March 5, 2024

Medline Industries, LP
Kelsey Closen
Official Correspondent
1 Three Lakes Drive
Northfield, Illinois 60093

Re: K233526/S001
Trade/Device Name: Medline Open-Back Level 3 Protective Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QPC
Dated: January 18, 2024
Received: February 1, 2024

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,

Bifeng Qian -S

Bifeng Qian, MD, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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)*
K233526

Device Name
Medline Open-Back Level 3 Protective Gown

Indications for Use *(Describe)*
Gown is a single use, disposable, non-sterile, non-isolation gown intended to be worn by healthcare personnel to provide moderate barrier protection (AAMI Level 3) in non-sterile and non-patient isolation situations.

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 (K233526)

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person

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

Summary Preparation Date

March 1, 2024

Type of 510(k) Submission

Traditional

Device Name / Classification

Trade Name: Medline Open-Back Level 3 Protective Gown
Common Name: Gown, Non-Sterile, Non-Isolation, Intended To Provide Moderate Barrier Protection
Classification Name: Gown, Non-Sterile, Non-Isolation, Intended To Provide Moderate Barrier Protection
Product Code: QPC
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 878.4040

Predicate Device

ProTEC-USA EZDoff Gown cleared in K210405.

Device Description

The Medline Open-Back Level 3 Protective Gown is a single use, disposable, non-sterile, non-isolation gown intended to be worn by healthcare personnel to provide moderate barrier protection (AAMI Level 3) in non-sterile and non-patient isolation situation. The Medline Open-Back Level 3 Protective Gown meets the level 3 barrier protection requirements in accordance with ANSI/AAMI Standard PB70:2012 "*Liquid Barrier Performance and Classification of Protective Apparel and Drapes intended for use in Health Care Facilities".*

The Medline Open-Back Level 3 Protective Gown is a blue polyethylene gown available in 3 configurations: regular/large, universal and XL. The gown has an open back with a tie for securement and thumb loops on the cuffs.

Indications for Use

Gown is a single use, disposable, non-sterile, non-isolation gown intended to be worn by healthcare personnel to provide moderate barrier protection (AAMI Level 3) in non-sterile and non-patient isolation situations.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Open-Back Level 3 Protective Gown	ProTEC-USA EZDoff Gown	N/A
510(k) Reference	K233526	K210405	N/A
Product Owner	Medline Industries, LP	Cadillac Products, Inc.	N/A
Product Code	QPC	QPC	Same
Regulation Number	878.4040	878.4040	Same
Intended Use	Gown is a single use, disposable, non-sterile, non-isolation gown intended to be worn by healthcare personnel to provide moderate barrier protection (AAMI Level 3) in non-sterile and non-patient isolation situations.	ProTEC-USA EZDoff Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The ProTEC-USA EZDoff Gown is a single use, disposable gown provided non-sterile. The back of the gown is open and non-protective. The gown is not intended for use in the operating room.	Same – *Medline's intended use mimics the product codes definition.*
Design Features	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Same
Design Configurations	Large/Regular, Universal, XL	Universal Size	Similar – *The difference in sizing does not impact the safety or effectiveness of the device. Performance testing supports the difference.*
Color	Blue	Blue	Same
Materials	Polyethylene	Polyethylene	Same
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
PB70 AAMI Level	Level 3	Level 3	Same
Flammability 16 CFR 1610	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Same
Liquid Barrier/ PB70	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for an isolation gown	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for an isolation gown	Same
Biocompatibility	Pass Cytotoxicity ISO 10993-5, Sensitization, and Irritation ISO 10993-10	Pass Cytotoxicity ISO 10993-5, Sensitization, and Irritation ISO 10993-10	Same
Tearing Strength/Resistance (ASTM D5587)	15.98±0.68N (Machine Direction) 9.41±0.46 (Transverse Direction)	8N (Machine Direction) 22N (Transverse Direction)	Same
Tensile Strength (ASTM D5034)	41.74±2.74N (Machine Direction) 30.29±3.52N (Transverse Direction)	52N (Machine Direction) 41N (Transverse Direction)	Same
Seam Strength (ASTM D1683)	35.01±3.91 N 7.87±0.88 lb.	Not Reported	Different- *predicate did not report seams strength testing*
Lint (ISO 9073-10)	Not reported, not used in OR	Log10<4	Different - *Not intended to be*

			used in the operating room. Therefore, the linting properties of the material are not a concern to the user or patient. The material and nature of manufacturing of material for this product has eliminated the risk of linting.

Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for the proposed device was conducted in accordance with ANSI/AAMI/ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA.

