May 6, 2022

Medline Industries LP
Adam Ostrower
Sr. Specialist RA
Three Lakes Drive
Northfield, Illinois 60093

Re: K214108
Trade/Device Name: Medline Orbis Chemo Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA, QSO
Dated: April 13, 2022
Received: April 13, 2022

Dear Adam Ostrower:

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,

Clarence W. Murray, III, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214108

Device Name
Medline Orbis Chemo Surgical Gown

Indications for Use *(Describe)*
The Medline Orbis Chemo Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect operating room personnel from transfer of microorganisms, body fluids, and particulate material. Additionally the gown is intended to protect healthcare personnel from exposure to chemotherapy drugs during their preparation, handling, and administration. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

The Medline Orbis Chemo Surgical 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 Orbis Chemo Surgical gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12 "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact."

Carmustine [3.3 mg/ml] >480
Cisplatin [1.0 mg/ml] >480
Cyclophosphamide [20 mg/ml] >480
Cytarabine Hydrochloride [100 mg/ml] >480
Dacarbazine [10 mg/ml] >480
Daunorubicin Hydrochloride [5 mg/ml] >480
Doxorubicin Hydrochloride [2 mg/ml] > 480
Etopside [20 mg/ml] >480
Fluorouracil [50 mg/ml] >480
Ifosfamide [50 mg/ml] > 480
Methotrexate [25 mg/ml] >480
Mitomycin C [0.5 mg/ml] >480
Mitoxantrone [2.0 mg/ml] >480
Paclitaxel [6 mg/ml] >480
Thiotepa [10 mg/ml] >480
Vincristine Sulfate [1 mg/ml] >480

Gown selection should be specifically chosen for the type of chemotherapy agent used. Users are recommended to review Material Safety Data Sheets for Chemotherapy Drugs being used to determine the required level of protection.

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 – K214108
[AS REQUIRED BY 21CFR807.92(c)]

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

Registration Number: 1417592

Contact Person
Adam Ostrower
Regulatory Affairs Sr. Specialist
Phone: 224-931-1513
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Summary Preparation Date
December 27th, 2021

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Orbis Chemo Surgical Gown
Common Name: Surgical Gown
Classification Name: Surgical Gown
Product Code: FYA, QSO
Classification Panel: General Hospital
Regulatory Class: II
Regulation Number: 21 CFR 878.4040

Predicate Device
Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Cardinal Health ChemoPlus Full Coverage Gown, Open Back
K193327

Device Description
The Medline Orbis Chemo Surgical Gown is a single-use, disposable, level 3 surgical gown available in sterile and non-sterile configurations. The multiple configurations and sizes are described in **Table 1** below. The Medline Orbis Chemo Surgical Gown is manufactured using a nonwoven polypropylene spunbond. Each gown is designed with a hook and loop closure at the neck, four ties at the waist, knitted polyester cuffs at the end of the sleeves as well as a transfer tab for ease in donning.

Table 1: Medline Orbis Chemo Surgical Gown configurations

Catalog #	Description	Sterile or Non-Sterile
DYNJP2015C	Orbis Chemo Surgical Gown, Breathable Film Gown, Small	Sterile
DYNJP2011C	Orbis Chemo Surgical Gown, Breathable Film Gown, Large	Sterile
DYNJP2012C	Orbis Chemo Surgical Gown, Breathable Film Gown, X-Large	Sterile
DYNJP2013C	Orbis Chemo Surgical Gown, Breathable Film Gown, XX-Large	Sterile
DYNJP2014C	Orbis Chemo Surgical Gown, Breathable Film Gown, XXX-Large	Sterile
DYNJP2019C	Orbis Chemo Surgical Gown, Breathable Film Gown, XXXX-Large	Sterile
DYNJP2012CL	Orbis Chemo Surgical Gown, Breathable Film Gown, X-Large, X-Long	Sterile
DYNJP2013CL	Orbis Chemo Surgical Gown, Breathable Film Gown, XX-Large, X-Long	Sterile
SPT-2015C	Orbis Chemo Surgical Gown, Breathable Film Gown, Small	Non-Sterile
SPT-2011C	Orbis Chemo Surgical Gown, Breathable Film Gown, Large	Non-Sterile
SPT-2012C	Orbis Chemo Surgical Gown, Breathable Film Gown, X-Large	Non-Sterile
SPT-2013C	Orbis Chemo Surgical Gown, Breathable Film Gown, XX-Large	Non-Sterile
SPT-2014C	Orbis Chemo Surgical Gown, Breathable Film Gown, XXX-Large	Non-Sterile
SPT-2012CL	Orbis Chemo Surgical Gown, Breathable Film Gown, X-Large, X-Long	Non-Sterile
SPT-2013CL	Orbis Chemo Surgical Gown, Breathable Film Gown, XX-Large, X-Long	Non-Sterile

Note: SPT, non-sterile gowns will be offered as part of a separate kit

Indications for Use

The Medline Orbis Chemo Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect operating room personnel from transfer of microorganisms, body fluids, and particulate material. Additionally the gown is intended to protect healthcare personnel from exposure to chemotherapy drugs during their preparation, handling, and administration. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

The Medline Orbis Chemo Surgical 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 Orbis Chemo Surgical gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12 “Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact.”

