March 5, 2019

MAC Medical Inc.
Gary Oliveros
Director Quality Compliance
820 South Mulberry Street
Millstadt, Illinois 62260

Re: K180842
Trade/Device Name: MAC Medical D-Series Blanket and Solution Warming Cabinets
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: January 28, 2019
Received: January 29, 2019

Dear Gary Oliveros:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Sapana Patel -S

for 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)*
K180842

Device Name
MAC Medical D-Series Blanket and Solution Warming Cabinets

Indications for Use *(Describe)*
The MAC Medical D-Series Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids, and/ or injection fluids in accordance with the recommended warming temperatures and storage guidelines provided by the manufacturers of such products.

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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510 (k) Summary K180842
MAC Medical D-Series Blanket and Solution Warming Cabinets
Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name:	MAC Medical, Inc.
Address:	820 South Mulberry Street Millstadt, IL 62260
Contact Person:	Gary Oliveros MAC Medical Director of Quality Compliance Telephone Number: (618) 476-3550 ext. 318 Fax Number: (618) 476-3337 Email: goliveros@macmedical.com
510 (k) Number:	K180842
Date Prepared:	March 4, 2019
Device Trade Name:	MAC Medical D-Series Blanket and Solution Warming Cabinets
Common Name:	Blanket and Solution Warming Cabinet
Device Classification:	Class II
Regulation Number:	21 CFR § 880.5725
Classification Name:	Warmer, Thermal Infusion Fluid Product
Product Code:	LGZ
FDA Panel:	General Hospital
Predicate Device:	K993797 - Entheremics Medical Systems Fluid Warming Cabinets K112702 – Imperial Surgical Blanket and Solution Warming Cabinets

Device Description:

The MAC Medical D-Series Blanket and Solution Warming Cabinets are designed to store and warm sterile IV solutions, surgical irrigation solutions, linens and/ or blankets to an acceptable level for hospital and surgical outpatient center applications.

The MAC Medical D-Series Warming Cabinets are constructed with stainless steel panels, headers and doors. The Warming Cabinets are doubled walled constructed and are fully insulated to provide uniform heating. Optional glass doors are double paned tempered glass with aluminum.

A pull-out shelf inside the top of the cabinet contains the heating element, fan, thermostat, and temperature sensor. The electronics are located on the outside of the cabinet and the power cable is connected in the back of the cabinet. The wheeled baskets run on mounted rails and automatically stop when they reach the full out position. The shelves and baskets can be removed for cleaning and repositioning.

Intended Use/ Indications for Use:

The MAC Medical D-Series Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids, and/ or injection fluids in accordance with the recommended warming temperatures and storage guidelines provided by the manufacturers of such products.

Comparison of Technical Characteristics:

Technical Characteristics	MAC Medical D-Series Warming Cabinet – K180842	Enthermics Medical Systems Fluid Warming Cabinet -K993797	Imperial Surgical Blanket and Solution Warming Cabinet – K112702
Intended Use/ Indications for Use	The MAC Medical D-Series Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids, and/ or injection fluids in accordance with the recommended warming temperatures and storage guidelines provided by the manufacturers of such products.	The Enthermics Medical Systems Fluid Warming Cabinet is designed to safely store and warm irrigation, or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products.	The Imperial Surgical Blanket and Solution Warming Cabinet is designed to safely store and warm blankets, hospital lines, irrigation, and/ or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products.
Heating System	Convection electric heating with circulating fan.	Electrothermal heating array.	Convection electric heating with circulating fan.
User Interface	Digital Display	Digital Display	Digital Display
Software	Not applicable	Not applicable	Not Applicable
Construction	Stainless Steel interior and exterior	Stainless Steel interior and exterior	Stainless steel interior and exterior Counter top model made with baked on powder coated steel outer shell with Stainless Steel interior
Electrical Safety Testing	IEC 61010-1 IEC 61326	IEC 61010-1	IEC 61010-1 (CSAC22.2)
Over Temperature Alarm	Audible and visual if chamber temperature exceeds 5° C (10° F) above set temperature. Internal sensor shuts off heating elements when over	Audible and visual if chamber temperature exceeds 5° C (10° F) above set temperature and an over temperature indicator will blink indicating an over	Audible and visual if chamber temperature exceeds 6°C above set temperature. Internal sensor shuts off heating elements when over