The following tests were performed to evaluate the biocompatibility of the proposed device:

- Cytotoxicity in accordance with ISO 10993-5:2009 *Biological Evaluation of Medical Devices-Part 5: Tests for in vitro Cytotoxicity*
- Sensitization in accordance with ISO 10993-10:2021 *Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization*
- Irritation in accordance with ISO 10993-10:2021 *Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization*

Performance Testing (Bench)

Non-clinical verification of the Medline Open-Back Level 3 Protective Gown has been conducted to evaluate the safety, performance, and functionality of the proposed device.
The following performance testing was conducted:

- AATCC 127: 2018 Water Resistance: Hydrostatic Pressure Test
- AATCC 42: 2017 Water Resistance: Impact Penetration
- ASTM D5587-15 (2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM D1683/D1683M-17:2017/(R)2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM D3776/D3776M-20 Test Methods for Mass Per Unit Area (Weight) of Woven Fabric
- ASTM D5034-21 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D882:2018 Tensile Properties of Thin Plastic Sheeting
- ASTM D1004-2021 Tear Resistance (Graves Tear) of Plastic Film and Sheeting
- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles

Testing Conducted	Purpose of test	Test Method	Standard	Test Criteria	Test Results
Biocompatibility					
Cytotoxicity	Biocompatibility -Test performed in accordance with ISO 10993-5:2009	L929 MEM Elution Test	ISO 10993-5:2009	Test scores <3 will be considered to be non-cytotoxic. Test scores of '3 or 4' will be considered cytotoxic. The negative control should display no cytotoxicity reaction and the positive control should score 3 or 4	Pass
Sensitization	Biocompatibility – Test Performed in accordance with ISO 10993-10:2010	Repeated Patch Dermal Sensitization Test	ISO 10993-10:2021	The test article must score a '1' or'0' to indicate no sensitization result, provided that the negative control scores <1. The positive control results should score at least a score of '1'	Pass
Irritation	Biocompatibility - Test performed in accordance with ISO10993-10:2010.	Primary Skin Irritation Test	ISO 10993-10:2021	The Primary Irritation Index (PII) of the test article must be < 0.5 in order to not exhibit any irritation. The positive control must also exhibit an irritation response (PII >0.4).	Pass
Performance Testing					
Tearing Strength/Resistance (ASTM D5587)	Performance testing – test performed in accordance with ASTM D5587	Average tear strength in both machine and cross machine direction	ASTM D5587	The average tear strength in both Machine and Cross- Machine Directions was assessed per ASTM F2407 – 2020.	Pass
Tensile Strength (ASTM D5034)	Performance testing – test performed in accordance with ASTM D5034	Average tensile strength in both machine and cross machine direction	ASMT D5034	The average tensile strength in both Machine and Cross-Machine Directions was assessed per ASTM F2407 – 2020.	Pass
Seam Strength (ASTM D1683)	Performance testing – test performed in accordance with ASTM D1683	Average seam strength	ASTM D1683	The average seam strength values were assessed per ASTM F2407 – 2020	Pass
Hydrostatic Pressure Test	Performance Testing in Accordance with AATCC 127: 2018	Chest area and sleeve seam were assessed per AMMI PB70 Level 3	AATCC 127	≥50cm	Pass

Impact Penetration	Performance testing in accordance with AATCC 42: 2017	Chest area and sleeve seam were assessed per AMMI PB70 Level 3	AATCC 42	≤1.0g	Pass

Mass Per Unit Area (Weight) of Woven Fabric	Performance Testing in accordance with ASTM D3776/D3776M-20	Mass per unit weight	ASTM D3776/D3776 M	Basis Weight per ASTM D3776/D3776M	Lot 1: 27.67 ± 0.58/ Lot 2: 28.00 ± 3.46 Lot 3: 30.67 ± 0.58
Tensile Properties of Thin Plastic Sheeting	Performance testing in accordance with ASTM D882:2018	Tensile Properties of plastic	ASTM D882	Determination of tensile properties of plastics in the form of thin sheeting and films (less than 1.0 mm (0.04 in.) in thickness).	**Average Machine data for 3 Lots** Load at Break (N) 12.79±1.21 Tensile Strength (Mpa) 16.64±3.40 % Elongation at Break 410.76±50.67 **Average Cross data for 3 Lots** Load at Break (N) 10.19±1.03 Tensile Strength (Mpa) 11.43±3.95 %Elongation at Break 522.42±58.80
Tear Resistance (Graves Tear) of Plastic Film and Sheeting	ASTM D1004-21	Tear resistance of plastic with machine	ASTM D1004	Determination of the tear resistance of flexible plastic film and sheeting at very low rates of loading, 51 mm (2 in.)/min	**Average Machine data for 3 Lots** Maximum Load (N) 2.93±0.34 Extension at Break (mm) 19.84±3.57 **Average Cross data for 3 Lots** Maximum Load (N) 3.23±0.20 Extension at Break (mm) 22.50±1.41
Flammability of Clothing Textiles	16 CFR Part 1610	Flammability of gown material	16 CFR Part 1610	Average burn time ≥ 3.5s Class 1 "normal Flammability" in accordance to 16 CFR Part 1610	Pass

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807 and based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Open-Back Level 3 Protective Gown are as safe, as effective and performs as well as or better than the legally marketed predicate device ProTEC-USA EZDoff Gown cleared in K210405.