April 27, 2018

Quality In Flow Ltd.
Neta Sherman
VP Product Realization; RA & QA Manager
Kibutz Einat POB 29
Kibutz Einat, 4880500
ISRAEL

Re: K180154
Trade/Device Name: QiF Blood and Fluid Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ, BSB
Dated: March 25, 2018
Received: March 28, 2018

Dear Neta Sherman:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K180154

Device Name
QiF Blood and Fluid Warmer

Indications for Use *(Describe)*
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.

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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K180154 510(k) SUMMARY

Manufacturer's Name:	Quality In Flow Ltd. Kibutz Einat; P.O.B. 29; Israel 4880500
Corresponding Official:	Neta Sherman VP Product Realization; RA & QA Manager
Telephone Number:	(972) (54) 660 0146
Email:	neta.sherman@qinflow.com
Preparation Date:	April 11, 2018
Device Trade Name:	QiF Blood and Fluid Warmer
Device Common or Usual Name:	Infusion Pump, blood and plasma warming device
Regulation Name:	Infusion Pump
Regulation Number:	21 C.F.R 880.5725
Product Code:	LGZ, BSB
Device Class:	Class II
Classification Panel:	General Hospital
Primary Predicate Device:	K171215; QiF Blood and Fluid Warmer

Purpose of 510(k)

The purpose of this 510(k) is to add the AC power supply module as an additional power source to the rechargeable detachable battery of the QiF blood and fluid warmer.

Indications for Use

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.

Device Description

The Quality in Flow QiF Blood and Fluid Warmer is a portable sterile Fluid Path, in-line Blood and Fluid Warmer.

The QiF device is composed of the following main components:

1. ***Disposable Unit (DU)*** – The disposable cartridge is made of a plastic oval box encasing a spiral Stainless Steel (SS) heat exchanger tube. The DU is located between the fluid container (intravenous solution or blood product) and the treated patient, outside of the patient body. The DU has a standard intravenous tube extension. The DU comprises the temperature sensors.

2. ***Base Unit (BU)*** – The BU controls the performance of the system and the outflow fluid temperature. The power source is a rechargeable detachable battery located within the BU or an AC power supply module; the BU contains firmware (SW) and electronics (HW).

3. ***Connecting Cable (CC) –*** a cable that connect between the BU and the DU to facilitate the transfer of data and electrical current.

Substantial Equivalence Discussion

Both the cleared device and the modified QiF Blood and Fluid Warmer are a portable, inline Blood and Fluid Warmer located between the fluid container (intravenous solution or blood product) and the treated patient, outside of the patient body. The device is comprised of a Base Unit (BU) and a sterile disposable cartridge (Disposable Unit). The Disposable Unit (DU) is composed of a plastic oval box encasing a spiral stainless steel heat exchanger tube. The Base Unit contains Firmware (software) and electronics (HW). 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"). The DU has a standard intravenous tube extension.

The QiF modified device has the same indications for use as its predicate device. A Substantial Equivalence Comparison table between the subject device and the predicate device is presented below:

	Quality in Flow – QiF Blood and Fluid Warmer [Subject device; K180154]	**Quality in Flow – QiF Blood and Fluid Warmer [K171215]**	**Comparison**
Intended Use	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.	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.	Same

Indications for 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
Fluids that Can be Warmed	IV Fluids, Blood, Blood Products	IV Fluids, Blood, Blood Products	Same
Components	Warmer with display and a sterile, disposable heat exchanger	Warmer with display and a sterile, disposable heat exchanger	Same
Safety Features	• System self-test • Overheat notification • Overheat cut-off • Battery under-voltage protection (cut-off)	• System self-test • Overheat notification • Overheat cut-off • Battery under-voltage protection (cut-off)	Same
Notification Types	• Overheat • Under heat • Low battery • Flow irregularity	• Overheat • Under heat • Low battery • Flow irregularity	Same
User Interface / Notifications	• Visual (LCD display) and audio • Self-test/mute button • On/off switch	• Visual (LCD display) and audio • Self-test/mute button • On/off switch	Same
Power Source	Rechargeable Battery or AC power supply module	Rechargeable Battery	Different AC power supply module was added as an additional power source
Power source case and attachment to Base Unit (BU)	A Rechargeable Battery connected to the bottom of the BU BU is inserted into the AC power supply module casing	A Rechargeable Battery connected to the bottom of the BU	Different AC power supply module was added as an additional power source
Infusion temp.	38±2°C	38±2°C	Same
Heating Method	Resistive heating	Resistive heating	Same

