September 17, 2024

Medline Industries, LP
Kelsey Closen
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093, USA

Re: K234132
Trade/Device Name: Medline Reusable Sterilization Wrappers
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 28, 2023
Received: December 28, 2023

Dear Kelsey Closen:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.09.17 11:49:46 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical
and Infection Control Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234132

Device Name
Medline Reusable Sterilization Wrappers

Indications for Use *(Describe)*
Medline Reusable Sterilization Wrappers are intended to be used to enclose another medical device or component that is to be sterilized by health care professionals. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Medline Reusable Sterilization Wrap is a non-sterile, reusable device, with a wash/dry/autoclave life cycle as indicated on the Wrap.

Medline Reusable Sterilization Wrappers are available in 3 different fabrics that are either single or double ply bonded sheets of cotton and polyester blends. Model Angelstat is reusable up to 50 times; Models Resistat and Ripstop are reusable up to 75 times . The Medline Reusable Sterilization Wrappers are available in Misty Green, Jade Green or Ceil Blue with configurations 12”x12” through 72”x72” and 60”x90”. The Medline Reusable Sterilization Wrappers are intended to be laundered then sterilized prior to use, and examined prior to use for defects and debris.

A prevacuum steam sterilization cycle at 270 F for 4 minutes has been validated for use on textile packs, with a minimum weight of 25 pounds and 30 minute dry time.

Medline recommends following the below standards for pack configuration and assembly in sterilization facilities.
• AAMI ANSI ST79
• AAMI ANSI ST65

Insert model and sizes

Item	Description	Color	Size	Pkg.
Resistat (1-ply)				
MDT01302012	ResiStat Reusable Sterilization Wrap	Ceil Blue	12" x 12"	5 dz/cs
MDT01302018	ResiStat Reusable Sterilization Wrap	Ceil Blue	18” x 18”	5 dz/cs
MDT01302024	ResiStat Reusable Sterilization Wrap	Ceil Blue	24” x 24”	5 dz/cs
MDT01302030	ResiStat Reusable Sterilization Wrap	Ceil Blue	30” x 30”	5 dz/cs
MDT01302036	ResiStat Reusable Sterilization Wrap	Ceil Blue	36” x 36”	5 dz/cs
MDT01302045	ResiStat Reusable Sterilization Wrap	Ceil Blue	45" x 45"	2 dz/cs
MDT01302054	ResiStat Reusable Sterilization Wrap	Ceil Blue	54" x 54"	1 dz/cs
MDT013020547	ResiStat Reusable Sterilization Wrap	Ceil Blue	54" x 72"	2 dz/cs
Rip-stop (1-ply)				
MDT01302124	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	24" x 24"	5 dz/cs
MDT01302130	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	30" x 30"	5 dz/cs
MDT01302136	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	36" x 36"	5 dz/cs
MDT01302145	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	45" x 45"	2 dz/cs
MDT01302154	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	54" x 54"	1 dz/cs
MDT013021607	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	60" x 76"	1 dz/cs
MDT013021609	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	60" x 90"	1 dz/cs
Angelstat Bias (2-ply)				
MDT01320018	Astat Bias Bound Reusable Sterilization Wrap	Ceil Blue	18" x 18"	5 dz/cs
MDT01320024	Astat Bias Bound Reusable Sterilization Wrap	Ceil Blue	24" x 24"	5 dz/cs
MDT01320030	Astat Bias Bound Reusable Sterilization Wrap	Ceil Blue	30" x 30"	5 dz/cs
MDT01320036	Astat Bias Bound Reusable Sterilization Wrap	Ceil Blue	36" x 36"	5 dz/cs

MDT01320045 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 45" x 45" 2 dz/cs
MDT01320045N Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 45" x 45" 2 dz/cs
MDT01320054 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 54" x 54" 1 dz/cs
MDT013200547 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 54" x 72" 1 dz/cs
MDT01320072 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 70" x 72" 1 dz/cs
MDT01320512 Astat Bias Bound Reusable Sterilization Wrap Jade Green 12" x 12" 5 dz/cs
MDT01320518 Astat Bias Bound Reusable Sterilization Wrap Jade Green 18" x 18" 5 dz/cs
MDT01320524 Astat Bias Bound Reusable Sterilization Wrap Jade Green 24" x 24" 5 dz/cs
MDT01320527 Astat Bias Bound Reusable Sterilization Wrap Jade Green 27" x 27" 5 dz/cs
MDT01320530 Astat Bias Bound Reusable Sterilization Wrap Jade Green 30" x 30" 5 dz/cs
MDT01320536 Astat Bias Bound Reusable Sterilization Wrap Jade Green 36" x 36" 5 dz/cs
MDT01320545 Astat Bias Bound Reusable Sterilization Wrap Jade Green 45" x 45" 2 dz/cs
MDT01320554 Astat Bias Bound Reusable Sterilization Wrap Jade Green 54" x 54" 1 dz/cs
MDT013205547 Astat Bias Bound Reusable Sterilization Wrap Jade Green 54" x 72" 1 dz/cs
MDT01321018 Astat Bias Bound Reusable Sterilization Wrap Misty 18" x 18" 5 dz/cs
MDT01321030 Astat Bias Bound Reusable Sterilization Wrap Misty 30" x 30" 5 dz/cs
MDT01321036 Astat Bias Bound Reusable Sterilization Wrap Misty 36" x 36" 5 dz/cs
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MDT01321072 Astat Bias Bound Reusable Sterilization Wrap Misty 70" x 72" 1 dz/c

