September 15, 2023

Molnlycke Health Care US, LLC
Megan Bevill
Regulatory Affairs Director, Americas and Antiseptics
5445 Triangle Parkway, Suite 400
Peachtree Corners, Georgia 30092

Re: K232508
Trade/Device Name: Barrier EasyWarm Active Self-Warming Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: August 16, 2023
Received: August 18, 2023

Dear Megan Bevill:

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/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 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 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,

Eric E. Richardson -S

for 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.

Submission Number *(if known)*

K232508

Device Name

Barrier EasyWarm Active Self-Warming Blanket

Indications for Use *(Describe)*

The Barrier EasyWarm Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.

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.

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510(k) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:	September 8, 2023
Applicant:	Mölnlycke Health Care US, LLC 5445 Triangle Parkway, Suite 400 Peachtree Corners, GA 30092 Registration number: 3004763499 Owner/Operator Number: 8030877
Official Correspondent:	Megan Bevill Regulatory Affairs Director, Americas and Antiseptics Tel: 770-547-9196 email: megan.bevill@molnlycke.com
Trade/Proprietary Names:	Barrier EasyWarm Active Self-Warming Blanket
Regulation Name:	Thermal regulating system
Device Class:	II
Regulation Number:	21 CFR 870.5900
Product Code:	DWJ
Predicate Device Name(s):	Barrier EasyWarm Active Self-Warming Blanket (K132048)

Reason for 510(k) Submission:
This premarket notification is being submitted to obtain clearance for minor design and labeling modifications to the Barrier EasyWarm Active Self-Warming Blanket, originally cleared for market under premarket notification K132048. Minor design and labeling modifications include the following:

- Introduction of a two-piece design to the assortment
- Changes to the warmers, resulting in a shift to a higher average temperature performance
- Upgrading of existing labeling statements to Contraindications
- Other minor labeling changes (e.g, administrative, formatting, and placement/presentation of information changes)

Description of Device:
The Barrier EasyWarm Active Self-Warming Blanket is a non-sterile, single use blanket that is intended to prevent hypothermia by providing warmth to the patient during the perioperative period. The blanket contains warming pads (or heating elements) that are contained within sealed pouches that are advantageously positioned and sewn into the blanket's fabric for appropriate distribution of heat. The warming pads contain iron, active coal, water, salt, clay with a sodium polyacrylate cover. The device is supplied in a vacuum sealed packaging. Once the blanket is removed from its packaging, the blanket produces heat via an exothermic chemical reaction that takes place within the warming pads upon exposure to air. The chemical reaction results from the oxidation of iron.

Intended Use/Indication for Use:
The Barrier EasyWarm Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.

Technological Characteristics:

Feature	Barrier EasyWarm Active Self-Warming Blanket	Barrier EasyWarm Active Self-Warming Blanket	Substantial Equivalence Comments
510(k) clearance	Subject of submission	K132048	NA
Rationale for inclusion	Subject of submission	Predicate device	NA
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care	NA
Regulation	21 CFR 870.5900	21 CFR 870.5900	Same regulation as predicate
Class name	Thermal regulating system	Thermal regulating system	Same classification as predicate
Class	II	II	Same classification as predicate
Product code	DWJ	DWJ	Same product code as predicate
Indication for use/Intended use	The Barrier EasyWarm Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.	The Barrier EasyWarm Active Self-Warming Blanket is intended to help prevent hypothermia by providing warmth to the patient during the perioperative period.	Same indications for use/intended use as predicate
Use environment	Healthcare facilities	Healthcare facilities	Same use environment as predicate
Presentation	One piece blanket (92 x 152 cm) with 12 warmers Two piece blanket (110/150 x 200 cm, assembled) with 12 warmers	One piece blanket (92 x 152 cm) with 12 warmers	The introduction of the new two-piece blanket style does not impact safety or effectiveness of the Barrier EasyWarm Self-Warming Blanket. The overall design, materials of construction, and warmer technology are the same. The two piece design allows the blanket to be separated for upper and lower body coverage in different surgical positions. The two pieces can be connected via a hook and loop closure.
Sterility	Non-sterile	Non-sterile	Same
Shelf Life	2 years	3 years	Based on real-time stability data available for the modified design
Materials of construction	Polypropylene blanket (blue for one-piece blanket, blue topside and white underside for two-piece blanket) Polyester sewing thread Polypropylene hem	Polypropylene blanket (blue) Polyester sewing thread Polypropylene hem	The materials of construction are the same for the subject and predicate devices, with the following exceptions:

	Polyamide hook and loop closure (two piece design only) Warmer containing activated charcoal, clay, iron, water, salt, and sodium polyacrylate	Warmer containing activated charcoal, clay, iron, water, salt, and sodium polyacrylate	• Use of white polypropylene on one side of two-piece blanket; the white polypropylene is identical to the blue polypropylene cleared under K132048 but with a white pigment instead of blue • Addition of polyamide hook and loop closure on the two-piece blanket Replacement of the color pigment in a portion of the blanket and addition of a hook and loop closure do not impact safety or effectiveness of the device.
Performance specification	Ave. skin temperature reached: 34-39°C Max skin temperature reached: 41°C Useful life: 10 hours	Ave. skin temperature reached: 35-36°C Max skin temperature reached: 40°C Useful life: 10 hours	The average temperature performance specification has been shifted higher while maintaining the same specification for maximum skin temperature reached. As the maximum skin temperature reached is still below the original limit of 42°C, there are no new issues of safety or effectiveness.

Performance Testing:
The subject devices were subjected to warmer/blanket performance testing (rise time, maintaining time, average temperature during 10 hours use, maximum temperature) to ensure performance according to specification.

In addition, the subject devices were subjected to thermal performance testing (skin temperature measurements via IR camera) in healthy human volunteers to demonstrate that the warming effect is safe and clinically effective.

Conclusion:
Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics as well as performance testing. The subject EasyWarm Active Self-Warming Blanket is at least as safe and effective, and performs at least as well as the predicate device, EasyWarm Active Self-Warming Blanket cleared under K132048.