February 26, 2025

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

Re: K242844
Trade/Device Name: Medline Level 4 Surgical Gown with Breathable Sleeves
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 22, 2025
Received: January 22, 2025

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.

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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
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

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)*
K242844

Device Name
Medline Level 4 Surgical Gown with Breathable Sleeves

Indications for Use *(Describe)*
The Medline Level 4 Surgical Gown with Breathable Sleeves is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 4 Surgical Gown with Breathable Sleeves meets the Level 4 requirements of ANSI/AAMIPB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

The Medline Level 4 Surgical Gown with Breathable Sleeves is also sold in a non-sterile version to re-packagers/kitting entities, to be sterilized using the validated ethylene oxide sterilization method according to ISO 11135-1 in its final finished form, as a kit component.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

[AS REQUIRED BY 21CFR807.92]

Submitter / 510(k) Sponsor

Medline Industries, Inc. Three
Lakes Drive Northfield, IL
60093
Registration Number: 1417592

Submission Contact

Kelsey Closen
Regulatory Affairs Specialist
Phone: 847-949-2283
Email: kclosen@medline.com

Summary Preparation Date

February 26, 2025

Type of 510(k) Submission

Traditional

Device Name / Classification

Regulation Name:	Surgical Apparel
Classification Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4040
Common Name:	Surgical Gown
Classification Name:	Surgical Gown
Trade Name:	Medline Level 4 Surgical Gown with Breathable Sleeves
Product Code:	FYA
Classification Panel:	II

Predicate Device

PREDICATE DEVICE:

- Medline Level 4 Surgical Gown, K182172

REFERENCE DEVICVE:

- Medline Orbis Surgical Gown, K202447

Device Description

The Medline Level 4 Surgical Gown with Breathable Sleeves is a single-use, sterile, disposable medical device that is provided in a variety of sizes (Large, X-Large, 2X-Large, 3X-Large and X-Long (only Sirus)) and styles (Sirus, Aurora and Eclipse). The Medline Level 4 Surgical Gown with Breathable Sleeves is constructed from nonwoven SMS (spunbond, meltblown, spunbond), a poly-fabric reinforcement on the chest front panel, and a breathable film (Polyester ether and polyester) for the sleeves. Each gown is designed with a hook and loop closure at the neck, ties at the waist, knitted cuffs at the end of the sleeves as well as a transfer tab for ease in donning. The Medline Level 4 Surgical Gown with Breathable Sleeves has been tested according to ANSI/AAMI PB70:2022 and meets AAMI Level 4 barrier level protection for a surgical gown.

Indication for Use

The Medline Level 4 Surgical Gown with Breathable Sleeves is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 4 Surgical Gown with Breathable Sleeves meets the Level 4 requirements of ANSI/AAMIPB70:2022 *Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities*.

The Medline Level 4 Surgical Gown with Breathable Sleeves is also sold in a non-sterile version to re-packagers/kitting entities, to be sterilized using the validated ethylene oxide sterilization method according to ISO 11135-1 in its final finished form, as a kit component.

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Level 4 Surgical Gown with Breathable Sleeves	Medline Level 4 Surgical Gown	N/A
510(k) Reference	K242844	K182172	N/A
Product Owner	Medline Industries, LP.	Medline Industries, LP.	Same
Product Code	FYA	FYA	Same
Intended Use	The Medline Level 4 Surgical Gown with Breathable Sleeves is a single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 4 Surgical Gown w/ Breathable Sleeves meets the Level 4 requirements of	The Medline Level 4 Surgical Gown is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 4 Surgical Gown meets the Level 4 requirements of ANSI/AAMI	Similar – *the proposed device also includes how the gowns are to be used when bulk non-sterile. Predicate is only offered as sterile device.*

