September 10, 2024

Standard Textile Co., Inc.
% Catherine Kang
Senior Principal Consultant
Rqm+
2790 Mosside Blvd Suite 800
Monroeville, Pennsylvania 15146

Re: K241214
Trade/Device Name: ProPel SG3™ Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: April 30, 2024
Received: August 9, 2024

Dear Catherine Kang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241214

Device Name
ProPel SG3™ Surgical Gown

Indications for Use *(Describe)*
ProPel SG3™ Surgical Gown is intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70.

The reusable Propel Surgical Gown is provided non-sterile and must be sterilized before use. Sterilization parameters are as follows:

Prevacuum Steam Sterilization: 132°C/270°F (temperature)/ 4 minutes (exposure time)/15 minute (dry time)

Item Number Gown Size Tag Color Gown Size
7565CC17 Yellow SM
7565CC16 Gold MD
7565CC15 Green LG
7565CC14 Red XL
7565CC13 Orange 2XL
7565CC12 Purple 3XL

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.

510(k) Summary
K241214

DATE PREPARED
September 6, 2024

Manufacturer Name	Standard Textile Co., Inc. One Knollcrest Drive Cincinnati, OH 45237
Official Contact	Richard M. Holbert, Jr., PhD Vice President, Research and Development Telephone: (513) 384-4189 Email: rholbert@standardtextile.com
Representative/Consultant	Catherine Kang, PhD RQM+ 2790 Mosside Blvd Suite 800, Monroeville, PA 15146 Telephone: (312) 318-4730 Email: ckang@rqmplus.com

DEVICE INFORMATION

Device trade name, or proprietary name: ProPel SG3™ Surgical Gown
Device common name: Surgical Gown
Classification name: Gown, Surgical
Product classification: II
Recommended classification regulation: 21 CFR 878.4040
Product Code(s): FYA
Panel: General Hospital

PREDICATE DEVICE IDENTIFICATION

The ProPel SG3™ Surgical Gown is substantially equivalent to the following predicate device:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K922753	ComPel XTR/Standard Textile Co., Inc.	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION

The ProPel SG3™ Surgical Gown is a reusable, woven surgical gown that provides an ANSI /AAMI PB70:2022 Level 3 Liquid Barrier Performance Barrier using 100% polyester with silicone coating in the critical zone. The critical zone inner ply and back of the surgical gown is made of polyester with electrostatic dissipative yarn (graphene) and silicone coating. The gown has polyester mesh and vented cape on the back panels of the gown for ventilation. The ProPel SG3™ Surgical Gown may undergo up to 60 reprocessing cycles.

The ProPel SG3™ Surgical Gown is available in small, medium, large, extra large (XL), 2XL and 3XL. The device will be sold as a non-sterile surgical gown that is to be laundered, sterilized and processed by the healthcare facility prior to first use and after each subsequent use.

INDICATIONS FOR USE

ProPel SG3™ Surgical Gown is intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70.

The reusable Propel Surgical Gown is provided non-sterile and must be sterilized before use. Sterilization parameters are as follows:

Prevacuum Steam Sterilization: 132°C/270°F (temperature)/ 4 minutes (exposure time)/15 minute (dry time)

Item Number	Gown Size Tag Color	Gown Size
7565CC17	Yellow	SM
7565CC16	Gold	MD
7565CC15	Green	LG
7565CC14	Red	XL
7565CC13	Orange	2XL
7565CC12	Purple	3XL

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has the same intended use and similar technological characteristics to the predicate device. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

ProPel SG3™ Surgical Gown has a similar design and dimensions and uses similar materials as the ComPel XTR cleared under K922753 as indicated in the table below and forms the basis for the determination of substantial equivalence.

<table>
<tr><th>Device Characteristic</th><th>ComPel XTR (Predicate Device K922753)</th><th>ProPel SG3™ Surgical Gown (Subject Device: K241214)</th><th>Comparison</th></tr>
<tr><td>Product Code/ Regulation</td><td>FYA
878.4040</td><td>FYA
878.4040</td><td>Same</td></tr>
<tr><td>Product Classification</td><td>II</td><td>II</td><td>Same</td></tr>
<tr><td>Intended Use</td><td>ComPel XTR is 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.</td><td>ProPel SG3™ Surgical Gown is 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.</td><td>Same</td></tr>
<tr><td>Indication for Use</td><td>ComPel XTR Surgical gowns are intended to be worn by operating room personnel during surgical procedures to protect them by inhibiting the migration of liquids through the surface of the critical areas of the gown. When processed according to instructions, ComPel XTR Surgical gowns will function and perform as a surgical gown. The ComPel XTR Surgical gowns are reusable through 75 wash, dry, and sterilization cycles. They are manufactured and distributed as non-sterile surgical gowns that are intended to be sterilized and processed by health care facilities and/or contract sterilization/laundry companies.</td><td>ProPel SG3™ Surgical Gown is intended to protect both surgical patients and operating room personnel from the transfer of microorganisms, body fluids, and particulate material. They are classified as Level 3 surgical gowns in accordance with ANSI/AAMI PB70-2022.