Technical Characteristics	MAC Medical D-Series Warming Cabinet – K180842	Enthermics Medical Systems Fluid Warming Cabinet -K993797	Imperial Surgical Blanket and Solution Warming Cabinet – K112702
	temperature occurs	temperature condition.	temperature occurs
Temperature Range	Blankets = 90° F - 160° F Irrigation Fluids = 90° F - 149° F Injection Fluids = 90° F - 103° F	Blankets = 86° F - 160° F Irrigation Fluids = 86° F - 150° F Injection Fluids = 86° F - 104° F	Blankets = N/A Irrigation Fluids = 98° F - 150° F Injection Fluids = 98° F - 104° F
Temperature Lock	Settings are factory set and keyed locked. The cabinet can be unlocked with a key in the field and the user can revise the setting based on the specific need.	N/A	Settings are factory set. The cabinet can be unlocked in the field and the user can revise the setting based on the specific need.
Temperature accuracy	Upper Chamber – ± 1° F Middle Chamber – ± 1° F Lower Chamber – ± 1° F	+ 0/ - 2° F – For settings 98° F to 104° F + 0/ - 3° F – For settings 110° F to 150° F	+ 0/ - 2.7° F
Installation	Free Standing or Recessed	Free Standing (Mobile) or Recessed	Free Standing or Recessed
Controls	Electronic temperature controller with LED display. Element on the red neon indicator display.	Electronic control consists of 4 digit LED display, on/off keys, integrated lock feature and a series of prompt sequence indicators.	Electronic temperature controller with LED display. Illuminated power switch/ breaker (red). Amber neon indicator for element on red neon indicator for trouble.
Unit Configuration	Single/ Dual/ Triple	Single	Single/ Dual
Unit Depth	Inside Cavity 18" or 24" Overall 20.5" or 26.5"	34.9"	22" or 28" for table top and full-size cabinets. 1
Cabinet Volume	Triple compartment capacity – 14.01 cu ft overall Upper – 3.89 cu ft Middle – 3.73 cu ft Lower – 6.4 cu ft	Single compartment - 7.8 cu ft	Dual compartment capacity - 18.1 cu ft overall 4.3 cu ft upper 13.8 cu ft lower
Voltage Requirements	120 VAC 50/60 HZ or 240 VAC 50/60 HZ	120 VAC 50/60 HZ or 230 VAC 50/60 HZ	120 VAC 60 HZ
Expected Life	10 years	Not available	Not available

Risk Management:

Risk Management has been implemented for the MAC Medical D-Series Blanket and Solution Warming Cabinets and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices. The MAC Medical D-Series Blanket and Solution Warming Cabinets are as safe and effective as the predicate devices when used as intended.

Summary of Non-Clinical Bench Testing:

Non-Clinical bench testing was performed on the MAC Medical D-Series Warming Cabinet. The Non-Clinical Bench Testing included:

- Electrical Safety testing in accordance with IEC 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General requirements;
- Electrical-magnetic Compatibility Testing in accordance with IEC 61326, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements;
- Temperature Range Heating Specification Testing Empty Chamber Qualification;
- Temperature Range Heating Specification Testing Product in Chamber Qualification; and
- Over Temperature Alarm Testing.

Conclusion:

The Non-Clinical testing indicates the device performance is substantially equivalent to the predicate devices. MAC Medical has demonstrated through the non-clinical bench test results the MAC Medical D-Series Warming Cabinet is as safe and effective as the predicate devices. Non-Clinical Bench Testing indicates the Warming Cabinet functions throughout the expected life of the device. Furthermore, the non-clinical bench test results clearly establish objective evidence to substantiate compliance to the documented intended use/ indications for use of the device which states, *"The MAC Medical D-Series Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids, and/ or injection fluids in accordance with the recommended warming temperatures and storage guidelines provided by the manufacturers of such products".*