April 24, 2019

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

Re: K182172
Trade/Device Name: Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 26, 2019
Received: March 28, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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)*
K182172

Device Name

Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora).

Indications for Use *(Describe)*

The Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) 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 (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) 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.

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510(k) SUMMARY – K182172

Submitter / 510(k) Sponsor

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

Submission Contact

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

Summary Preparation Date

August 9, 2018

Type of 510(k) Submission

Traditional

Device Name / Classification

Regulation Name:	Surgical Apparel
Regulatory Panel:	General & Plastic Surgery
Regulation #:	21 CFR 878.4040
Common Name:	Surgical Gown
Classification Name:	Surgical Gown
Proprietary Name:	Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora).
Product Code:	FYA
Classification Panel:	II

Predicate Device

PREDICATE DEVICE:

- Kimberly Clark (Halyard) ULTRA Fluid Barrier Surgical Gown

PREDICATE DEVICE K NUMBER:

- K080795 (Kimberly-Clark Corp./Halyard)

Device Description

The Medline Level 4 Surgical Gown (Sirus, Eclipse, and Aurora) is a Class II medical device regulated under FDA product code FYA, General & Plastic Surgery Panel, and regulation 21 CFR 878.4040. The device description of the Medline Level 4 Surgical Gown is in accordance with the *Guidance on Premarket Notification* [510(k)] *Submissions for Surgical Gowns and Surgical Drapes,* issued on August 1, 1993.

The Medline Level 4 Surgical Gown (Sirus, Eclipse, and Aurora) is a single-use, sterile, disposable medical device that is provided in a variety of sizes and styles. The Medline Level 4 Surgical Gown (Sirus, Eclipse, and Aurora) constructed from nonwoven SMS (spubound, meltblown, spunbond), a poly-fabric reinforcement on the chest front panel and on both 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 (Sirus, Eclipse, and Aurora) has been tested according to ANSI/AAMI PB70:2012 and meets AAMI Level 4 barrier level protection for a surgical gown.

Table 1: Device Models

Item Number	Device Description	Sleeve Style	Size
DYNJP2707	Aurora Surgical Gown, Poly Reinforced,	Set-in	Large
DYNJP2708	Aurora Surgical Gown, Poly Reinforced,	Set-in	X-Large
DYNJP2709	Aurora Surgical Gown, Poly Reinforced,	Set-in	XX-Large
DYNJP2724	Aurora Surgical Gown, Poly Reinforced,	Set-in	Large, X-Long
DYNJP2725	Aurora Surgical Gown, Poly Reinforced,	Set-in	X-Large, X-Long
DYNJP2726	Aurora Surgical Gown, Poly Reinforced,	Set-in	XX-Large, X-Long
DYNJP2807	Aurora Surgical Gown, Poly Reinforced,	Raglan	Large
DYNJP2808	Aurora Surgical Gown, Poly Reinforced,	Raglan	X-Large
DYNJP2809	Aurora Surgical Gown, Poly Reinforced,	Raglan	XX-Large
DYNJP220	Eclipse Surgical Gown, Poly Reinforced	Set-in	Large
DYNJP2202	Eclipse Surgical Gown, Poly Reinforced	Set-in	X-Large
DYNJP2203	Eclipse Surgical Gown, Poly Reinforced	Set-in	XX-Large
DYNJP2204	Eclipse Surgical Gown, Poly Reinforced	Set-in	Large, X-Long
DYNJP2205	Eclipse Surgical Gown, Poly Reinforced	Set-in	X-Large, X-Long
DYNJP2206	Eclipse Surgical Gown, Poly Reinforced	Set-in	XX-Large, X-Long
DYNJP2201S	Sirus Surgical Gown, Poly Reinforced	Set-in	Large
DYNJP2202S	Sirus Surgical Gown, Poly Reinforced	Set-in	X-Large
DYNJP2203S	Sirus Surgical Gown, Poly Reinforced	Set-in	XX-Large

