November 10, 2022

Feliks Plastik Laminasyon Ve Ambalaj Malzemeleri
℅ Darren Reeves
President
DP Distribution & Consulting, LLC
12240 Hunting Horn Lane
Rockville, Virginia 23146

Re: K221139
Trade/Device Name: Bodygard SFS Surgical Gown Level 4
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: October 7, 2022
Received: October 11, 2022

Dear Darren Reeves:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
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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)*
K221139

Device Name
Bodygard SFS Surgical Gown Level 4

Indications for Use *(Describe)*
The Bodygard SFS Surgical Gown Level 4 is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Bodygard SFS Surgical Gown Level 4 met the requirements for Level 4 classification.

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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K221139 510(k) Summary
Traditional 510(k)

In accordance with 210 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Bodygard SFS Surgical Gown Level 4 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

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Preparation Date: 11/08/2022

Subject Device:

Trade Name: Bodygard SFS Surgical Gown Level 4
510(k) #: K221139
Common Name: Surgical Gown
Classification Name: Surgical Gown (21 CFR 878.4040, Product Code FYA)

Predicate Device: Disposable Surgical Gown, Disposable Reinforced Surgical Gown (K212869)

Device Description:

The Bodygard SFS Surgical Gown Level 4 is a single use poly reinforced surgical gown, SMS Nonwoven/Film/SMS Nonwoven (SFS) that provides AAMI Level 4 liquid barrier protection in the critical zones (arms and chest) and non-critical zones of the gown. The Bodygard SFS Surgical Gown Level 4 is manufactured using ultrasonic bonding technique are available in the color blue and four different sizes (M, L, XL, and XXL).

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. The Bodygard SFS Surgical Gown Level 4, meets the requirements for Level 4 classification, are disposable medical devices and provided in sterile.

Intended Use and Indication for Use:
The Bodygard SFS Surgical Gown Level 4 is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Bodygard SFS Surgical Gown Level 4 met the requirements for Level 4 classification.

Comparison of Predicate Device:

Table 2 Technological Characteristic Comparison

Elements of Comparison	**Proposed Device** **Bodygard SFS Surgical Gown Level 4**	**Predicate Device K212869** **Disposable Surgical Gown, Disposable Reinforced Surgical Gown (Sterile)**	**Remark**
510 (k) Number	K221139	K212869	N/A
Product Code	FYA	FYA	Same
Regulation Number	21CFR 878.4040	21CFR 878.4040	Same

Indication for Use	The Bodygard SFS Surgical Gown Level 4 is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Bodygard SFS Surgical Gown Level 4 met the requirements for Level 4 classification.	Disposable Surgical Gown and Disposable Reinforced Surgical Gown are intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.	Similar
Style	Poly Reinforced	Non-reinforced/Reinforced	Similar
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Material	Complete gown has 4 components/Component A Fabric SMS Nonwoven/ Lamination Reinforcement Film/SMS Nonwoven (SFS)/Component B Knit Cuff Component C Velcro/Component D Sewing thread SMS	Level 4 Standard Surgical Gown: SMS nonwoven, PE film, Polyester and blue masterbatch; Level 4 Reinforced Surgical Gown: SMS nonwoven Polyester, PE film reinforced film and Blue masterbatch	Similar
Weight per square	60 g/m²	65 g/m²	Similar
Label and Labeling	Conforms with 21 CFR Part 801	Conforms with 21 CFR Part 801	Same
Size	M, L, XL, and XXL	S, M, L, XL, XXL, and XXXL	Similar
Break Strength (ASTM D 5034-09)	>30 N	>30 N	Same

