Quality in Flow Ltd.
Omer Pechter
Director of RA and QA
11 Ha'avoda st.
Rosh Ha'ayin, 4801761
Israel

December 8, 2022

Re: K211800
Trade/Device Name: Warrior Blood and Fluid Warmer, Warrior EXTREME Blood and Fluid Warmer, Warrior Lite Blood and Fluid Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: LGZ, BSB
Dated: December 2, 2022
Received: December 5, 2022

Dear Omer Pechter:

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 -S

Courtney H. Lias, Ph.D.
Office 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k211800

Device Name
QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME / Warrior Lite)

Indications for Use *(Describe)*
The Warrior Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

The Warrior EXTREME Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

The Warrior Lite Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

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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K211800 510(K) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92.

Submitter

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Contact Person:	Omer Pechter Director of RA & QA

Date Prepared:	December 8, 2022
Device Trade Name	QinFlow Blood and Fluid Warmer (Warrior / Warrior EXTREME / Warrior Lite)
Device Common or Usual Name	Warmer, Thermal, Infusion Fluid
Regulation Name	Infusion Pump
Regulation Number	21 C.F.R. 880.5725
Product Code	LGZ
Regulation Name	Blood and plasma warming device
Regulation Number	21 C.F.R. 864.9205
Product Code	BSB
Device Class	Class II
Classification Panel	General Hospital

Predicate Device

Predicate Name and 510(k) Number:	K180154; QiF Blood and Fluid Warmer

Device Description

The QinFlow Blood and Fluid Warmer (Warrior / Warrior EXTREME / Warrior lite) is a portable sterile fluid path, in-line blood and fluid warmer intended for warming blood, blood products, and intravenous fluids prior to administration. The device is composed of the following main components:

1. ***Disposable Unit (DU) / Compact Disposable Unit (CDU)*** – The DU/CDU is a single-use, sterile disposable unit located between the fluid container (intravenous solution or blood product) and the treated patient, outside of the patient body. The disposable unit is made of an Expanded Polypropylene (EPP) encasing a spiral Stainless Steel (SS) heat exchanger tube to warm the inlet fluid. The DU/CDU has a standard intravenous tube extension and luer connections that can be used with any standard IV/blood set.

2. ***Base Unit (BU)*** – The BU controls the system outflow fluid temperature and provide information signals to the user through an LCD (for Warrior and Warrior EXTREME) and LED indication panel (for Warrior Lite). The Bu contains firmware (SW) and electronics (HW).

3. ***Power source*** – The power source is a rechargeable detachable battery located within the BU (Lite Battery for Warrior Lite and Enhanced Battery for Warrior and Warrior EXTREME or an AC power supply module (for Warrior and Warrior EXTREME.)

4. ***Connecting Cable (CC)*** – a cable consisting, and power wires connects between the Warrior and Warrior EXTREME BU and the DU/CDU to facilitate the transfer of data and electrical current. The DU /can be connected to the Warrior / Warrior EXTREME BU using the CC only or with an additional Extension cable accessory.

5. The ***CDU*** can be connected directly onto the Warrior Lite BU or using an Extension cable accessory. The DU can be connected to the Warrior Lite using the Extension cable only.

Indications for Use

The Warrior Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

The Warrior EXTREME Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

The Warrior Lite Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.

Technological Characteristics

The technological characteristics of the QinFlow Blood and Fluid Warmer remain the same as the previously cleared device under K180154.

The table below compares technological features of the proposed and the predicate. The similarities or differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. As shown in the device comparison table below, both the subject and predicate devices have the same intended use for warming blood, blood products, and intravenous fluids prior to administration. Like the predicate device, the proposed device is a portable, software controlled in-line fluid warmer located between the fluid container (intravenous solution or blood / blood product) and the treated patient, outside of the patient body. The Warrior lite Base Unit technological characteristic and principle of operation are the same as the QiF predicate device. It is simply a smaller size device. The Warrior Lite battery is also smaller than the predicate device battery and contain less cells; as such its fluid warming capacity of the Warrior Lite is smaller than the predicate device. Any other differences were supported by acceptable results of safety and/or performance testing.

