May 31, 2024

Mequ A/S
Ulrik Andersen
CEO
Ole Maaløes Vej 3
2200
København
Denmark

Re: K232107
Trade/Device Name: °M Warmer System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ, BSB
Dated: May 3, 2024
Received: May 3, 2024

Dear Ulrik Andersen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
Assistant Director, Infusion Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232107

Device Name
°M Warmer System

Indications for Use *(Describe)*
The °M Warmer System is indicated for use to warm blood, blood products, colloids and crystalloid solutions prior to parenteral administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia. The field environment includes road, rotary and fixed-wing ambulances.

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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°MEQU

K232107 510(k) Summary

Submitter:	MEQU A/S
Address:	Ole Maaløes Vej 3 København 2200 Denmark
Phone number:	+45 61 75 68 48
Fax number:	MEQU A/S does not have a fax number
Contact person:	Ulrik Krogh Andersen
Date prepared:	07/14/2023
Trade name:	°M Warmer System
Common name:	In-line infusion fluid warmer
Classification name:	Warmer, Thermal Infusion Liquid (21 CFR 880.5725, product code LGZ) Warmer, Blood, Non-Electromagnetic Radiation (21 CFR, 864.9205, product code BSB)
Substantial equivalence is claimed to:	enFlow IV Fluid Warmer (K112902)

Indications for use

The °M Warmer System is indicated for use to warm blood, blood products, colloids and crystalloid solutions prior to parenteral administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.
The field environment includes road, rotary and fixed-wing ambulances.

Description

The °MEQU °M Warmer System consists of three components:
- a single-patient use, disposable warmer unit
- a multi-patient, reusable, rechargeable battery pack for powering the warmer
- a reusable charger for recharging the battery pack.

The warmer contains a sterile fluid path with standard Luer lock connectors allowing it to be connected in the infusion fluid line. The fluid path includes a parylene coated aluminium heating chamber in which fluids passing through the warmer are heated. Heat is generated using resistive heating elements, using power supplied by the rechargeable battery pack.
The warmer contains the electronics and software to control the temperature of the chamber and thus the temperature of the outgoing fluid.

Remaining power in the battery pack is indicated to the user during use. When depleted, the battery pack can be re-charged using the charger.

Substantial equivalence

The °M Warmer System is substantially equivalent to the cleared enFlow IV Fluid Warmer. The °M Warmer System has the same intended use.

The technological characteristics and principles of operation are substantially similar, both the °M Warmer System and the enFlow IV Fluid Warmers are composed of a reusable power source and a sterile, disposable, single patient use cartridge.

The enFlow IV Fluid Warmer has a reusable warming unit and the °M Warmer System has a disposable warming unit.

Both the subject and predicate devices control the operation of the system and the outflow temperature of the infuscate and contains software, hardware and the power source.

The subject and predicate device use the same heating method, i.e., resistive heating. The disposable cartridge of both the subject and predicate devices contains a fluid path that serves as a heat exchanger. The heat exchanger of the subject and predicate devices contains metal that heat the blood, blood product or parenteral/intravenous fluid by resistive heating.

The only main technological differences between the °M Warmer System and its predicate are: The °M Warmer System has a disposable warming unit, it does not have AC-mains power inlet, it has no audio warnings, the material composition of the heat exchanger fluid path and maximum output temperature.

The Alarm function in °M Warmer is constructed to have a low thermal delay to alarm sensor and has the lowest activation threshold for the Alarm.

These differences do not raise any concerns to safety and effectiveness and equivalent performance has been demonstrated. Thus, °M Warmer System is substantially equivalent.

