March 11, 2022

Elevate Textiles
Nathaniel Terry
Technical Director
22 American Street
Mt. Holly, North Carolina 28210

Re: K201351
Trade/Device Name: Maxima Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 8, 2021
Received: December 13, 2021

Dear Nathaniel Terry:

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 Clarence W. Murray III, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201351

Device Name
Maxima Surgical Gown

Indications for Use *(Describe)*

The reusable Maxima Surgical Gown is intended to be used by operating room personnel during surgical procedures to help protect both the patient and the health care worker from transfer of micro-organisms, body fluids, and particulate material.

The reusable Maxima Surgical Gown is provided non-sterile. Sterilization parameters are as follows:
* Prevac Steam Sterilization - 135°C/274°F (temperature) / 3 minutes (exposure time) / 20 minutes (dry time)

Elevate Textiles Item Numbers / gown color / liquid barrier protection / gown size
MAXAL3S / Royal Blue B103 / AAMI Level 3 / Small
MAXAL3M / Royal Blue B103 / AAMI Level 3 / Medium
MAXAL3L / Royal Blue B103 / AAMI Level 3 / Large

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 (K201351)
[As required by section 807.92(c)]

Submitter:
Elevate Textiles
22 American Street
Mt Holly NC, 28120

Contact Person:
Nathaniel Terry
Technical Director / Regulatory Affairs
Telephone: 336-684-1683
Email: Nathaniel.terry@elevatetextiles.com

Summary Preparation Date
December 1, 2021

Type of Submission
Traditional 510(k)

Device Name / Classification

Trade Name:	Maxima® Surgical Gown
Common Name:	Sterile Surgical Gown
Classification Name:	Surgical Gown, Class 2

Predicate Device - Maxima® Surgical Gown claims substantial equivalence to:
K150598 Blockade Surgical Gown manufactured by Medline Industries, Inc

Device Description
The Maxima® Surgical Gown is a reusable woven surgical gown for use in sterile conditions. It is made of 100% filament polyester that provides AAMI PB70:2012 Level 3 Liquid Barrier Performance Barrier in the critical zone up to 75 reprocessing cycles. The back of the gown provides AAMI Level 3 Liquid Barrier Performance Barrier up to 75 reprocessing cycles. The seam in the critical zone of the sleeves are sealed with a permanent seam tape which seals the stitch area enabling it to perform as AAMI Level 3 up to 75 reprocessing cycles.

Maxima® Surgical Gown will be manufactured in small, medium, and larges sizes. Maxima® Surgical Gowns will be sold as non-sterile reusable surgical gowns that are to be laundered, sterilized and processed by health care facilities and/or contract laundry and sterilization companies before first use and after each subsequent use.

Indications for Use
The Maxima Surgical Gown is a reusable surgical gown intended to be used by operating room personnel during surgical procedures to help protect both the patient and the health care worker from transfer of micro-organisms, body fluids, and particulate material.

The Maxima Surgical Gown is provided non-sterile. Sterilization parameters are as follows:

* Prevac Steam Sterilization - 135°C/274°F (temperature) / 3 minutes (exposure time) / 20 minutes (dry time)

Elevate Textiles Item Numbers / Gown Color / Liquid Barrier Protection / Gown Size

MAXAL3S / Royal B103 / AAMI Level 3 / Small
MAXAL3M / Royal B103 / AAMI Level 3 / Medium
MAXAL3L / Royal B103 / AAMI Level 3 / Large