In summary, proposed device has the following technological characteristics which are comparable to the predicate device:

1. **Intended use/Indications for Use:** Warming blood, blood products, and intravenous fluids prior to administration except for the addition of pediatric population and transport environment. Both the predicate and proposed device flow rates can support both adult and pediatric population. The change in indications for use statement is intended to clarify the patient population and no new risks were identified.
2. **Environment of Use:** The environment of use remains the same as the predicate except for the addition of the transport environment.
3. **Technology (Operating Principle):** Software-controlled electromechanical system with in-line fluid warming using resistive heating at a constant outlet temperature of 100.4 ± 3.6 °F (38 ± 2°C). The fluid flows through a spiral heat exchange tube in sterile, single- use Disposable Unit and heated to the required physiological temperature while flowing inside the tube.
4. **Design Configuration:** The device is comprised of a Base Unit (BU) and a sterile disposable cartridge (Disposable Unit (DU) or Compact Disposable Unit (CDU)). The DU / CDU is composed of an EPP encasing a spiral stainless-steel heat exchanger tube. The Base Unit contains firmware (software) and electronics. The Base Unit controls the performance of the system and the fluid outflow temperature. The power source is either a rechargeable detachable battery located within the Base Unit or an AC power supply module (also referred as "AC unit"; for Warrior and Warrior EXTREME). The DU / CDU has a standard intravenous tube extension.
5. **Materials Compatibility:** Fluid-contacting and patient contacting materials are the same
6. **User Interface:** Warrior/Warrior EXTREME Base unit with visual display and button controls on the front panel and Warrior Lite Base unit with Panel LED indication and on/off button.
7. **Sterility:** Using Ethylene Oxide **(**ETO) sterilization method

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
Indications for Use	The Warrior Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia. The Warrior EXTREME Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous	The Warrior Lite Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.	The QiF Blood and Fluid Warmer device is intended for warming blood, blood products, and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in hospital, clinics, and field environments, to help prevent hypothermia.	Both the subject and predicate devices have essentially the same intended use. The change was made to specify the intended user population and the transport environment in accordance with 21 CFR 814.20(b)(3)(i). The change does not raise different questions of safety and effectiveness.

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
	fluids prior to administration in adults and pediatric patients. It is intended to be used by healthcare professionals in hospital, clinics, field and transport environments to help prevent hypothermia.			
Intended Use	Intended for warming blood, blood products and intravenous solutions in adults and pediatric patients during medical emergencies whenever parenteral introduction of normothermic fluid are desired or indicated. It is intended to be used by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia.	Intended for warming blood, blood products and intravenous solutions in adults and pediatric patients during medical emergencies whenever parenteral introduction of normothermic fluid are desired or indicated. It is intended to be used by healthcare professionals in hospital, clinical, field and transport environments to help prevent hypothermia	Intended for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.	Both the subject and predicate devices have essentially the same intended use. The change was made to specify the intended user population and the transport environment in accordance with 21 CFR 814.20(b)(3)(i). The change does not raise different questions of safety and effectiveness.
Intended Users	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)	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	Hospital, Clinic, Field and Transport	Same
Operating Principle	Resistive heating	Resistive heating	Resistive heating	Same
Intended fluid(s) to be warmed	IV Fluids, Blood, Blood	IV Fluids, Blood, Blood	IV Fluids, Blood, Blood Products, Plasma	Same

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
Intended route(s) of administration	IV	IV	IV	Same
System Components	**1.** Base Unit **2.** Disposable Unit (Sterile, Heat exchanger) **3.** Connecting Cable **4.** Compact Disposable Unit (optional) Extension Cable Accessory (optional)	**1.** Base Unit **2.** Disposable Unit (Sterile, Heat exchanger) **3.** Compact Disposable Unit (optional, New) Extension Cable Accessory (optional when using CDU)	**1.** Base Unit **2.** Disposable Unit (Sterile, Heat exchanger) Connecting Cable	Optional use of the following components: 1. Compact Disposable Unit (CDU) 2. Extension Cable The change does not raise different questions of safety and effectiveness.
Power Source	Rechargeable Battery or AC power supply module	Rechargeable Lite Battery	Rechargeable Battery or AC power supply module	The Warrior Lite can only be operated with the rechargeable Lite Battery. The change does not raise different questions of safety and effectiveness.
User Interface	**1.** Visual (LCD display) and audio **2.** Self-test/mute button On/off switch	**1.** Visual (LED panel) On/off button	**1.** Visual (LCD display) and audio **2.** Self-test/mute button On/off switch	Warrior Lite provides information signals through LED panel instead of LCD display. The change does not raise different questions of safety and effectiveness.
Heating Method	Resistive Heating	Resistive Heating	Resistive Heating	Same
Heating Control	software controls the heating process and the operation of the device	software controls the heating process and the operation of the device	software controls the heating process and the operation of the device	Same
Warmer Type	Same as predicate	Same as predicate	In-line	Same

