DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 20, 2017

Quality in Flow, Ltd.
Neta Sherman
Official Correspondent
POB 29
Kibutz Einat, 4880500
ISRAEL

Re: K163708
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 24, 2017
Received: March 24, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*
K163708

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
Quality in Flow's QiF Blood and Fluid Warmer
K163708

Manufacturer: Quality in Flow Ltd.

Phone: (972) (54) 6600146
Contact Person: Neta Sherman

Date Prepared: April 20, 2017

Subject Device
Name of Device – QiF Blood and Fluid Warmer
Common Name – QiF Blood and Fluid Warmer
Regulation Number – 21 C.F.R 880.5725
Regulation Name – Infusion Pump
Regulatory class – class II
Product Code – LGZ, BSB
Classification Panel – General Hospital

Predicate Device
510(k) Number- K150404
Name of Device – QiF Blood and Fluid Warmer
Common Name – QiF Blood and Fluid Warmer
Regulation Number – 21 C.F.R 880.5725
Regulation Name – Infusion Pump
Regulatory Class – class II
Product Code – LGZ, BSB
Classification Panel – General Hospital

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.

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 Disposable Unit is located between the fluid container (intravenous solution or blood product) and the treated patient, outside of the patient body. The Disposable Unit has a standard intravenous tube extension. The Disposable Unit comprises the temperature sensors.

2. ***Base Unit (BU)*** – The Base Unit controls the performance of the system and the outflow fluid temperature. The power source is a rechargeable detachable battery

located within the Base Unit; the Base Unit contains firmware (SW) and electronics (HW).

3. ***Connecting Cable (CC) –*** a cable consisting data and power wires connects between the Base Unit and the Disposable Unit to facilitate the transfer of data and electrical current.

Purpose of 510(k)

The purpose of this 510(k) is to modify the QiF Blood and Fluid Warmer in the following ways:

1. The rechargeable Battery pack was upgraded to an enhanced model with increased capacity with a new charger adaptor.

2. Integrated DU (a single DU for warming both blood, blood products and IV fluids, instead of two separate DUs, one for blood/blood products and one for IV fluids). The Blood DU was chosen for warming both blood, blood products and IV fluids. By doing so, the algorithm and precautions of blood warming, which are stricter than those of IV fluid warming, remain, and the fluids are warmed with the same DU as the blood/blood products.

3. Additional Testing: DU shelf life extended from 1 year to 3 years.

4. Additional testing and labeling change: storage temperature of -30°C to 70°C (-22°F to 158°F), operating altitude (10,499 ft to 15,000 ft), and operating temperature of -5°C to 40°C (23°F to 104°F). Theses parameters were added to the device labeling.

5. Labeling change: due to the integrated DU, some changes were required in the labeling. In addition, one warning regarding usage of fluid pump was revised, and instructions regarding charger adapter correct orientation, and battery charging were added. The troubleshooting instructions were also revised for enhanced clarity.

Performance Data

Performance tests were performed in order to demonstrate that the modified device has equivalent performance to its predicate.

1. The rechargeable Battery pack upgrade: Risk analysis was performed and it was concluded that no additional risks were raised by the battery upgrade. Validation activities included electrical testing by certified labs.
2. Integrated Disposable Unit (DU) (same unit now warms both blood, blood products and IV fluids, instead of two separate DU's, one for blood/blood products and one for IV fluids).
   The integrated DU does not include a change in technology or performance as it is the same as the predicate Blood DU (BDU). The modification is to the software only. Software validation was performed and showed the software functioned as intended without bugs.
   The risk discussion showed there is a clear overall risk elimination, and all the potential risks from the change are reduced, validated and the residual risk is acceptable.

3. DU shelf life extended from 1 year to 3 years. The cleared device IFU indicated shelf life of one (1) year, based on real time shelf life tests. The update of the DU shelf life is increased to three (3) years based on successful accelerated testing validation.
4. Operating and storage climate change: The operating altitude (10,499ft to 15,000ft) is verified per IEC 60601-1-11 section 4.2.2.C. Storage temperature of -30°C to 70°C (-22°F to 158°F), and operating temperature of -5°C to 40°C (23°F to 104°F) is verified through functional testing at boundary conditions by a certified lab. Device preconditioning included:
    a. Climate (temperature)
    b. Bump test
    c. Vibration

    Verification endpoints included:
    a. Visual inspection
    b. Warming to set point temperature
    c. Warming rates
    d. Device functionality (Software and Hardware)

In all instances, the modified device functioned as intended and demonstrated equivalent performance.