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

510(k) SUMMARY – K234132
[AS REQUIRED BY 21CFR807.92(c)]

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

Registration Number: 1417592

Contact Person
Contact Person: Kelsey Closen, Regulatory Affairs Specialist
Phone: 847-949-2283
Email: KClosen@medline.com

Summary Preparation Date
August 05, 2024

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Reusable Sterilization Wrappers
Common Name: Sterilization Wrapper
Classification Name: Wrap, Sterilization
Product Code: FRG
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 880.6850

Predicate Device
Standard Supreme Sterilization Wrapper
K172207

Device Description
The Medline Reusable Sterilization Wrappers are offered in bulk, non-sterile packaging. The Medline Reusable Sterilization Wrappers are available in 3 different fabrics that are either single or double ply bonded sheets of cotton and polyester blends. The Medline Reusable Sterilization Wrappers are available in Misty Green, Jade Green or Ceil Blue with configurations 12”x12” through 72”x72” and 60”x90”. The Medline Reusable Sterilization Wrappers are intended to be sterilized and laundered per the instructions.

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Indications for Use

Medline Reusable Sterilization Wrappers are intended to be used to enclose another medical device or component that is to be sterilized by health care professionals. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Medline Reusable Sterilization Wrap is a non-sterile, reusable device, with a wash/dry/autoclave life cycle as indicated on the Wrap.

Medline Reusable Sterilization Wrappers are available in 3 different fabrics that are either single or double ply bonded sheets of cotton and polyester blends. Model Angelstat is reusable up to 50 times; Models Resistat and Ripstop are reusable up to 75 times . The Medline Reusable Sterilization Wrappers are available in Misty Green, Jade Green or Ceil Blue with configurations 12”x12” through 72”x72” and 60”x90”. The Medline Reusable Sterilization Wrappers are intended to be laundered then sterilized prior to use, and examined prior to use for defects and debris. A prevacuum steam sterilization cycle at 270 F for 4 minutes has been validated for use on textile packs, with a minimum weight of 25 pounds and 30 minute dry time.

Medline recommends following the below standards for pack configuration and assembly in sterilization facilities.
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Insert model and sizes

Item	Description	Color	Size	Pkg.
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MDT01302018	ResiStat Reusable Sterilization Wrap	Ceil Blue	18” x 18”	5 dz/cs
MDT01302024	ResiStat Reusable Sterilization Wrap	Ceil Blue	24” x 24”	5 dz/cs
MDT01302030	ResiStat Reusable Sterilization Wrap	Ceil Blue	30” x 30”	5 dz/cs
MDT01302036	ResiStat Reusable Sterilization Wrap	Ceil Blue	36” x 36”	5 dz/cs
MDT01302045	ResiStat Reusable Sterilization Wrap	Ceil Blue	45" x 45"	2 dz/cs
MDT01302054	ResiStat Reusable Sterilization Wrap	Ceil Blue	54" x 54"	1 dz/cs
MDT013020547	ResiStat Reusable Sterilization Wrap	Ceil Blue	54" x 72"	2 dz/cs
Rip-stop (1-ply)				
MDT01302124	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	24" x 24"	5 dz/cs
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MDT013021609	Rip-Stop Reusable Sterilization Wrap	Ceil Blue	60" x 90"	1 dz/cs

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Angelstat Bias (2-ply)
MDT01320018 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 18" x 18" 5 dz/cs
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MDT01320030 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 30" x 30" 5 dz/cs
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MDT013200547 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 54" x 72" 1 dz/cs
MDT01320072 Astat Bias Bound Reusable Sterilization Wrap Ceil Blue 70" x 72" 1 dz/cs
MDT01320512 Astat Bias Bound Reusable Sterilization Wrap Jade Green 12" x 12" 5 dz/cs
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MDT013210547 Astat Bias Bound Reusable Sterilization Wrap Misty 54" x 72" 1 dz/cs
MDT01321072 Astat Bias Bound Reusable Sterilization Wrap Misty 70" x 72" 1 dz/cs