Carmustine [3.3 mg/ml] >480
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Vincristine Sulfate [1 mg/ml] >480

Gown selection should be specifically chosen for the type of chemotherapy agent used. Users are recommended to review Material Safety Data Sheets for Chemotherapy Drugs being used to determine the required level of protection.

Summary of Technological Characteristics

Table 2: Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Orbis Chemo Surgical Gown	Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Cardinal Health ChemoPlus Full Coverage Gown, Open Back	Different
510(k) Reference	N/A	K193327	Different
Product Owner	Medline Industries Inc.	Cardinal Health 200, LLC	Different
Product Code	FYA, QSO	FYA	Same
Intended Use	The Medline Orbis Chemo Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect operating room personnel from transfer of microorganisms, body fluids, and particulate material. Additionally the gown is intended to protect healthcare personnel from exposure to chemotherapy drugs during their preparation,	The Cardinal Health™ ChemoPlus™ Full Coverage Gowns, Open Back, are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling, and administration. The open back gowns are single use, disposable medical devices provided nonsterile. The open back gown is nonprotective in the back. The open back gowns are not	Similar

	handling, and administration. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1. The Medline Orbis Chemo Surgical 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 Orbis Chemo Surgical gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12 "Standard Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact."	intended for use in the operating room.	
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Color	Light Blue	Blue	Similar

Design Features	Polyester Knit Cuff Hook and Loop Neck Closure Waist Ties Ultrasonic Sealed Seams	Polyester Knit cuff Hook and Loop Neck Closure Belt Ties integrated in the back of gown Taped seams	Similar
Sizes	Small-XXXX-Large	Medium to XX-Large	Different
Materials	Nonwoven polypropylene spunbond fabric	Nonwoven polypropylene spunbond fabric with a polyethylene laminate coating (also referred to as laminate)	Similar
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Surface, Intact, < 24 hours	Surface, Intact, < 24 hours	Same

Sterile vs. Non-Sterile	Sterile and Non-Sterile	Sterile and Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Performance per AAMI PB70:2012	AAMI Level 3	AAMI Level 3	Same
Evaluation per ASTM F739-12	Carmustine, Cisplatin, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel, Thiotepa, Vincristine Sulfate. Results showed no average standardized breakthrough for up to 480 minutes.	Carmustine, Cisplatin, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel, Thiotepa, Vincristine Sulfate. Results showed no average standardized breakthrough for up to 480 minutes.	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.	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	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same

Summary of Non-Clinical Testing

Non-clinical performance testing was completed on the Medline Orbis Chemo Surgical Gown to demonstrate the subject device is in accordance with the relevant test methods described in **Table 3** below.

Table 3: Summary of Non-Clinical Testing and Standards Applied

Standard	Name	Acceptance Criteria	Result
ISO 10993-5	ISO MEM Elution Using L-929 Mouse Fibroblast Cells	Cytotoxicity	Pass
ISO 10993-10	ISO Intracutaneous Irritation Test	Irritation and Sensitization	Pass
AATCC 42-17	Water Resistance	Water Resistance	Pass

AATCC 127-18	Hydrostatic Pressure	Water Resistance	Pass
ASTM D5034-09	Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Tensile Strength	Pass
ASTM D5587-15	Tearing Strength of Fabrics by Trapezoid Procedure	Trapezoid Tear	Pass
ASTM D3776/D3776M-09a	Basis Weight-Mass Per Unit Area (Weight) of Fabric	Material Weight	Pass
ASTM D3786/D3786M-13	Bursting Strength of Textile Fabrics-Diaphragm Bursting Strength Tester Method	Burst Strength	Pass
ASTM D1683-17	Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics	Seam Strength	Pass
16 CFR 1610	Flammability of Clothing Textiles	Flammability	Pass
ANSI/AAMI/ISO 10993-7: 2008(R)2012	Biological evaluation of medical devices –Part 7: Ethylene oxide sterilization residuals	EO and ECH Residuals	Pass
ANSI AAMI PB70:2012	Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Healthcare Facilities	Fluid Resistance	Pass
ASTM F739-12	Permeation of Liquids and Gasses Through Protective Clothing	Chemical Penetration, under continuous contact	Pass
ISO 9073-10-2004	Test methods for nonwovens Lint and other particles generation in the dry state	Particulate	Pass

Summary of Clinical Testing
Not applicable.

Conclusion
The conclusions drawn from the nonclinical test demonstrate that the device, Medline Orbis Chemo Surgical Gown, is as safe, as effective and perform as well or better than the legally marketed predicate device, Cardinal Health ChemoPlus Full Coverage Gown, Closed Back, Cardinal Health ChemoPlus Full Coverage Gown, Open Back, K193327.