April 24, 2026

MEQU A/S
Lene Margrete Moesby
Senior Regulatory Affairs Specialist
Fruebjergvej 3
2100 Ø
København Ø
Denmark

Re: K260988
Trade/Device Name: °M Warmer System with °M Station
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ, BSB
Dated: March 25, 2026
Received: March 25, 2026

Dear Lene Margrete Moesby:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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)*
K260988

Device Name
°M Warmer System with °M Station

Indications for Use *(Describe)*
The °M Warmer System with °M Station 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 pro-fessionals in hospital, clinical, and field environments to help prevent hypothermia.
The field environment includes road 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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K260988 510(k) Summary

Submitter:	MEQU A/S
Address:	Fruebjergvej 3 København Ø 2100 Denmark
Phone number:	+45 3110 5487
Contact person:	Mrs. Lene Margrete Moesby
Date prepared:	22 Apr 2026
Trade name:	°M Warmer System with °M Station
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:	°M Warmer System (K232107)

Purpose of 510(k)

The purpose of this 510(k) is to add the °M Station as an additional AC mains power source to the °M Warmer in the °M Warmer System.

Indications for use

The °M Warmer System with °M Station 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 ambulances.

Device Description

The °M Warmer System with °M Station consists of:

1. **°M Warmer** – A single-use, sterile, disposable in-line fluid warming unit
2. **°M Station** – A new multi-patient, reusable AC mains power supply providing continuous power to the °M Warmer during use.

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 aluminum 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.

The °M Station is a transportable accessory designed to be used as an AC mains power supply for the °M Warmer in hospital/clinic settings or in ground-based ambulances.

Substantial equivalence

The subject device °M Warmer System with °M Station is substantially equivalent to the cleared °M Warmer System. Both the cleared device and the °M Warmer System with °M Station is a portable IV fluid warming system.

The differences between the predicate and subject device do not raise any concerns regarding safety and effectiveness and equivalent performance have been demonstrated. Thus, °M Warmer System with M Station is substantially equivalent.

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

	°M Warmer System with °M Station (Subject device)	**°M Warmer System (K232107)**	**Comparison**
Indications for Use	The °M Warmer System with °M Station 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 ambulances.	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.	Difference: °M Warmer System with °M Station is more specific in the supported field environment in the indications 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)	Same
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) instantaneous activated from 43 °C.	Same
Usage Environment	Clinic and Field. The field environment includes road ambulances.	Clinic and Field. The field environment includes road, rotary and fixed-wing ambulances.	Difference: °M Warmer System with °M Station is more specific in the supported field environment.

	°M Warmer System with °M Station (Subject device)	°M Warmer System (K232107)	Comparison
Components	- Disposable warmer with integrated fluid path - Power source (AC mains)	- Disposable warmer with integrated fluid path - Power source (rechargeable battery pack) - Charger	Difference: The °M Warmer System with °M Station is operated with AC mains power supply.
Infusion temperature	39±3°C @ 150ml/min at 5°C input temperature	39±3°C @ 150ml/min at 5°C input temperature	Same
Flow Rate	Up to 150ml/min at 5°C input temperature	Up to 150ml/min at 5°C input temperature	Same
Operating Environment	15 % RH to 95 % RH (relative humidity). Temperature range of 0°C to +40°C; non-condensing.	15 % RH to 95 % RH (relative humidity). Temperature range of 0°C to +40°C; non-condensing.	Same
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 aluminum.	Sterile fluid path consisting of plastic tubing, silicone gasket and biocompatible parylene coated anodized aluminum.	Same
Warmer type	Inline	Inline	Same
Power Source	AC mains power supply	Rechargeable battery	Difference: AC mains power supply was added as an additional power source for the °M Warmer
Biocompatibility	The fluid path is made of biocompatible parylene coated anodized aluminum.	The fluid path is made of biocompatible parylene coated anodized aluminum.	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
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 to demonstrate substantial equivalence to the predicate device:

Bench testing
Electrical Safety and EMC testing was performed in accordance with

- IEC 60601-1 Edition 3.2 2020-08 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”
- IEC 60601-1-2 Edition 4.1 2020-09 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”
- IEC 60601-1-12 Edition 1.1 2020-07 “Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment”

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

Conclusion
The modifications to the °M Warmer System by adding a °M Station (AC mains power supply) do not raise different questions of safety and effectiveness and are supported by risk management activities. Based on the equivalence to the predicate device, and the results of the non-clinical performance data, MEQU A/S find that the °M Warmer System with °M Station is as safe, as effective, and performs as well as the predicate device cleared under K232107.