The reusable Propel Surgical Gown is provided non-sterile and must be sterilized before use. Sterilization parameters are as follows:

Prevacuum Steam Sterilization: 132°C/270°F (temperature)/ 4 minutes (exposure time)/15 minute (dry time)

<table><tr><th>Item Number</th><th>Gown Size Tag Color</th><th>Gown Size</th></tr><tr><td>7565CC17</td><td>Yellow</td><td>SM</td></tr><tr><td>7565CC16</td><td>Gold</td><td>MD</td></tr><tr><td>7565CC15</td><td>Green</td><td>LG</td></tr><tr><td>7565CC14</td><td>Red</td><td>XL</td></tr><tr><td>7565CC13</td><td>Orange</td><td>2XL</td></tr><tr><td>7565CC12</td><td>Purple</td><td>3XL</td></tr></table></td><td>Similar. Both devices are surgical gowns that are indicated to protect operating room personnel.</td></tr>
<tr><td>ANSI/AAMI PB70 Level Classification in Critical Zones</td><td>Level 3*</td><td>Level 3</td><td>Similar. Predicate predated standards for testing but was subsequently confirmed</td></tr>
</table>

Device Characteristic	ComPel XTR (Predicate Device K922753)	ProPel SG3™ Surgical Gown (Subject Device: K241214)	Comparison
			to meet ANSI/AAMI PB70, which the subject device also meets.
Design	• Tape ties • Metal snaps • 100% polyester knit cuffs • Overlapping back panels	• Tape Ties • Plastic interlocking snaps • 100% polyester knit cuffs • Overlapping back panels with vent and mesh	Similar. Both devices include tape ties and snaps for fastening the gown, 100% polyester knit cuffs and overlapping back panels. The addition of a vent and mesh in the subject device does not impact safety or effectiveness.
Materials	• 100% dyed Dacron polyester with silicone coating (outer ply critical zone) • 100% polyester with carbon yarns (inner ply critical zone and back panels)	• 100% polyester with silicone coating (outer ply front and sleeves) • Polyester with electrostatic dissipative yarn (graphene) and silicone coating (inner ply front, sleeves, outer back panels)	Similar. Both gowns contain 100% polyester with silicone coating. The subject device includes additional materials that passed biocompatibility testing.
Color	Blue	Green	Different. Subject device passed biocompatibility testing. No impact on safety or effectiveness.
Sizes	Small/medium Large/extra large 2XL	Small Medium Large Extra Large 2XL 3XL	Similar. Both gowns are available in a variety of sizes.
Reusable	Yes, up to 75 times	Yes, up to 60 times	Both gowns are reusable with fewer reuses for the subject device.
Sterility	Provided nonsterile to user for steam sterilization	Provided nonsterile to user for steam sterilization	Same
Tensile Strength	Warp/Fill 150 lbf/123 lbf	≥ 30 N (≥ 7 lbf)	Similar. Predicate predated current standards but has been tested against the requirements. Performance of the subject device demonstrates the product meets this requirement.
Tear Strength	N/A	≥ 10 N (≥ 2.3 lbf)	Similar. Predicate predated current standards but has been tested against the requirements.

Device Characteristic	ComPel XTR (Predicate Device K922753)	ProPel SG3™ Surgical Gown (Subject Device: K241214)	Comparison
			Performance of the subject device demonstrates the product meets this requirement.
Seam Strength	N/A	≥ 30 N (≥ 7 lbf)	Different. Predicate predated current standards. Performance of the subject device demonstrates the product meets this requirement.
Hydrostatic Resistance	25 lbs/14 lbs (min.) Mullens Hydrostat (1X/75X)	≥ 50 cm (Level 3)	Similar. Predicate predated standards for testing but was subsequently confirmed to meet ANSI/AAMI PB70 Level 3 requirements, which the subject device also meets.
Impact Penetration	N/A	≤ 1.0 g (Level 3)	
Lint Generation	<100 (Linting coefficient of 3)	Linting coefficient of 3	Same
Flammability	Class I	Class I	Same
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic	Under the conditions of the study, the device is non-cytotoxic	Same
Sensitization	Under the conditions of study, not a sensitizer	Under the conditions of study, not a sensitizer	Same
Irritation	Under the conditions of study, not an irritant	Under the conditions of study, not an irritant	Same
Pyrogenicity	N/A	Non-pyrogenic	Different. Predicate predated standards for testing. Performance of the subject device demonstrates the product is nonpyrogenic.
Acute Systemic Toxicity	No acute systemic toxicity	No acute systemic toxicity	Same

