July 4, 2019

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

Re: K190950
Trade/Device Name: Medline Level 2 Surgical Gown (Eclipse Non-Reinforced), Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 13, 2019
Received: April 11, 2019

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. 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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190950

Device Name
Medline Level 2 Surgical Gown (Eclipse Non Reinforced), Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)

Indications for Use *(Describe)*

The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) 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 Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns meet the respective level requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns have been validated using an ethylene oxide (EtO) sterilization process. The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns are also sold as bulk single-use, non-sterile, to repackager/relabeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user.

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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K190950
510(k) SUMMARY
[AS REQUIRED BY 21CFR807.92]

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

Registration Number: 1417592

Contact Person
Pauline Maralit, M.B.A, RAC (US)
Regulatory Affairs Specialist
Phone: 847-949-2283
Email: pmaralit@medline.com

Summary Preparation Date
July 2, 2019

Type of 510(k) Submission
Traditional 510(k)

Device Name / Classification

Name of Device:	Surgical Apparel
Proprietary Name:	Medline Level 2 Surgical Gown (Eclipse Non Reinforced), Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)
Common Name:	Surgical Gown
Classification Name:	Surgical Gown
Product Code:	FYA
Classification Panel:	General & Plastic Surgery
Regulatory Class:	II
Regulation #:	21 CFR 878.4040

Predicate Device

K020593 Allegiance Healthcare Converters SMS Polyolefin Gowns (Primary Predicate)
K170762 Cardinal Health™ Non-Reinforced (Secondary Predicate)

Device Description

The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) is a Class II medical device under the FDA product code FYA, General & Plastic Surgery Panel, and Regulation 21 CFR 878.4040. The Medline Level 2 and Level 3 Surgical Gowns are categorized into several device configurations based on gown reinforcement (critical zones), sleeve style and size.

The Medline Level 2 Surgical Gown is offered in one fabric style referred to as "ECLIPSE", it is non-reinforced, has a set-in sleeve and is manufactured in a range of sizes from small to XXXX-large. Please refer to **Table 1** below for additional information regarding these gown configurations. The chest and sleeve critical zones, as well as the overall body, of the Medline Level 2 Surgical Gown (Eclipse Non Reinforced) is constructed from a blue polyolefin/polypropylene SMS (spunbond, meltblown, spunbond). The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) has been tested according to ANSI/AAMI PB70:2012 and meets the AAMI Level 2 barrier level protection for a surgical gown. The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) is a single use, disposable medical device that will be provided in both a sterile and non-sterile packaging configuration and a variety of sizes.

The Medline Level 3 Surgical Gown is offered in three different fabric styles entitled "ECLIPSE," "SIRUS," and "AURORA." The Medline Level 3 Surgical Gown is offered in both a fabric reinforced or non-reinforced design, may have either a set-in or raglan sleeve, and available in sizes ranging from small to XXXX-large. **Table 1** provides a description of each of the Medline Level 3 Surgical Gown configurations included in this submission. The chest and sleeve critical zones, as well as the overall body, of all Medline Level 3 Surgical (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) configurations are constructed from a blue polyolefin/polypropylene SMS (spunbond, meltblown, spunbond). The Medline Level 3 Surgical Gowns with fabric reinforcement are manufactured with additional fabric along the critical zones of the gown; **Table 1** highlights the gown models containing fabric reinforcement in blue. The Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical

Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) has been tested according to ANSI/AAMI PB70:2012 and meets the AAMI Level 3 barrier level protection for a surgical gown. The Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) is a single use, disposable medical device that will be provided in both a sterile and non-sterile packaging configuration and a variety of sizes.