Detailed comparison between the predicate and the subject device is provided in the table below:

	°M Warmer System (Subject device)	**enFlow IV Fluid Warmer (K112902)**	**Comparison**
Indications for Use	The °M Warmer System is indicated for use to warm blood, blood products, colloids and crystalloid solutions prior to parenteral administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia. The field environment includes road, rotary and fixed-wing ambulances.	Indicated 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.	Difference: Similar. °M Warmer is more specific in the indication for use.
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 professional (i.e. paramedic, nurse doctor etc.)	Healthcare professional (i.e. paramedic, nurse doctor etc.)	Same

User Interface / Notifications	Visual (LED)	Visual (LED) and audio	Difference: The M warmer does not have an audible alarm or a configurable audible alarm. This difference does not raise a new question on safety and effectiveness.
Notification Types	Overheat Under heat Low battery	Overheat Under heat Low battery	Same
Alarm Sensor	Two redundant temperature sensors.	Two redundant temperature sensors.	Same
Alarm Condition / Alarm indicators	Visual (RED LED) instantaneous activated from 43 °C.	Visual (RED LED) and Audible alarm activated from 45 °C with 20 seconds delay and instantaneous activated at 50 °C.	Difference: The enFlow activates RED LED later at the higher temperatures and have audible alarm.
Usage Environment	Clinic and Field. The field environment includes road, rotary and fixed-wing ambulances.	Clinic and Field	Same
Components	- Disposable warmer with integrated fluid path - Power source (rechargeable battery pack) - Charger	- Warmer - Disposable fluid path cartridges - Power source (rechargeable battery pack or AC mains power)	Difference: enFlow has fluid path cartridges and AC mains power while the subject device has integrated fluid path.
Infusion temperature	39±3°C @ 150ml/min at 5°C input temperature	40±2°C @ 200ml/min at 20°C input temperature	Similar, within the physiological range

Flow Rate	Up to 150ml/min at 5°C input temperature	Up to 200 ml/min at 20°C input temperature	Similar, within the physiological range
Operation Environment	15 % RH to 95 % RH (relative humidity). Temperature range of 0°C to +40°C; non-condensing.	10 % RH to 90 % RH (relative humidity). Temperature range of −5°C to +50°C.	Similar, RH and Temperature ranges slightly different and °M Warmer indicate non-condensing.
Heating technology	Software-controlled resistive heating	Software-controlled resistive heating	Same
Fluid path	Sterile fluid path consisting of plastic tubing, silicone gasket and biocompatible parylene coated anodized aluminium.	Sterile fluid path consisting of plastic tubing and biocompatible coated aluminium.	Same
Warmer type	Inline	Inline	Same
Power Source	Rechargeable battery	Rechargeable battery and 110-120 or 220-240 VAC	Difference: In addition to rechargeable battery, enFlow has additional 110-120 or 220-240 VAC.
Biocompatibility	The fluid path is made of biocompatible parylene coated anodized aluminum.	The fluid path is made of biocompatible coated aluminum (natural) extrusion	Similar. Both devices are biocompatible.
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
Sterility	The disposable unit is provided sterile for single patient use.	The disposable unit is provided sterile for single patient use.	Same

Product specific Standard with which the Device Complies	ASTM 2172:2002, Standard specification for blood/ Intravenous Fluid Irrigation Fluid Warmers	ASTM 2172:2002, Standard specification for blood/ Intravenous Fluid Irrigation Fluid Warmers	Same

Performance data from non-clinical studies
The following non-clinical testing was conducted:

Sterilization and shelf-life validation were conducted in accordance with
- ISO 11137-1:2006/Amd.:1 2013, ASTM F1980-16
- FDA Shelf Life of Medical Devices guidance, issued April 1991

Software verification and validation was performed in accordance with
- IEC 62304:2006/A1:2015
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005

Electrical Safety and EMC testing was performed in accordance with
- IEC 60601-1:2005/A1:2012, IEC 60601-1-2:2014, IEC 60601-1-12:2014.

Aluminum leaching testing

Heater safety testing was performed in accordance with
- - ASTM F2172-02: 2011

Flow rate testing was performed in accordance with
- ISO 8536-4: 2019

Biocompatibility testing was performed in accordance with
- ISO 10993-1 Fifth edition 2018-08
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on September 4, 2020

Biological safety has been evaluated according to the ISO 10993-series in order to verify that the level of leaching substances and metals are below the specified limits for daily intake.

Clinical studies
The claim of substantial equivalence is not based on an assessment of clinical performance data.

Conclusion

The °M Warmer System has similar technological characteristics to the enFlow IV Fluid Warmer, and has the same intended use.The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The °M Warmer System is substantially equivalent to the enFlow IV Fluid Warmer cleared under K112902 with respect to the indications for use, target populations, treatment method, and technological characteristics.