Summary of Technological Characteristics

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Maxima® Surgical Gown	Blockade Surgical Gown	N/A
510(k) Reference	K201351	K150598	N/A
Product Owner	Elevate Textiles	Medline Industries Inc.	N/A
Product Code	FYA	FYA	same
Intended Use	Intended to be used by operating room personnel during surgical procedures to help protect both the patient and the health care worker from transfer of micro-organisms, body fluids, and particulate material.	Intended to be used by operating room personnel during surgical procedures to help protect both the patient and the health care worker from transfer of micro-organisms, body fluids, and particulate material.	same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	same
Color	Royal B103	Ceil, Jade	different
Design Features	belt ties knit cuffs neck closure: metal snaps	belt ties knit cuffs neck closure: metal snaps	same
Sizes	Small, Medium, Large	Large, X-Large XX-Large	similar
Materials	Woven polyester	Woven polyester	same
Performance Specifications	Level 3 ANSI/AAMI PB70 Barrier protection	Level 3 ANSI/AAMI PB70 Barrier protection	same
Prescription vs. OTC	OTC	OTC	same
Contact Durations	Surface, Breached or Compromised, $\leq$ 24 hours	Surface, Breached or Compromised, $\leq$ 24 hours	same
Sterile vs. non-sterile	Sterile when used	Sterile when used	same
Single Use vs. Reusable	reusable	reusable	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	same
Flammability	Meets the requirements of CPSC 16 CFR 1610 Class 1	Meets the requirements of CPSC 16 CFR 1610 Class 1	same
Lint Level	Log_{10} (lint count) 1.89	Log_{10} (lint count) 1.89	same
Tensile Strength	Warp: 138.9 lbf Fill: 82.01 lbf	Warp: 138.9 lbf Fill: 82.01 lbf	same
Seam Strength	Warp: 78 lbf Fill: 65.4 lbf	Warp: 78 lbf Fill: 65.4 lbf	same
Tear Resistance	Warp: 25.3 lbf Fill: 7.4 lbf	Warp: 25.3 lbf Fill: 7.4 lbf	same
Sterilization Method	Prevac steam autoclave	Prevac steam autoclave	same

Summary of Non-Clinical Testing

Performance testing was performed to verify that the device meets the acceptance criteria. The testing done on the Maxima® Surgical Gown was conducted to demonstrate the safety and effectiveness of the subject device in accordance with the relevant test methods cited below, including the appropriate biocompatibility test.

Test Conducted	Test Standard	Acceptance Criteria	Test Result
Cytotoxicity ISO MEM Elution Using L-929 Mouse Fibroblast Cells	**ISO 10993-5 Cytotoxicity:** Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	non-cytotoxic	non-cytotoxic
Skin Irritation ISO Intracutaneous Irritation Test	**ISO 10993-10 Irritation:** Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization	non-irritating	non-irritating
Skin Sensitization ISO Guinea Pig Buehler Sensitization Test	**ISO 10993-10 Sensitization:** Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization	non-sensitizing	non-sensitizing
Water Resistance	**AATCC 127:** Test Method for Water Resistance: Hydrostatic Pressure	>50 cm AQL 4.0	Avg. 70.3 cm
Water Resistance	**AATCC 42:** Test Method for Water Resistance: Impact Penetration	<1.0 g AQL 4.0	Mean 0.01 g
Breaking Strength	**ASTM D5034:** Standard Test Method For Breaking Strength And Elongation Of Textile Fabrics (Grab Test)	>30 lbf	Warp: 138.9 lbf Fill: 82.01 lbf
Tear Strength	**ASTM D 5587:** Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	>1.5 lbf	Warp: 25.3 lbf Fill: 7.4 lbf
Seam Strength	**ASTM D1683:** Standard Test Method For Failure In Sewn Seams Of Woven Fabrics	>30 lbf	Warp: 78 lbf Fill: 65.4 lbf
Weight	**ASTM D3776/D3776M-09a:** Standard Test Methods For Mass Per Unit Area (Weight) Of Fabric	Documentation Only	88 gsm
Flammability	**16 CFR 1610:** Standard for the Flammability of Clothing Textiles	Class 1	Class 1
Lint Generation	**EN ISO 9073-10:** Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state	Documentation Only	$\log_{10}$ (lint count) 1.89
Evaporative Resistance	**ASTM F1868:** Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate	Documentation Only	R_{et} Critical Zone 0.01193 R_{et} Noncritical Zone 0.01157

Summary of Clinical Testing

Not applicable

Conclusion

Based on the information provided in this premarket notification, Elevate Textiles concludes that the Maxima® Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device K150598 Medline Blockade Surgical gown.