July 22, 2022

Barco Tekstil Sanayi ve Ticaret A.S.
℅ Mehmet Örmeci
Consultant
MEDCER Uluslararasi Medikal Belgelendirme A.S.
Taspinar Mah. 2800 Cad. A-2 Apt. No:6 B/49
Ankara, Golbasi 06830
Turkey

Re: K211399
Trade/Device Name: Sterile Level 3 Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 21, 2022
Received: June 21, 2022

Dear Mehmet Örmeci:

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, M.D., 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211399

Device Name
Sterile Level 3 Surgical Gown

Indications for Use *(Describe)*
The Sterile Level 3 Surgical Gown 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, the surgical gowns 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Submitter	BARCO TEKSTIL SANAYI VE TICARET A.S.
510(k) Submitter Adress	Muratbey Mahallesi Karatoprak Caddesi No. 17 Catalca Istanbul, TR 34540
510(k) Submitter Telephone No	Phone: +90 212 867 49 00 Fax: +90 212 494 32 34
Primary Correspondent Contact Information	Mehmet Fatih Ormeci (Consultant) +90-532-397-3043 mformeci@gmail.com Fax: +90 212 494 32 34
Summary Preparation Date	07/21/2022

Trade Or Proprietary Name	Sterile Level 3 Surgical Gown
Common Name	Surgical Gown
Classification Name	Gown, Surgical
Regulation Number	21 CFR 878.4040
Product Code	FYA

Subject Device Name	**Subject Device 510k No**	**Predicate Device 510k No**	**Predicate Device Manufacturer**
Sterile Level 3 Surgical Gown	K211399	K202706	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD. Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China

Device Description

Sterile Level 3 Surgical Gown

The Sterile Level 3 Surgical Gown is a Class II medical device under the FDA product code of FYA, General & Plastic Surgery Panel, and Regulation 21 CFR 878.4040. The device description of the Sterile Level 3 Surgical Gown is in accordance with the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued on August 1, 1993 and Guidance for Industry and FDA Staff: Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings, issued on December 9, 2015.

The Sterile Level 3 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. The proposed devices are single use and EtO sterilized. The Sterile Level 3 Surgical Gowns are available in six sizes, including S, M, L, XL, XXL and XXXL. The belt ties are integrated into the body. Per ANSI/AAMI PB70:2012 Liquid barrier

performance and classification of protective apparel and drapes intended for use in health care facilities, the proposed devices meet the requirements for Level 3 classification. The Sterile Level 3 Surgical Gown is provided as blue color. The Sterile Level 3 Surgical Gown is made of 50 Gsm PP (SMMS nonwoven polypropylene).

Model Name	Size	Reference No	Colour	Level	Fabric	Sterilization	FDA Code
Sterile Level 3 Surgical Gown	S	GS101-L3U-50S-S	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA
Sterile Level 3 Surgical Gown	M	GS101-L3U-50S-M	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA
Sterile Level 3 Surgical Gown	L	GS101-L3U-50S-L	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA
Sterile Level 3 Surgical Gown	XL	GS101-L3U-50S-XL	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA
Sterile Level 3 Surgical Gown	XXL	GS101-L3U-50S-XXL	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA
Sterile Level 3 Surgical Gown	XXXL	GS101-L3U-50S-XXXL	Blue	3	50 Gsm PP (Nonwoven Polypropylene)	Sterile	FYA

Indications For Use

Sterile Level 3 Surgical Gown

The Sterile Level 3 Surgical Gown 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, the surgical gowns met the requirements for Level 3 classification.

Technological Characteristics

Shown below is the technological characteristics comparison of the subject device and the predicate device.