Fluid Path	Located within the sterile disposable cartridges (DU). Spiral stainless steel tube and a short segment of a PVC tube The tube serves as the conductor of electrical current.	Located within the sterile disposable cartridges (DU). Spiral stainless steel tube and a short segment of a PVC tube The tube serves as the conductor of electrical current.	Same
Flow Rate	Based on gravity or fluid pump, up to 160 – 180 ml/min	Based on gravity or fluid pump, up to 160 – 180 ml/min	Same
Software	The software control the heating process and the operation of the device	The software control the heating process and the operation of the device	Same
Biocompatibility	The fluid path is made of biocompatible Stainless Steel, PVC and luer connections	The fluid path is made of biocompatible Stainless Steel, PVC and luer connections	Same
Sterility	The disposable unit is provided sterile for single patient use	The disposable unit is provided sterile for single patient use	Same
Single Use or Reusable	Single Use	Single Use	Same
Shelf Life	DU shelf life – 3 years	DU shelf life – 3 years	Same
Storage conditions	-4°F to 140°F & 93% RH	-4°F to 140°F & 93% RH compliance to -22°F to 158°F	Different The QiF device operated with battery and operated with AC power supply module are both certified for the same storage conditions; the QiF device operated with battery was also validated for broader storage conditions

Operating conditions	41°F &15%RH to 104°F & 93% RH	41°F &15%RH to 104°F & 93% RH compliance with 23°F to 104°F	Different The QiF device operated with battery and operated with AC power supply module are both certified for the same operating conditions; the QiF device operated with battery was also validated for broader operating conditions
Altitude	-1312 to 10,499 ft	-1312 to 15,000 ft	Different The QiF device operated with battery and operated with AC power supply module are both certified for the same altitude conditions; the QiF device operated with battery was also validated for broader altitude conditions
Dimensions of Base Unit with Battery	Approximately 235x160x75 mm (9.25x6.5x2.9 in)	Approximately 235x160x75 mm (9.25x6.5x2.9 in)	Same
Dimensions of Base Unit with AC power supply module	Approximately 300×190×180 mm (11.8×7.5×7.1 in)	N/A	N/A
Dimensions of Disposable Unit in sterile bag	Approximately 210x160x45mm (8.3x 6.5x1.8 in)	Approximately 210x160x45mm (8.3x 6.5x1.8 in)	Same
Warmer Type	Inline warmer	Inline warmer	Same

Heat Insulation	Yes: the heat exchanger is encased within an expanded polypropylene (EPP) oval box to prevent any contact between the user and warm tube intended to provide thermal and electrical isolation between the device and the user.	Yes: the heat exchanger is encased within an expanded polypropylene (EPP) oval box to prevent any contact between the user and warm tube intended to provide thermal and electrical isolation between the device and the user.	Same

The differences between the subject device and the predicate device are the addition of the AC power supply, AC power supply casing, narrowing of the storage, operating, and altitude conditions of use.

The operating and storage conditions and the altitude of use of the AC power supply module are within the ranges of the QiF cleared predicate device; The labeling of the QiF device operated with the AC power supply module specifically indicates the storage and operating conditions and this difference does not raise different questions of safety and effectiveness.

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.

Performance Testing Summary

Based on a risk analysis of the changes, the following testing was conducted to demonstrate substantial equivalence to the predicate device:

- Performance testing, including heating fluid to set-point temperature from various inlet temperatures in various flow rates and system performance through flow rate irregularities, demonstrated that the subject device has equivalent performance to the predicate device.

- Validation of the subject device included performance testing, environmental testing and electrical safety testing per:
    - IEC-60601-1:2005: General Requirements For Basic Safety And Essential Performance
    - IEC 60601-1-2:2010 Medical Electrical Equipment. General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic compatibility
    - IEC 60601-1-6:2013 Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability

- A risk analysis was completed in accordance with ISO 14971:2012, Medical Devices – Applications of Risk Management to Medical Devices

In all instances, the subject device functioned as intended and demonstrated equivalent performance to the predicate device.

Conclusions

The modifications to the device do not raise different questions of safety and effectiveness and are supported by risk management activities. The QiF Blood and Fluid Warmer is substantially equivalent to the QiF Blood and Fluid Warmer, cleared under K171215.