Table 1: Medline Level 2 and Level 3 Surgical Gown Configurations

Item Number	Device Description	Sleeve Style	Size
	ECLIPSE		
DYNJP2001	Level 2 Surgical Gown, Non-Reinforced	Set-In	Large
DYNJP2002	Level 2 Surgical Gown, Non-Reinforced	Set-In	X-Large
DYNJP2003	Level 2 Surgical Gown, Non-Reinforced	Set-In	XX-Large
DYNJP2004	Level 2 Surgical Gown, Non-Reinforced	Set-In	XXX-Large
DYNJP2005	Level 2 Surgical Gown, Non-Reinforced	Set-In	Small/Medium
DYNJP2009	Level 2 Surgical Gown, Non-Reinforced	Set-In	XXXX-Large
	ECLIPSE		
DYNJP2101	Level 3 Surgical Gown, Fabric Reinforced	Set-in	Large
DYNJP2102	Level 3 Surgical Gown, Fabric Reinforced	Set-in	X-Large
DYNJP2103	Level 3 Surgical Gown, Fabric Reinforced	Set-in	XX-Large
	SIRUS		
DYNJP2001S	Level 3 Surgical Gown, Non-Reinforced	Set-in	Large
DYNJP2002S	Level 3 Surgical Gown, Non-Reinforced	Set-in	X-Large
DYNJP2002SL	Level 3 Surgical Gown, Non-Reinforced	Set-in	X-Large, X-Long
DYNJP2003S	Level 3 Surgical Gown, Non-Reinforced	Set-in	XX-Large
DYNJP2003SL	Level 3 Surgical Gown, Non-Reinforced	Set-in	XX-Large, X-Long
DYNJP2004S	Level 3 Surgical Gown, Non-Reinforced	Set-in	XXX-Large
DYNJP2005S	Level 3 Surgical Gown, Non-Reinforced	Set-in	Small/Medium
DYNJP2009S	Level 3 Surgical Gown, Non-Reinforced	Set-in	XXXX-Large
DYNJP2101S	Level 3 Surgical Gown, Fabric Reinforced	Set-in	Large
DYNJP2102S	Level 3 Surgical Gown, Fabric Reinforced	Set-in	X-Large
DYNJP2103S	Level 3 Surgical Gown, Fabric Reinforced	Set-in	XX-Large
DYNJP2401	Level 3 Surgical Gown, Non-Reinforced	Raglan	Large
DYNJP2402	Level 3 Surgical Gown, Non-Reinforced	Raglan	X-Large
DYNJP2403	Level 3 Surgical Gown, Non-Reinforced	Raglan	XX-Large

DYNJP2501	Level 3 Surgical Gown, Fabric Reinforced	Raglan	Large
DYNJP2502	Level 3 Surgical Gown, Fabric Reinforced	Raglan	X-Large
DYNJP2503	Level 3 Surgical Gown, Fabric Reinforced	Raglan	XX-Large
	AURORA		
DYNJP2701	Level 3 Surgical Gown, Non-Reinforced	Set-in	Large
DYNJP2702	Level 3 Surgical Gown, Non-Reinforced	Set-in	X-Large
DYNJP2703	Level 3 Surgical Gown, Non-Reinforced	Set-in	XX-Large
DYNJP2704	Level 3 Surgical Gown, Fabric Reinforced	Set-in	Large
DYNJP2705	Level 3 Surgical Gown, Fabric Reinforced	Set-in	X-Large
DYNJP2706	Level 3 Surgical Gown, Fabric Reinforced	Set-in	XX-Large
DYNJP2715	Level 3 Surgical Gown, Non-Reinforced	Set-in	Small/Medium
DYNJP2801	Level 3 Surgical Gown, Non-Reinforced	Raglan	Large
DYNJP2802	Level 3 Surgical Gown, Non-Reinforced	Raglan	X-Large
DYNJP2803	Level 3 Surgical Gown, Non-Reinforced	Raglan	XX-Large
DYNJP2804	Level 3 Surgical Gown, Fabric Reinforced	Raglan	Large
DYNJP2805	Level 3 Surgical Gown, Fabric Reinforced	Raglan	X-Large
DYNJP2806	Level 3 Surgical Gown, Fabric Reinforced	Raglan	XX-Large

Indications for Use

The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) 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 Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) meet the respective level requirements of ANSI/AAMI PB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for the use in healthcare facilities.*

The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)

have been validated using an ethylene oxide (EtO) sterilization process. The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) are also sold as bulk single-use, non-sterile, to re-packager/re-labeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user.