*At the time of 510(k) clearance, AAMI levels for surgical gowns had not yet been established. Testing subsequently performed established that the gown meets AAMI PB70 Level 3 requirements.

SUMMARY OF NON-CLINICAL TESTING

The test results of non-clinical testing demonstrated that the proposed device met its acceptance criteria or testing endpoints with the use of following standards.

- ANSI/AAMI PB70:2022: Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.
- ASTM F2407-20: Standard Specification for Surgical Gowns Intended for

Use in Healthcare Facilities
- 16 CFR 1610: Standard for flammability of clothing textiles
- AATCC Method 42: Test Method for Water Resistance: Impact Penetration
- AATCC Method 127: Test Method for Water Resistance: Hydrostatic Pressure
- ASTM D1683: Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
- ASTM D5034: Standard Test Method for Breaking Strength and Elongation of Textile Fabrics
- ASTM D5587: Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
- ASTM F1868-17: Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials
- ASTM D4846-96 (2011): Standard Test Method for Resistance to Unsnapping of Snap Fasteners
- ISO 10993-5:2009: Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021: Biological evaluation of medical devices—Part 10: Tests for skin sensitization
- ISO 10993-11:2017: Biological evaluation of medical devices—Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices—Part 23: Tests for irritation
- USP <151> Pyrogen Test

The table below provides a summary of non-clinical testing performed.

Test Methodology	Test Method/ Applicable Standard(s)	Acceptance Criteria	Result
Tensile Strength	ASTM D5034/ ASTM F2407-20	≥ 30 N (≥ 7 lbf)	PASS
Tear Strength	ASTM D5587/ ASTM F2407-20	≥ 10 N (≥ 2.3 lbf)	PASS
Seam Strength	ASTM D1683/ ASTM F2407-20	≥ 30 N (≥ 7 lbf)	PASS
Hydrostatic Resistance	AATCC Method 127/ ANSI/AAMI PB70	≥ 50 cm per AAMI PB70 for Level 3	PASS
Impact Penetration	ATCC Method 42/ ANSI/AAMI PB70	≤ 1.0 g per AAMI PB70 for Level 3	PASS
Lint Generation	ISO 9073-10	---	Coefficient for linting is 3 for both predicate and subject device
Flammability	16 CFR 1610	Pass Class I Flammability	PASS Class I
Snap Strength	ASTM D4846-96	Fasteners provide peel strength of ≤ 1.5 lbf (easy doff) and shear force ≥ 4.5 lbf (secure)	PASS

Test Methodology	Test Method/ Applicable Standard(s)	Acceptance Criteria	Result
Evaporative Resistance	ASTM F1868-17	Evaporative resistance of critical zone (average of 3 specimens) ≤ 350 Pa m^2/W; evaporative resistance of the back mesh (2-ply average of 3 specimens) ≤ 5 Pa m^2/W	PASS
Critical Zone Fabric Weight Testing	ASTM D3776/D3776M-20	---	Gown critical zone fabric construction weighs less than 7.83 OSY
Use Life Tracking	---	QCM label is legible and RFID Chip can be read at the beginning and end of use life (after 60 reuses)	PASS
Cytotoxicity	ISO 10993-5	Less than/equal to grade 2 (mild reactivity)	PASS
Sensitization	ISO 10993-10	No evidence of causing delayed dermal contact sensitization	PASS
Irritation	ISO 10993-23	No erythema, no edema	PASS
Pyrogenicity	USP <151>/ ISO 10993-11	Temperature rise within acceptable limits	PASS
Acute Systemic Toxicity	ISO 10993-11	No mortality or evidence of systemic toxicity	PASS

SUMMARY OF CLINICAL TESTING

Not Applicable

CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that ProPel SG3™ Surgical Gown is as safe, as effective, and performs as well as or better than the predicate device.