	ANSI/AAMIPB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities. The Medline Level 4 Surgical Gown with Breathable Sleeves is also sold in a non-sterile version to re-packagers/kitting entities, to be sterilized using the validated ethylene oxide sterilization method according to ISO 11135-1 in its final finished form, as a kit component.	PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Gown Color	Blue	Blue	Same
Design Features	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Reinforced Material Set-in/Standard Sleeves	Hoop & Neck Closures Tie Waist Closure Cuffs Film Reinforcement Sleeves	Similar – *The proposed has some design features that differ slightly from the predicate but have the same functions*
Design Configurations	3 Styles: Sirus, Eclipse, and Aurora Large, X-Large, 2X-Large, 3X-Large and X-Long (only Sirus)	3 Styles: Sirus, Eclipse, and Aurora Large, X-Large, 2X-Large, 3X-Large (only Sirus) and X-Long	Similar- *The proposed device will have size 3X-Large available in the 3 sizes and size X-Long will only be available in Sirus*
Material Composition	Nonwoven SMS polypropylene Anti-Static, Repellency Poly-Reinforcement Film Breathable film (Polyester ether and polyester) White Knitted Cuffs	Nonwoven SMS polypropylene Anti-Static, Repellency Film Reinforcement Cuffs	Similar- *The proposed device will have a poly-reinforcement film and a polyester ether and polyester breathable film.*
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Surface, Intact, $\leq$ 24 hours	Surface, Intact, $\leq$ 24 hours	Same
Sterile vs. Non-Sterile	Sterile, Non-Sterile	Sterile	Similar -*the proposed device will also be available as bulk non-sterile*
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single	Single	Same

Performance Specifications:	Level 4 barrier protection Breathability	Level 4 barrier protection	Similar - *Refer to K202447 for breathability claim*
Biocompatibility	Meets requirements per: ISO 10993-5 Cytotoxicity ISO 10993-23 Irritation ISO 10993-10 Sensitization	Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating, and non-sensitizing per ISO 10993-5 & ISO 10993-10	Same
Flammability	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Meets requirements of Flame Resistant CPSC 16 CFR 1610 Class 1	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same

Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The subject surgical gown was assessed for performance using the following standards and test methods. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoints.

Standard	Standard Title	Acceptance Criteria	Results
ISO 10993-5 Cytotoxicity	ISO MEM Elution Using L-929 Mouse Fibroblast Cells	Non-cytotoxic	Pass- Non-cytotoxic
ISO 10993-23 Irritation	ISO Intracutaneous Irritation Test	Non-irritating	Pass- Non-irritating
ISO 10993-10 Sensitization	ISO Guinea Pig Maximization Sensitization Test	Non-sensitizing	Pass- Non-sensitizing
ASTM F1671	Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens	4.0 AQL	Pass
AATCC 42	Water Resistance: Impact Penetration Test	≤4.5 g	Pass
AATCC 127	Water Resistance: Hydrostatic Pressure Test	≥50 cmH20	Pass
ASTM D5034-09 (2013)	Breaking Strength and Elongation of Textile Fabrics (Grab Test)	≥20 N	Pass
ASTM D5587-15	Tearing Strength of Fabrics by Trapezoid Procedure	≥20 N	Pass
ASTM D1683	Standard Method for Failure in Sewn Seams of Woven Apparel Fabrics	≥20 N	Pass
16 CFR 1610	Flammability of Clothing Textiles	Meets Class 1 Requirements	Pass
ASTM E96	Water Vapor Transmission of Materials	Reinforced Outside Material >800 g/m²/24 hrs	Pass

		Sleeve Material >1200 g/m²/24 hrs	Pass
ANSI/AAMI PB70:2022	Liquid Barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	Meets ANSI/AAMI PB 70:2012 Level 3 and Level 4 Liquid Barrier requirements	Pass

Summary of Clinical Testing

Not applicable.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Medline Level 4 Surgical Gown with Breathable Sleeves is as safe and as effective and perform as well as or better than the legally marketed predicate device, the Medline Level 4 Surgical Gown, K182172.