Summary of Technological Characteristics

TABLE 2: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device (Primary)	Predicate Device (Secondary)	Comparison Analysis
Product Name	The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)	Convertors® SMS Polyolefin Standard Gown	Cardinal Health™ Non-Reinforced Surgical Gown	N/A
510(k) Reference	K190950	K020593	K170762	N/A
Product Owner	Medline Industries, Inc.	Allegiance Healthcare Corporation	Cardinal Health	N/A
Product Code	FYA	FYA	FYA	Same
Intended Use	The Medline Level 2 Surgical Gowns and Medline Level 3 Surgical 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	Convertors® SMS Polyolefin Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body	The Cardinal Health Non-Reinforced Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate	Similar

	fluids, and particulate matter. The Medline Level 2 Surgical Gowns and the Medline Level 3 Surgical Gowns meets the respective level requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.	fluids and particulate material.	material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Cardinal Health Non-Reinforced Surgical Gowns are single use, disposable medical devices, provided sterile and non-sterile.	
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Color	Blue	Light Blue	Dark Blue	Different
Design Features	Available in Fabric Reinforced and Non-Reinforced Hook and Loop Closure at neck Belt Ties Knit Cuffs Transfer Tab Raglan or Set-in/Standard Sleeves	Standard, Fabric-Reinforced and Poly Reinforced Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab	Non-Reinforced Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab	Similar
Sizes	Small to XXXX-Large	Large to XX-Large	Small to XXXX-Large	Same
Materials	Nonwoven SMS polypropylene/Polyolefin	Nonwoven Polyolefin (Polypropylene) SMS	Nonwoven Polyolefin (Polypropylene) SMS	Same
Performance Specifications	Level 2 PB70 Barrier Protection Level 3 PB70 Barrier Protection	N/A (preceded AAMI PB70 performance standards)	Level 3	Similar

Prescription vs. OTC	OTC	OTC	OTC	Same
Contact Durations	Surface, Intact, ≤ 24 hours	Surface, Intact, ≤ 24 hours	Surface, Intact, ≤ 24 hours	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Sterile	Same
Single Use vs. Reusable	Single Use	Single Use	Single Use	Same
Biocompatibility	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.	Met requirements per: ISO 10993-5 Cytotoxicity ISO 10993-10 Irritation ISO 10993-10 Sensitization	Met requirements per: ISO 10993-5 Cytotoxicity ISO 10993-10 Irritation ISO 10993-10 Sensitization	Same
Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements of Flame Resistant CPSC, Part 1610 – Class 1	Meets requirements of Flame Resistant CPSC, Part 1610 – Class 1	Same
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same

Summary of Non-Clinical Testing

Performance testing was performed to verify that the device meets the acceptance criteria. The testing done on the Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) were conducted to demonstrate the safety and effectiveness of the subject device in accordance with the relevant test methods cited below, including the appropriate biocompatibility tests. While the *color characteristic* amongst the proposed and predicate devices are different, each of the devices were tested per the requirements of ISO 10993-1. Under the test conditions outlined in ISO 10993-5 & ISO 10993-10, the Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) were shown to be non-cytotoxic, non-irritating, and non-sensitizing and therefore the difference in the colors amongst the devices does not raise new questions with regards to safety and effectiveness.

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 F1929-15	Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
AATCC 127	Water Resistance: Hydrostatic Pressure Test
AATCC 42	Water Resistance: Impact Penetration Test
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
ANSI/AAMI/ISO 10993-7: 2008(R)2012	Biological evaluation of medical devices –Part 7: Ethylene oxide sterilization residuals

Summary of Clinical Testing

Not applicable.

Conclusion

Based on the information provided in this premarket notification, Medline Industries, Inc. concludes that the Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) are as safe, as effective, and perform as well or better than the legally marketed predicate devices: K020593 Allegiance Healthcare Converters SMS Polyolefin Standard Gown and K170762 Cardinal Health™ Non-Reinforced Surgical Gown.