DYNJP2204S	Sirus Surgical Gown, Poly Reinforced	Set-in	Large, X-Long
DYNJP2205S	Sirus Surgical Gown, Poly Reinforced	Set-in	X-Large, X-Long
DYNJP2206S	Sirus Surgical Gown, Poly Reinforced	Set-in	XX-Large, X-Long
DYNJP2219SL	Sirus Surgical Gown, Poly Reinforced	Set-in	XXX-Large, X-Long
DYNJP2601	Sirus Surgical Gown, Poly Reinforced	Raglan	Large
DYNJP2602	Sirus Surgical Gown, Poly Reinforced	Raglan	X-Large
DYNJP2603	Sirus Surgical Gown, Poly Reinforced	Raglan	XX-Large

Indications for Use

The Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) 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 (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) meets the Level 4 requirements of ANSI/AAMIPB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities*.

Technological Characteristics

The final proposed finished device was tested in accordance with the *Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*- August 1993, *Guidance for Industry and FDA Staff - Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings issued by the FDA*- December 9, 2015, and ANSI/AAMIPB70:2012 *Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities*. Testing was performed on the body and sleeve (equivalent design/technology), sleeve seam, and tie attachment to generate the test data shown in the comparison **Table 2**. Additional performance testing was conducted to further characterize the device.

TABLE 2: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Element of Comparison	Subject Device	Predicate Device	Comparison Analysis
Product Name	Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora)	ULTRA Fluid Barrier Surgical Gown	Different
510(k) Reference	K182172	K080795	Different
Product Owner	Medline Industries, Inc.	Kimberly-Clark Corp. (Halyard)	Different
Product Code	FYA	FYA	Same
Intended Use	The Medline Level 4 Surgical Gown is a sterile, single use	The Kimberly-Clark* ULTRA Surgical Gown and ULTRA Film	Similar

	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/AAMIPB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.	Reinforced Surgical Gown are sterile, single use surgical gowns intended to protect surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. The ULTRA Surgical Gown meets Level 3 of the AAMI Liquid Barrier classifications, and the ULTRA Film-Reinforced Surgical Gown meets Level 4 of the AAMI Liquid Barrier classifications.	
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Gown Color	Blue	Blue	Same
Design Configurations	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Reinforced Material Raglan or Set-in/Standard Sleeves	Hoop & Neck Closures Tie Waist Closure Cuffs Film Reinforcement Raglan Sleeves	Similar
Material Composition	Nonwoven SMS polypropylene Anti-Static, Repellency Poly-Reinforcement Film White Knitted Cuffs	Nonwoven SMS polypropylene Anti-Static, Repellency Film Reinforcement Cuffs	Same
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Surface, Intact, $\leq$ 24 hours	Surface, Intact, $\leq$ 24 hours	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single	Single	Same
Performance Specifications:	Level 4 barrier protection	Level 4 barrier protection	Same
Biocompatibility	Met requirements per: ISO 10993-5 Cytoxticity ISO 10993-10 Irritation ISO 10993-10 Sensitization	Complied with 10993 requirements for surface devices with limited contact with breeched or compromised surfaces	Same

Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	NFPA Test Method 702-1980 for Class 1	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same

The proposed Medline Level 4 Surgical Gown (Sirus, Eclipse, Aurora) is substantially equivalent to the predicate, ULTRA Fluid Barrier Surgical Gown, with regards to claims, design, technology, and intended use.

- **Claim**: ANSI/AAMI PB70 Level 4 rating
- **Design**: SMS, Single-Use, Disposable
- **Technology**: Reinforcement material along chest and sleeve (critical zones)
- **Intended Use**: Surgical apparel intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

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 F1929-15	Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
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 F1929	Resistance to Dye Penetration Test
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

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

Not applicable.

Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the Medline Level 4 Surgical Gowns (Sirus, Eclipse and Aurora) are as safe, as effective, and performs as well as or better than the legally marketed predicate device, Kimberly-Clark (Halyard) ULTRA Fluid Barrier Surgical Gown.