Item	Subject Device Sterile Level 3 Surgical Gown K211399	Predicate Device K202706	Remark
Product Code	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Intended Use/Indications for Use	The Sterile Level 3 Surgical Gown 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, the surgical gowns met the requirements for Level 3 classification.	Surgical gowns 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, the surgical gowns met the requirements for Level 3 classification.	Same
Style	Non-reinforced	Non-reinforced	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Weight per square (g)	50 Gsm	55g/m2	**Different 1.1.**
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL, XXXL	Same
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cm	>50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same
Breaking strength	>20N	>20N	Same
Tearing strength	>20N	>20N	Same
Linting	Log10<4	Log10<4	Same
Material	SMMS nonwoven polypropylene	SMS polypropylene nonwoven + PE	**Different 1.2**
Level	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
Biocompatibility			
Cytotoxicity	According to ISO 10993-5: 2009, the test material demonstrated no cytotoxic effect under the condition of this study.	No Cytotoxicity	Same
Irritation	The test result showed that the irritant response of the test article extract was categorized as negligible under the test condition. Complies with ISO 10993-10:2010.	No Irritation	Same
Sensitization	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. Complies with ISO 10993-10:2010.	No Sensitization	Same
Sterile	Sterile	Sterile/Non-sterile	Same

Discussion

Sterile Level 3 Surgical Gown

The indications for use statement for the subject device is identical to the predicate device. There are no technological differences between the predicate and subject devices except for the following:

- Different 1.1: The subject device is 50 gsm and the predicate device is 55 gsm. These slight differences have no adverse effect on clinical safety and performance. All of the subject device are tested in accordance with related standards given in Non-Clinical Testing Section of this summary. The requirements of the standards are met.

- Different 1.2: Subject device is made from SMS nonwoven polypropylene and the predicate device is made from SMS nonwoven polypropylene + PE. The subject device biocompatibility results and performance results demonstrate product safety. These slight differences have no adverse effect on clinical safety and performance. All of the subject device are tested in accordance with related standards given in Non-Clinical Testing Section of this summary. The requirements of the standards are met.

The intended use, principle of operation, materials, and sterilization information for the subject device are the same as the predicate device. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness.

Non-Clinical Performance Testing

Sterile Level 3 Surgical Gown

Non clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed subject device complies with the following standards:

Test Method	Purpose	Acceptance Criteria	Result
16 CFR 1610	Flammability of Textiles	Class 1	Class 1
ASTM D5034-09(2017)	Tensile Strength	≥7 lbf	Warp:20,59 lbf, Weft: 30,48 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	RIGHT ARMHOLE SEAM STRENGTH / SLIPPAGE: 8.1 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	LEFT ARMHOLE SEAM STRENGTH / SLIPPAGE: 9.8 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	RIGHT SHOULDER SEAM STRENGTH / SLIPPAGE: 14.1 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	LEFT SHOULDER SEAM STRENGTH / SLIPPAGE: 14.7 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	RIGHT SLEEVE SEAM STRENGTH / SLIPPAGE: 9.0 lbf
ASTM D1683/ D1683M-17(2018)	Seam Strength (Garment)	≥7 lbf	LEFT SLEEVE SEAM STRENGTH / SLIPPAGE: 9.1 lbf
ASTM D5587-15 (2019)	Tear Strength	≥ 2.3 lbf	Warp:5,817 lbf, Weft: 8,958 lbf
ISO 9073-10	EVALUATION OF PARTICLES RELEASE	log 10 ≤4	It is suitable according to ≤ 4 criteria.
AATCC 127:2017 Option 2	Water Resistance: Impact Penetration Test	≥ 50 cm	53,7 - 65,8 cm. LEVEL 3.
AATCC 42:2007	Impact Penetration Test	no more than 1.0 grams (g).	Max 0.08. LEVEL 3

ISO 10993-7:	EO Residue Test	10µg/cm²	Not detected.
ISO 10993-5	Cytotoxicity	Not Cytotoxic	Not Cytotoxic
ISO 10993-10	Sensitization	Not Sensitive	Not Sensitive
ISO 10993-10	Irritation	Not Irritant	Not Irritant
ASTM F88/F88M	Seal Strength of Flexible Barrier Materials	Package Seal integrity must be intact.	Passed
ASTM F1929:2015	Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	No leakage observe	Passed
ASTM D3776 / D3776M - 20	Mass Per Unit Area (Weight) of Fabric	-	50 GSM

Clinical Performance Testing

The clinical performance testing is not applicable to the subject device.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device.