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
Flow Rate	Based on gravity or fluid pump, up to 180 ml/min	Based on gravity or fluid pump, up to 170 ml/min	Based on gravity or fluid pump, up to 160 – 180 ml/min	The flow rates are within the specified range of the predicate device. The differences do not raise different questions of safety and effectiveness
Materials/ Biocompatibility	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible.	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible.	Biocompatibility testing demonstrates tubing/fluid path to be biocompatible.	Same
Sterilization	ETO	ETO	ETO	Same
Storage conditions	-4°F to 140°F & 93% RH (-20oC to 60oC & 93% RH)	-20 °C to 70 °C & 93% RH (-4 °F to 158 °F & 93% RH)	-4°F to 140°F & 93% RH (-20oC to 60oC & 93% RH)	A wider range of storage conditions was successfully tested per IEC 60601-1-12 for Warrior lite. The change does not raise different questions of safety and effectiveness.
Operation Temperature & Humidity	41°F & 15%RH to 104°F & 90% RH (5ºC & 15%RH to 40ºC & 90%RH	23ºF to 122ºF& 90%RH (-5ºC to 50ºC & 90%RH)	41°F & 15%RH to 104°F & 93% RH (5ºC & 15%RH to 40ºC & 93%RH)	A wider range of operating temperatures was successfully tested for per IEC 60601-1-12 for Warrior Lite. The change does not raise different questions of safety and effectiveness.
Transient Operating Conditions	-4ºF & 15%RH to 122ºF & 90%RH (-20ºC & 15%RH to 50ºC & 90%RH)	-4ºF & 15%RH to 122ºF & 90%RH (-20ºC & 15%RH to 50ºC & 90%RH)	41°F & 15%RH to 104°F & 93% RH (5ºC & 15%RH to 40ºC & 93%RH)	The change does not raise different questions of safety and effectiveness as demonstrated by additional testing of transient operating conditions per IEC 60601-1-12.
Atmospheric Pressure/(Altitude)	-400 to 4572 meters (-1312 to 15,000 ft) Operated with AC power supply module	Operated with lite battery: -400 to 4572 meters (-1312 to 15,000 ft)	Operated with battery -400 to 4572 meters (-1312 to 15,000 ft)	Same

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
	-400 to 3200 meters (-1312 to 10,499 ft)		Operated with AC power supply module -400 to 2000 meters (-1312 to 10,499 ft)	
Nominal Input Voltage	100-240 VAC 18-25.2 DC	100-240 VAC 18-25.2 DC	100-240 VAC 15-21 DC	Same
Temperature set point	100.4 ±3.6 °F (38 ±2 °C)	100.4 ±3.6 °F (38 ±2 °C)	100.4 ±3.6 °F (38 ±2 °C)	Same
Measurement Accuracy	±2ºC (±3.6ºF)	±2ºC (±3.6ºF)	±2ºC (±3.6ºF)	Same
Input Temperature Requirements	At least 4°C (39.2°F)	At least 4°C (39.2°F)	At least 4°C (39.2°F)	Same
Warm-up time	Up to 30 seconds	Up to 30 seconds	Up to 30 seconds	Same
Warmed Volume Capacity	2.8 – 5L	1.25 – 2.4L	Operated with battery: 2.8 – 5L	The Warrior Lite battery is also smaller than the predicate device battery and contain less cells; as such its fluid warming capacity of the Warrior Lite is smaller than the predicate device. The change does not raise different questions of safety and effectiveness.

