February 24, 2022

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

Re: K202845
Trade/Device Name: Bodygard SFS Surgical Gown Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: February 8, 2022
Received: February 8, 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,

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)*
K202845

Device Name
BodyGard SFS Surgical Gown Level 3

Indications for Use *(Describe)*
The Bodygard SFS Surgical Gown Level 3 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 3 met the requirements for Level 3 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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510(k) Summary-K202845
Traditional 510(k)

In accordance with 21 CFR §807.92 and the following information is provided for the Bodygard SFS Surgical Gown Level 3 510(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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Date: 02/17/2022

Subject Device: **Trade Name:** Bodygard SFS Surgical Gown Level 3
Common Name: Surgical Gown
Classification Name: Surgical Gown (21 CFR 878.4040, Product Code FYA)

Predicate Device: Medical Surgical Gowns (K202844)

Purpose and Device Description:

The Bodygard SFS Surgical Gown Level 3 is a poly reinforced surgical gown, SMS Nonwoven/Film/SMS Nonwoven (SFS) that provides AAMI Level 3 liquid barrier protection in the critical zones (arms and chest) and non-critical zones of the gown. The Bodygard SFS Surgical Gown Level 3 is manufactured using ultrasonic bonding technique and are available in 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 3, meets the requirements for Level 3 classification, are disposable medical devices and provided in sterile.

Intended Use and Indication for Use:
The Bodygard SFS Surgical Gown Level 3 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 3 met the requirements for Level 3 classification.

Technological Characteristic Comparison of Predicate Device:

Table 1 Technological Characteristic Comparison

Elements of Comparison	**Proposed Device K202845** **Bodygard SFS Surgical Gown Level 3**	**Predicate Device K202844** **Medical Surgical Gowns**	**Comparison**
510 (k) Number	K202845	K202844	N/A
Product Code	FYA	FYA	Same
Regulation Number	878.4040	878.4040	Same
Indication for Use	The Bodygard SFS Surgical Gown Level 3 is a poly reinforced surgical gown, SMS Nonwoven/Film/SMS Nonwoven (SFS) that provides AAMI Level 3 liquid barrier protection in the critical zones (arms and chest) and non-critical zones of the gown. The Bodygard SFS Surgical Gown Level 3 is manufactured using ultrasonic bonding technique	The Medical Surgical Gowns is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from trans- fer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and	Similar

	and are available in 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 3, meets the requirements for Level 3 classification, are disposable medical devices and provided in sterile.	classification of protective apparel and drapes intended for use in health care facilities, the Medical Surgical Gowns met the requirements for Level 3 classification.	
Style	Poly Reinforced	Poly reinforced	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Material	Spundbond SMS polypropylene, polyester, PP Velcro	SMS Nonwoven, polyethylene	Similar
Weight per quoate	60 g/m2	55 g/m2	Similar
Size	M, L, XL, and XXL	S, M, L, XL, XXL, XXXL	Similar
Break Strength	>30N	>20N	Similar
Tear Strength	>20N	>20N	Similar
Seam Strength	> 50 N	Not known	
lint	Log10＜4	Log10＜4	Same
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50cm	>50cm	Same
Water impact	≤1.0 g	≤1.0 g	Same

Level	Level 3 Per AAMI PB70	Level 3 per AAMI PB 70	Same
Water Vapor Transmission	Average transmission/permeatio n rate 4.360 gm/m2 day	Unknown	Unknown
Elements of Comparison	**Proposed Device**	**Predicate Device**	**Remark**
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Skin Irritation	No Irritation	No Irritation	Same
Sensitization	No Sensitization	No Sensitization	Same
Sterile	Ethylene Oxide (EO), SAL=10^{-6}	Ethylene Oxide (EO), SAL=10^{-6}	Same

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

Test Method	**Purpose**	**Acceptance Criteria**	**Results**
AATCC 127	Water resistance Hydrostatic Pressure	>50cmH2O (AQL 4%, RQL=20%)	All were > 50cmH2O
AATCC 42	Water Resistance impact penetration	<1.0 g penetration (AQL 4%, RQL=20%)	All were < 1 g penetration
ASTM D 5034-09	Breaking Strength	>30 N (AQL 4%, RQL=20%)	All were >30N
ASTM D5587- 14	Tearing Strength	>20 N (AQL 4%, RQL=20%)	All were >20 N
16 CFR 1610	Flammability testing	Class I	Meets Class I
ASTM D4169- 16	Seam Strength	>50 N (AQL 4%, RQL=20%)	All were>50 N
D6701-16	Water vapor transmission of	>500gram/m2 Day WVTR	Passed

	Nonwoven and plastic Barriers		
ASTM D3776/D	Mass Per Area (Weight) of fabric	-	Has met acceptance criteria
ASTM F1670	Resistance by synthetic Blood	No Penetration at 2 psi (13.8 kPA)	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 with-stand 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 in-ternal pressurization (Bubble test)	Package integrity must be intact with- out 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	Device is noncytotoxic
ISO 10993-10	Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitization / Irritation	Device must not be irritant	Device is not an irritant
ISO 10993-10	Biological Evaluation of medical devices – Part	Device must not be sensitizer	Device is not a sensitizer

	10: Tests for irritation and skin sensitization / sensitization		
ISO 10993-7	Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization Residuals	Residual Ethylene oxide levels must be below limits	Ethylene Oxide residual levels are below limitations

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 3 is as safe, as effective, and performs as well as or better than the legally marketed predicate device Medical Surgical Gowns.