Blood components	IV Fluids, Blood, Blood components	IV Fluids, Blood, Blood components
Resuscitation Flow Rate (mL/min) with 10 mL/kg bolus over 5 minutes	100 - 200	70 - 200	71.2 - 90.6	25 – 79	6.6 - 25
Resuscitation Flow Rate (mL/min) with 20 mL/kg bolus over 5 minutes	100 - 200	79 - 200	142.2 - 181.2	50 - 158	17.6 -50
Resuscitation Volume (mL) **From AHA Pediatric Advanced Life Support Guidelines**	1000 – 2000 mL	20 mL/kg bolus up to X3 isotonic crystalloids. 10 mL/kg PRBC's for hemorrhagic shock	20 mL/kg bolus up to X3 isotonic crystalloids. 10 mL/kg PRBC's for hemorrhagic shock	20 mL/kg bolus up to X3 isotonic crystalloids. 10 mL/kg PRBC's for hemorrhagic shock	20 mL/kg bolus up to X3 isotonic crystalloids. 10 mL/kg PRBC's for hemorrhagic shock
Labelling	Currently available	Additional warnings and precautions regarding hypothermia, contamination, infection, thermoregulation	Additional warnings and precautions regarding hypothermia, contamination, infection, thermoregulation	Additional warnings and precautions regarding hypothermia, contamination, infection, thermoregulation	Additional warning to not use with low birth weight infants Additional warnings and precautions regarding hypothermia, contamination, infection, thermoregulation
Biocompatibility	ISO 10993	No additional requirements	No additional requirements	No additional requirements	No additional requirements
Electrical Safety	IEC 60601	No additional requirements	No additional requirements	No additional requirements	No additional requirements

Risk Analysis Summary:
The predicate K181775 Quantum system is indicated for adult patients. Hypothermia prevention also applies to pediatric patient care. The Quantum can achieve its intended use at the resuscitation flow rates indicated for pediatric patients. Additional requirements or safety measures were assessed, including biocompatibility, electrical safety, design, and changes in the users and use scenarios of the device. The system has no additional biocompatibility or electrical safety requirements when used with pediatrics. The design of the patient contacting component, the tubing set, was assessed to address whether any additional risk may arise when using with pediatric population. The users are generally the same, however there are differences in use cases when being used with pediatrics. Clinician users of the Quantum who treat pediatric patients would have the same credentials as current Quantum users, and by training be knowledgeable in appropriate fluid volume requirements and flow rates for pediatric patients. Hence, this narrows the focus of the risk assessment down to use. The table above lists the various fluid volume and flow requirements for pediatric patients which can all be achieved with the current Quantum System. The Quantum Use Failure Modes and Effects Analysis (FMEA) and Thermal Tube Set (TTS) Design FMEA has been updated to assess if any additional risks arise when considering a pediatric patient population and labeling was updated to include warnings and precautions specific to the pediatric population in order to mitigate for the change in risk severity. Risk severity has been increased for risks related to contamination, air embolisms, hypothermia and others, since pediatric patients are at a higher risk for certain failure modes as compared to adult patients.
Considering risks involved with device use with pediatric patients, existing risks were revaluated to confirm whether their severity scores remained the same or were increased due to possibly more serious effects with pediatric patients, and the analysis was reviewed in order to identify any new risks. Existing risks that relate to IV administration and blood warmer use that are inherent to the devices had their severity unchanged when considering pediatric population since these risks were related to operator training and basic knowledge. Some existing risks were identified that could have more serious effects with pediatric patients.

A risk benefit analysis demonstrated that, even with increased risk severity for some risks, the risks were inherent to IV administration sets/sterile products and there is a benefit to providing treatment/warming versus risks associated with potential hypothermia. No new risks were identified when using the Quantum with pediatric patients older than 28 days of age and of normal birth weight that were not identified with adults. The pediatric nurses and physicians have similar training to adult nurses and physicians pertaining to transfusions. Warming at the lower flow rates and volumes can be achieved with the Subject device. Therefore, the Quantum would be beneficial to pediatric patients when fluid warming is desired. Clinician users of the Quantum who treat pediatric patients would have the same credentials as current Quantum users, and by training be knowledgeable in appropriate fluid volume requirements and flow rates for pediatric patients.

Conclusions
The Quantum Blood and Fluid Warming System is indicated for use in both adult and pediatric patients greater than 28 days old of normal birthweight and is substantially equivalent to the predicate device, based on the performed risk analysis.