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
Disposable Unit / Compact Disposable Unit Shelf Life	DU Shelf Life is 3 years CDU Shelf Life is 3 years	DU Shelf Life is 3 years CDU Shelf Life is 3 years	DU Shelf Life is 3 years	Same
Base Unit Service Life	5 years	5 years	5 years	Same
Water and particles Ingress rate	Warrior EXTREME: IP56 Warrior: IP33	IP56	IP22	Warrior EXTREME, Warrior lite IP of IP56 is different and tested successfully per IEC 60601-1-12. The change does not raise different questions of safety and effectiveness.
Physical Dimensions of components	Dimensions of Base Unit with battery H xW x L millimeter (inch) 232x156x78 mm (9.13x6.14x3.07 in)	Dimensions of Base Unit with battery H xW x L millimeter (inch) 136×82×83 mm (5.35×3.23×3.27 in)	Operated with battery: Dimensions of Base Unit with battery H xW x L millimeter (inch) 232x156x78 mm (9.13x6.14x3.07 in) Operated with AC module: Approximately 300×190×180 mm (11.8×7.5×7.1 in)	Warrior Lite BU dimensions with Lite Battery was designed to be smaller. The change does not raise different questions of safety and effectiveness
Weight of components	Approximately 1720g (3.79lb)	Approximately 790g (1.54lb)	Operated with battery Approximately 1720g (3.79lb) Operated With AC module: Approximately 3700 g (~8 lb)	Warrior Lite BU weight with lite Battery was designed to be lower. The change does not raise different questions of safety and effectiveness
BU Display (LED/LCD)	LCD	LED	LCD	Warrior Lite provides information signals through LED panel instead of LCD display. The change does not raise different questions of safety and effectiveness.

Device Comparison				
Technological Features	Subject Devices		Predicate	Summary
	QinFlow Blood and Fluid Warmer (Warrior/Warrior EXTREME)	QinFlow Blood and Fluid Warmer (Warrior Lite)	QiF Blood and Fluid Warmer (Warrior, K180154)	
Alarm Conditions / Indicators	Visual (LCD display) and audio Self-test/mute button On/off switch	Visual (LED panel) On/off button	Visual (LCD display) and audio Self-test/mute button On/off switch	Warrior Lite provides information signals through LED panel instead of LCD display. The Warrior Lite does not have: 1. audible information signals 2. self-test/mute button The change does not raise different questions of safety and effectiveness.

Performance Data

Performance testing requirements were determined through the application of a risk management process, applicable FDA guidance documents and performance standards (21 CFR §880.5725). Performance testing in support of substantial equivalence determination included:

- **Functional:** Testing to verify that the device functions as intended, and all design and functional specifications are met for all models/system configurations.
- **Software Verification and Validation:** Software verification and validation testing were conducted and documentation is provided for a Major level concern per IEC 62304 and as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- **Safety Testing**
    a. Electrical: Testing per IEC 60601-1:2005 to demonstrate compliance with applicable electrical safety requirements.
    b. Electromagnetic Compatibility: Testing per IEC 60601-1-2:2014 to demonstrate compliance with applicable electromagnetic interference requirements.
    c. EMS Equipment Safety: Testing per IEC 60601-1-12:2014 to demonstrate compliance with applicable emergency medical equipment requirements.
- **Hemocompatibility Testing:** Testing to demonstrate safe use with blood products
- **Usability Assessment**: Simulated use testing in accordance with IEC 62366:2007 and FDA's Medical Use-Safety: Incorporating Human Factors Engineering into Risk Management Guidance to demonstrate that the Warrior Lite can be used safely and effectively by intended users.
- **Shelf-life and Sterilization Validation:** Shelf-life testing and Sterilization assessment per ISO 11135: 2014 for sterilization validation was conducted with acceptable results.

Conclusions

The QinFlow Blood and Fluid Warmer (Warrior, Warrior EXTREME and Warrior Lite) is as safe and as effective as previously cleared predicate device (K180154), as demonstrated by performance data and risk assessment. The intended use, technological characteristics and principle of operation are substantially equivalent to the predicate device and do not raise any new concerns with regard to safety or effectiveness. Thus, the QinFlow Blood and Fluid Warmer is substantially equivalent to the predicate device.