December 1, 2023

Medline Industries LP
Claire Pigman
Sr. Manager, Regulatory Affairs
3 Lakes Drive
Northfield, Illinois 60093

Re: K231211
Trade/Device Name: Medline ComfortTemp Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: October 31, 2023
Received: November 1, 2023

Dear Claire Pigman:

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,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231211

Device Name
Medline ComfortTemp Patient Warming System

Indications for Use *(Describe)*
The Medline ComfortTemp Patient Warming System is intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.

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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Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

K231211
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, LP
3 Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Submission Contact: Claire Pigman, Sr. Manager Regulatory Affairs
Email: cpigman@medline.com

Summary Preparation Date
December 1, 2023

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline ComfortTemp Patient Warming System
Common Name: Patient Warming System
Classification Name: Thermal Regulating System
Product Code: DWJ
Classification Panel: Cardiovascular
Regulatory Class: II
Regulation Number: 21 CFR 870.5900

Predicate Device
K210603, 3M Bair Hugger Model 675 Total Temperature Management System

Device Description
The Medline ComfortTemp Patient Warming System is intended to prevent and treat hypothermia. In addition, the patient warming system provides thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The patient warming system is for adult and pediatric patients. The Medline ComfortTemp Patient Warming System is used in acute care, post-acute care, operating room, and procedural rooms. The system consists of a reusable blower unit, a reusable hose, and single-patient

Medline Industries, LP
Three Lakes Drive
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use, disposable blankets. Replacement filters and hoses for the blower unit are additionally available as needed. All components of the ComfortTemp Patient Warming System are non-sterile. The blower unit connects to the single-patient use blanket through a reusable hose and provides forced warm air into the blanket using a PTC (positive temperature coefficient) heater, a fan/blower and a user-controlled interface. Depending on the model, the ComfortTemp blanket is placed either around, over, or underneath adult and/or pediatric patients. The blanket is comprised of two polypropylene and polyethylene layers, which allow the forced warm air to be dispersed over the patient's skin.

Indications for Use

The Medline ComfortTemp Patient Warming System in intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patients thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.

Summary of Technological Characteristics

Please refer to Table 1 for a side-by-side comparison of the subject device and the predicate device, the 3M Bair Hugger Model 675 Total Temperature Management System (K210603).

Table 1. Comparison of Subject and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline ComfortTemp Patient Warming System	3M Bair Hugger Model 675 Total Temperature Management System	N/A
510(k) Reference	K231211	K210603	N/A
Product Owner	Medline Industries, LP	3M Company	N/A
Product Code	DWJ	DWJ	Same
Regulation Number	21 CFR 870.5900	21 CFR 870.5900	Same
Intended Use	Intended to prevent and treat hypothermia. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients.	The Bair Hugger temperature management system is intended to prevent and treat hypothermia. In addition the temperature management system can be used to provide patient thermal comfort when continuations exist may cause patients to feel too warm or too cold. The temperature management system can be used with adult and pediatric patients	Same
Regulation Number	21 CFR 870.5900	21 CFR 870.5900	Same

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System Components	Reusable Blower unit Reusable Connecting hose Single Patient Use Blankets	Model 675 portable warming unit (with optional rolling cart) Warming blanket or warming gown. Connecting hose	Same
Blanket Design Configurations	Adult Full Body Blanket Adult Full Body, Multi-Access Blanket Adult Upper Body Blanket Adult Lower Body Blanket Adult Underbody Blanket Large Pediatric/Adult Underbody Blanket Pediatric Underbody Blanket Adult Large Underbody Blanket	Adult Full Body Blanket Adult Full Body, Multi-Access Blanket Adult Upper Body Blanket Adult Lower Body Blanket Adult Underbody Blanket Large Pediatric/Adult Underbody Blanket Pediatric Underbody Blanket Adult Large Underbody Blanket	Same
Materials	Polyethylene Polypropylene	SMS Polyethylene Polypropylene	Similar
Prescription vs. OTC	Rx Only	Rx Only	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use vs. Reusable	Single Patient Use Blankets Reusable Blower Unit and Hose	Single Patient Use Blankets Reusable Blower Unit and Hose	Same
Blower Input Rating	110-120 VAC, 50/60Hz	110-120 VAC, 50/60Hz	Same
Blower Motor Airflow	39.5 +/-2 CFM Non-adjustable, one speed	Up to 44 CFM Non-adjustable, one speed	Similar
Blower Heating Element	800W PTC	1190 W Resistive	Different
Blower Unit Filter	0.3 micron	MERV 14	Similar
Temperature Sensor Range	-55°C to +125°C	Not known	N/A
Temperature Accuracy	+/- 1.5ºC	+/- 3ºC	Similar – temperature accuracy rating on subject device blower is tighter
Blower Unit Temperature Settings	High: 43º C Medium: 38º C Low: 32º C Ambient Room Temperature	High: 43º C Medium: 38º C Low: 32º C Ambient Room Temperature	Same
Blower Unit Alarms	High Temperature Low Temperature Over Temperature	Over-Temperature Under-Temperature	Same – subject device includes an additional alarm
Blower Weight	12 lbs	10lbs	Similar