Tear Strength (ASTM D5587-14)	>20 N	>20 N	Same
Seam Strength (ASTM D1683-17)	>50 N	>50 N	Same
Linting (ISO 9073-10:2003)	Log10 < 4	Log10 < 4	Same
Flammability (16 CFR 1610)	Class I	Class I	Same
Hydrostatic pressure (AATCC 127)	>50 cm	>50 cm	Same
Water impact (AATC Test Method 42)	≤1.0 g	≤1.0 g	Same
Barrier Penetration (ASTM F1671)	No detectable transfer of the Phi-X174 Bacteriophage	No detectable transfer of the Phi-X174 Bacteriophage	Same
Barrier Protection Level	Level 4 per AAMI PB 70	Level 4 per AAMI PB 70	Same
Water Vapor Transmission (ASTM D6701)	Average transmission/per-meation rate 4.360 g/m² day	Unknown	Unknown
Elements of Comparison	**Proposed Device**	**Predicate Device**	**Remark**
Biocompatibility			
Cytotoxicity (ISO 10993-5)	No Cytotoxicity	No Cytotoxicity	Same
Skin Irritation (ISO 10993-10)	No Irritation	No Irritation	Same
Sensitization (ISO 10993, 10993-1, and 10993-10)	No Sensitization	No Sensitization	Same
Sterile	Ethylene Oxide (EO), SAL=10-6 Sterile	Ethylene Oxide (EO), SAL=10-6 Sterile	Same
Ethylene Oxide Residuals (ISO 10993-7)	EO <4 mg/device; ECH <9 mg/device. The device met requirements of ISO 10993-7:2008	Data not available, required to meet the requirements of ISO 10993-7:2008	Unknown

Summary of Non-Clinical Test:

Non-Clinical Tests:

The product was tested in alignment with "Guidance on Premarket Notification 510(k) Submissions for Surgical Gowns and Surgical" Guidance Document

Table 3:

Test Method	Purpose	Acceptance Criteria	Results
AATCC 127	Water resistance Hydrostatic Pressure	>50 cm H2O (AQL 4%, RQL=20%)	All test samples were > 50 cm H2O
AATCC 42	Water Resistance impact penetration	<1.0 g penetration (AQL 4%, RQL=20%)	All test samples were < 1 g penetration
ASTM D 5034-09	Breaking Strength	>30 N (AQL 4%, RQL=20%)	All test samples were >30N
ASTM D5587-14	Tearing Strength	>20 N (AQL 4%, RQL=20%)	All test samples were >20 N
16 CFR 1610	Flammability testing	Class I	Meets Class I
ASTM D1683-17	Seam Strength	>50 N (AQL 4%, RQL=20%)	All test samples were >50 N
D6701-16	Water vapor transmission of Nonwoven and plastic Barriers	>500 g/m² Day WVTR	Passed
ASTM D3776/D	Mass Per Area (Weight) of fabric	Has met acceptance criteria according to ASTM F2407	Has met acceptance criteria according to ASTM F2407
ASTM F1670	Resistance by synthetic Blood	No Penetration at 2 psi (13.8 kPA)	Passed
ASTM F1671	Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens	No detectable transfer of the Phi-X174 Bacteriophage	Passed
ISO 9073-10:2003	Lint and Other particles generation in the dry state	Log 10<4	Below Log10<4 Passed
ASTM D4169-16	Performance testing of shipping containers and systems	Products must withstand the distribution environment	Passed

ASTM F88-07A	Seal strength of Flexible Barrier Materials	Package Seal integrity must be intact.	Passed
ASTM F2096-04	Detecting Gross Leaks in medical packaging by internal pressurization (Bubble test)	Package integrity must be intact without failed seal locations.	Passed
ASTM F1980-07	Accelerated Aging of Sterile Barrier Systems for medical devices	Package integrity must be intact after accelerated aging	Passed
ISO 10993-5	Biological Evaluation of medical devices – Part 5: tests for In vitro cytotoxicity of medical devices	Device must not be cytotoxic	Under the condition of the testing, the device is non-cytotoxic
ISO 10993-10	Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitization / Irritation	Device must not be irritant	Under the condition of the testing, the device is not an irritant
ISO 10993-10	Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitization/ sensitization	Device must not be sensitizer	Under the condition of the testing, the device is not a sensitizer
ISO 10993-7	Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals	Residual Ethylene oxide levels must be below limits EO <4 mg/device. The device met requirements of ISO 1099-7:2008	Ethylene Oxide residual levels are below limitations. Data not available, required to meet the requirements of ISO 10993-7:2008

Summary of Clinical Tests:

No clinical tests were performed.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the device Bodygard SFS Surgical Gown Level 4 is as safe, as effective, and performs as well as or better than the legally marketed predicate device Disposable Surgical Gown, Disposable Reinforced Surgical Gown.