Medline Industries, Inc.
Pauline Maralit
Regulatory Affairs Specialist
3 Lakes Drive
Northfield, Illinois 60093

Re: K172954
Trade/Device Name: Medline Prevention CoolZone Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 4, 2018
Received: June 6, 2018

Dear Pauline Maralit:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172954

Device Name
Medline Prevention CoolZone Gown

Indications for Use *(Describe)*

The Medline Prevention CoolZone 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 Prevention CoolZone Gown meets the Level 4 requirements of ANSI/AAMI PB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*.

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."

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

510(k) SUMMARY : K172954

[AS REQUIRED BY 21 CFR 807.92]

Submitter / 510(k) Sponsor

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

Contact Person

Pauline Maralit
Regulatory Affairs Specialist
Phone: 847-949-2283
Email: Pmaralit@medline.com

Summary Preparation Date

June 14, 2018

Type of 510(k) Submission for K172954

Traditional 510(k) Premarket Submission

Device Name / Classification

Name of Device:	Gown, Surgical
Proprietary Name:	Medline Prevention CoolZone Gown
Common Name:	Surgical Gown
Classification Name:	Surgical Apparel
Product Code:	FYA
Classification Panel:	General & Plastic Surgery
Regulatory Class:	II
Regulatory Class:	21 CFR 878.4040

Predicate Device

PREDICATE DEVICE NAME: Kimberly-Clark *MicroCool* Surgical Gown
PREDICATE DEVICE K NUMBER: K091357

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Device Description

The Medline Prevention CoolZone Gown is manufactured from a breathable, non-woven, polypropylene fabric, with an SMS material at the back. The fabric is a three-layer lamination resistant to liquid penetration. The film layer is a multi-layer polypropylene olefin, breathable film. The Medline Prevention CoolZone Gown has been tested according to AAMI PB70:2012 and meets Level 4 requirements of the AAMI Liquid Barrier classifications for a surgical gown.

The sterilized version of the device is a folded gown packaged with one hand towel wrapped inside the CSR wrap and placed inside a peel pouch. The Medline Prevention CoolZone Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.

TABLE 1: DEVICE MODELS

Item Number	Device Description	Version	Size
DYNJP2901T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	Large, X-Long
DYNJP2902T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	X-Large, X-Long
DYNJP2903T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	XX-Large, X-Long
DYNJP2906T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	Large
DYNJP2907T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	X-Large
DYNJP2908T	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Sterile	XX-Large
SPT-2901TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	Large, X-Long
SPT-2902TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	X-Large, X-Long
SPT-2903TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	XX-Large, X-Long
SPT-2906TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	Large
SPT-2907TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	X-Large
SPT-2908TR	Medline Prevention CoolZone Surgical Gown, Breathable Film Gown	Non-Sterile	XX-Large

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

Indications for Use

The Medline Prevention CoolZone 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 Prevention CoolZone Gown meets the Level 4 requirements of ANSI/AAMI PB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.*

Substantial Equivalence

TABLE 2: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Attribute	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Prevention CoolZone Gown	Kimberly Clark *MicroCool* Surgical Gown	Different
510(k) Reference	K172954	K981393	Different
Product Owner	Medline Industries, Inc.	Kimberly Clark	Different
Product Code	FYA	FYA	Same
Intended Use	The Medline Prevention CoolZone Gowns are 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 Prevention CoolZone Gown meets the Level 4 requirements of the AAMI Liquid Barrier classifications. The Medline Prevention CoolZone Gowns are also sold as bulk non-sterile, single use items, to repackager/relabeler	The Kimberly-Clark *MicroCool* Surgical Gown, Breathable High Performance, KG400 (hereinafter referred to as "*MicroCool* Surgical Gown") are 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 *MicroCool* Surgical Gowns meet the Level 4 requirements of the AAMI PB70: 2003 Liquid Barrier classifications. The *MicroCool* Surgical	Same

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

	establishments for further packaging and Ethylene Oxide (EtO) sterilization.	Gowns are also sold as bulk non-sterile, single use items, to repackager/ relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.	
Regulation Number	878.4040	878.4040	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Design Configurations	Neck Closure: Tab Belt: Ties Cuffs: Knit Transfer Tab	Neck Closure: Tab Belt: Ties Cuffs: Knit Transfer Tab	Same
Material Composition	Breathable, SMS non-woven	Breathable, repellent, SMS non-woven	Similar
Performance Specifications in Critical Zone	Meets ANSI/AMMI PB70:2012 Level 4 Liquid Barrier requirements.	Meets PB70 AMMI Level 4 Liquid Barrier requirements.	Same
Performance Specifications in Non-Critical Zone	Meets ANSI/AMMI PB70:2012 Level 1 Liquid Barrier requirements.	Not Available	Different
Prescription vs. OTC	OTC	OTC	Same
Sterile vs. Non-Sterile	Sterile & Bulk Non-Sterile	Sterile & Bulk Non-Sterile	Same
Color	Dark Blue/Light Blue	Light Blue	Similar
Sterilization Method	EtO –Ethylene Oxide	EtO –Ethylene Oxide	Same
Gown Sizes	Large, Large/X-Long, X-Large, X-Large/X-Long, XX-Large, XX-Large/X-Long	Large, Large/X-Long, X-Large, XX-Large, Small, X-Large/X-Long	Similar
16 CFR Part 1610 Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets the requirements of Flame Resistant CPSC 1610 Class 1	Same
Biocompatibility ISO-10993	The test extract from cytotoxicity test was found not to be cytotoxic per ISO 10993-5. Test extracts from the irritation and	The test device from cytotoxicity testing was found not to be cytotoxic per ISO 100993-5. Test devices from the	Same

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093

	sensitization testing were found not to be an irritant nor sensitizer per ISO 10993-10.	irritation and sensitization testing were found not to be an irritant nor a sensitizer as per ISO 10993-10.	

Summary of Non-Clinical Testing

ISO 10993-5 Cytotoxicity	ISO MEM Elution Using L-929 Mouse Fibroblast Cells
ISO 10993-10 Irritation	ISO Intracutaneous Irritation Test
ISO 10993-10 Sensitization	ISO Guinea Pig Maximization Sensitization Test
ASTM F88/F88M-15	Seal Strength of Flexible Barrier Materials
ASTM F1929-15	Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ISTA 3A	Packaged-Products for Parcel Delivery System Shipment 70Kg or Less
ASTM F1671	Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens
ASTM D5034-09 (2013)	Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM D5587-15	Tearing Strength of Fabrics by Trapezoid Procedure
ASTM D3776/D3776M-09a	Basis Weight-Mass Per Unit Area (Weight) of Fabric
ASTM D3786/D3786M-13	Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method
16 CFR 1610	Flammability of Clothing Textiles
ASTM E96	Standard Test Methods for Water Vapor Transmission of Materials
ANSI/AAMI/ISO 10993-7:2008(R)2012	Biological evaluation of medical devices –Part 7: Ethylene oxide sterilization residuals
AATCC 42	Water Resistance: Impact Penetration Test
AATCC 127	Water Resistance: Hydrostatic Pressure Test
ANSI/AAMI PB70:2012	Liquid Barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

Summary of Clinical Testing

Clinical testing was not required for this device.

Conclusion

Based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Prevention CoolZone Gowns are substantially equivalent to the predicate device [Kimberly Clark *MicroCool* Surgical Gown (K981393)].