Risk analysis identified the following risks and mitigations:

Risk	**Mitigation**
New battery overheats, affects electrical safety or EMC	Battery testing per IEC62133:2012 Electrical safety testing per IEC 60601-1:2005 +CORR.1:2006 + CORR.2:2007 + AM1:2012 (or IEC 60601-1:2012 reprint))and IEC60601-1-11:2010 EMC testing per IEC60601-1-2:2007
Software does not recognize combined DU and does not work as intended	Software validation testing to show continued essential performance
Packaging does not maintain sterility for the extended shelf-life	Packaging validation
Functionality after storage at low (-30 ºC) and high (70 ºC) temperature	Tested per EN 1789:2007+A2:2014 standard at a certified laboratory.
Functionality at low (0 ºC, -5 ºC) and high (40 ºC) temperature	Tested per EN 1789:2007+A2:2014 standard at a certified laboratory.
Functionality at low pressures (altitude of 15,000 ft)	Testing per IEC 60601-1-11 section 4.2.2.c
Warning modification for use with a pump allows increased flow rates where there is inadequate time for heating or causes user notification warnings to not be delivered as intended	Performance testing to show outflow temperature achieved at high flow rates. Validation testing under irregular flow scenarios to demonstrate continued proper functionality and user notification.

Technological Characteristics

The modified QiF Blood and Fluid has the same technological characteristics as the predicate QiF Blood and Fluid Warmer, to which it is a modification.
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 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 a rechargeable detachable battery located within the Base Unit. The Disposable Unit has a standard intravenous tube extension.

Substantial Equivalence

An abbreviated SE Table is presented below:

	Quality in Flow – QiF Blood and Fluid Warmer model 01 [K163708]	**Quality in Flow – QiF Blood and Fluid Warmer model 01 [K150404]**	**SE Justification**
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
Components	Warmer with display and a sterile, disposable heat exchanger	Warmer with display and a sterile, disposable heat exchanger	Same

	Quality in Flow – QiF Blood and Fluid Warmer model 01 [K163708]	Quality in Flow – QiF Blood and Fluid Warmer model 01 [K150404]	SE Justification
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	Rechargeable Battery	Same
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, Up to ~160 – 180 ml/min	Similar. Fluid pump can be used with limit of up to 180 ml/min based on testing up to 220 ml/min
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

	Quality in Flow – QiF Blood and Fluid Warmer model 01 [K163708]	Quality in Flow – QiF Blood and Fluid Warmer model 01 [K150404]	SE Justification
Single Use or Reusable	Single Use	Single Use	Same
Shelf Life	DU shelf life – 3 years	DU shelf life – 1 year	Extended shelf life was validated through bench top testing
Storage conditions	-4°F to 140°F & 93% RH and compliance to -22°F to 158°F	-4°F to 140°F & 93% RH	Similar. Expanded operating conditions were validated through performance testing in a certified lab
Operating conditions	41°F &15%RH to 104°F & 93% RH and compliance with 23°F to 104°F	41°F &15%RH to 104°F & 93% RH	Similar. Expanded operating conditions were validated through performance testing in a certified lab
Altitude	-1312 to 10,499 ft.	-1312 to 15,000 ft.	Similar. Expanded operating conditions were validated through performance testing in a certified lab
Dimensions of Base Unit with Battery	Approximately 235x160x75 mm (9.25x6.5x2.9 in)	Same	Same
Dimensions of Disposable Unit in sterile bag	DU: Approximately 210x160x45mm (8.3x 6.5x1.8 in)	Same	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

Conclusion

The QiF modified device has the same indications and similar technological characteristics and principles of operation as its predicate device. The technological differences between the QiF Blood and Fluid Warmer modified and its predicate device do not raise different issues of safety or effectiveness. Performance data demonstrates that the modified QiF Blood and Fluid Warmer is substantially equivalent.