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Shelf Life and Sterilization

The Medline ComfortTemp Patient Warming System is non-sterile and is not labeled with an expiration date.

Summary of Testing and Supporting Information

Testing was conducted on the Medline ComfortTemp Patient Warming System to demonstrate its equivalence to the 3M Bair Hugger Model 675 Total Temperature Management System. A summary of testing is presented below.

Performance Testing (Bench)

Non-clinical verification of the Medline ComfortTemp Patient Warming System has been conducted to evaluate the performance and functionality of the subject device. To evaluate the ComfortTemp blower/warming unit and hose, the following testing was performed –

- Air Flow Testing
- Relative Noise Level
- Hose Connection Strength
- Thermocouple/Temperature Verification
- Weight Verification
- Drop Testing
- Functionality post Distribution Simulation
- Life Cycle Testing
- Simulated Wipe Testing

To evaluate the ComfortTemp blankets, the following testing was performed –

- Tensile Strength and Elongation per ASTM D5034 – 2021
- Tearing Strength per ASTM D5587 – 2015 (Reapproved 2019)
- Film Thickness per ASTM D6988-13
- Seal Strength per ASTM F88/F88M-21
- Basis Weight per ASTM D3776/D3776M-17
- Flammability per 16 CFR Part 1610-19
- Port Connection Strength
- Peel Adhesion per ASTM D3330 – 2004 (Reapproved 2018)
- Heat Mapping Testing
- Flow Rate Testing
- Radiopacity Testing
- Air Permeability Testing
- Visual Inspection post Distribution Simulation

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Usability Testing

Human factors/usability testing was conducted on the Medline ComfortTemp Patient Warming System in accordance with the FDA guidance document, *Applying Human Factors and Usability Engineering to Medical Devices*. The study was conducted in a simulated-use format in which intended users performed tasks necessary to use the ComfortTemp System as intended.

Cleaning Validation

The cleaning instructions for the reusable blower unit and hose were validated in accordance with ANSI/AAMI ST98-2022, *Cleaning Validation of Health Care Products – Requirements for Development and Validation of a Cleaning Process for Medical Devices.* The study utilized a simulated test soil to evaluate the effectiveness of the cleaning procedure based on protein residual analysis, hemoglobin residual analysis, and visual inspection.

Biocompatibility Testing

The biological evaluation for the Medline ComfortTemp Patient Warming System was conducted in accordance with FDA guidance document "*Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*" and ISO 10993-1 *Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process.* The ComfortTemp blankets are categorized as a surface-contacting device, on intact skin for a limited duration (≤ 24 hours). The blower unit and hose components are not intended to come in contact with the patient. The following biocompatibility tests were performed on a final, finished ComfortTemp blanket:

- Cytotoxicity in accordance with ISO 10993-5:2009 *Biological evaluation of medical devices – Part: 5 Tests for cytotoxicity*
- Skin Sensation in accordance with ISO 10993-10:2010 *Biological evaluation of medical devices – Part: 10 Tests for irritation and skin sensitization*
- Skin Irritation in accordance with ISO 10993-10:2010 *Biological evaluation of medical devices – Part: 10 Tests for irritation and skin sensitization*

Performance Testing (Animal)

This section does not apply. No animal testing was performed.

Performance Testing (Clinical)

This section does not apply. No clinical testing was performed.

Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Medline Industries, LP concludes that the Medline ComfortTemp Patient Warming System

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is substantially equivalence to the predicate device, 3M Bair Hugger Temperature Management System (K210603).