Summary of Technological Characteristics

TABLE 1: COMPARISON OF SUBJECT AND PREDICATE DEVICES

Device Characteristic	Subject Device	Predicate Device	Comparison Analysis
Product Name	Medline Reusable Sterilization Wrappers	Standard Supreme Sterilization Wrapper	N/A
510(k) Reference	K234132	K172207	N/A
Product Owner	Medline Industries, LP	Standard Textile Co., Inc.	N/A
Product Code	FRG	FRG	Same
Intended Use	Medline Reusable Sterilization Wrappers are intended to be used to enclose another medical	Standard Supreme Sterilization Wrappers are intended to be used to enclose another medical device that is to be sterilized by	Same

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	device or component that is to be sterilized by health care professionals. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Medline Reusable Sterilization Wrap is a non-sterile, reusable device, with a wash/dry/autoclave life cycle as indicated on the Wrap.	a health care provider. They are intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. Standard Supreme Sterilization Wrappers will function as a sterilization wrap when processed according to instructions. Standard Supreme Sterilization Wrappers are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile sterilization wraps that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies	
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Color Options	3 colors Misty, Ceil and Jade	3 colors Misty, Ceil and Jade	Same
Design Configurations	- Sizes 12”x12” through 72”x72” and 60”x90” - 3 Colors: Misty, Jade and Ceil Blue - 3 fabric options: Cotton and polyester blends	- Sizes 12x12 – 70x70 - 3 Colors: Misty, Jade and Ceil Blue - 1 fabric option: cotton and polyester blend	Similar – *Medline offers a larger size and different fabrics these additional sizes and fabrics do not create any risk or concerns based on performance and biocompatibility testing*
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Same
Sterilization	Steam	Steam	Same
Disposable vs. Reusable	Reusable	Reusable	Same
Use Life	Ripstop and Resistat are 75 wash, dry, autoclave	75 wash, dry, autoclave	Similar- Medline Angelstat is different than the proposed device for

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	Angelstate is 50 wash, dry, autoclave		use life but this differences does not create any risk or concerns based on performance testing

Summary of Non-Clinical Testing

Test Performed	Test Method	Acceptance Criteria	Result
Resistance to Water Penetration	AATCC 127-2018	Test and Report - Average hydrostatic pressure	Pass
Tensile Strength and Elongation	ASTM D5034-21	Test and Report – Average load at break and elongation at break for machine and cross direction	Pass
Particle Generation	ISO 9073-10:2004	Test and Report – Average lint counts of particles and coeffect of linting	Pass
Cytotoxicity	ISO 10993-5	Non-Cytotoxicity - device did not show cytotoxicity potential	Pass
Sensitization	ISO 10993-10	Non-sensitizing - device showed no significant evidence of causing delayed dermal contact sensitization	Pass
Irritation	ISO 10993-10	Non-irritating – the irritation response category of the device was classified as Negligible	Pass
Acute Systemic Toxicity	ISO 10993-11	Non-systemic toxicity – device did not show systemic toxicity potential	Pass
Sterilization Validation	ST79:2017	All biological indicators shall be negative, positive controls shall be positive, chemical integrators shall demonstrate adequate steam penetration, negative	Pass

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		and environmental controls shall be negative	
Dry Time Validation	ST79:2017	Average pre and post sterilization wrought difference of less than 0.2% within 5 minutes of cycle completion, no visible moisture following 30 minute colling period and all integrators shall demonstrate steam penetration	Pass
Cleaning Validation	AAMI TIR30:2011	Each test sample shall show a TOC level of less than 12µg/cm2 and no visible soil after cleaning	Pass

Biocompatibility Testing

The biological evaluation for the Medline Reusable Sterilization Wrappers 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*."

Performance Testing (Bench)

The following performance testing was conducted on the Medline Reusable Sterilization Wrappers:

- ASTM D5034: Tensile Strength
- ISO 9073-10: Linting
- AATCC 127: Water Resistance (Rip-stop/Resistat only based on claim)

Other Testing

- Sterilization Validation
- Dry Time Validation
- Cleaning Validation

Conclusion

In accordance with 21 CFR Part 807, the conclusions drawn from the non-clinical tests in this premarket notification demonstrates that the Medline Reusable Sterilization Wrappers are as safe and as effective,

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and perform as well as or better then the legally marketed predicate device, Standard Supreme Sterilization Wrappers (K172207).