February 16, 2023

Bayteks Teknik Tekstil San. ve Tic. A.S.
℅ Sarah Fitzgerald
Senior Consultant, Quality and Regulatory Affairs
Emergo by UL
2500 Bee Cave Road, Building 1
Suite 300
Austin, Texas 78746

Re: K213844
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: February 13, 2023
Received: February 15, 2023

Dear Sarah Fitzgerald:

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, MD, 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)*
K213844

Device Name
Surgical Gown

Indications for Use *(Describe)*
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. This device is provided sterile.

Per ASNI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the standard (non-reinforced) surgical gowns meet Level 2 classification and the reinforced surgical gowns meet 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.**

# 510(k) Summary

# SURGICAL GOWN

# K213844

The following information is provided in accordance with 21 CFR 807.92 for the premarket 510(k) summary:

**1. Submission Sponsor**

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**2. Submission Correspondent**

Emergo Global Consulting, LLC
2500 Bee Cave Road Building
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Contact: Sarah Marie Fitzgerald, Senior Consultant, Quality and Regulatory Affairs

**3. Date Prepared**

February 15, 2023

**4. Device Identification**

| | |
|---|---|
| Trade/Proprietary Name: | Surgical Gown |
| Common/Usual Name: | Surgical Gown |
| Regulation Number: | 21 CFR 878.4040 |
| Product Code: | FYA |
| Class: | II |
| Review Panel: | General Hospital |

**5. Legally Marketed Predicate and Reference Devices**

Predicate Device name: Surgical Gown
510(k) number: K202706

Manufacturer: B.J.ZH.F. Panther Medical Equipment Co., Ltd.

Reference Device name: Medline Surgical Gown
510(k) number: K190950
Manufacturer: Medline Industries, Inc.

**6. Indication for Use Statement**

Surgical gowns are 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. This device is provided sterile.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the standard (non-reinforced) surgical gowns meet Level 2 classification and the reinforced surgical gowns meet Level 3 classification.

**7. Device Description**

Surgical gowns are intended to be worn by healthcare professionals to protect both the patient and the healthcare professional from the transfer or microorganisms, body fluids, and particulate material. The proposed devices are single use, disposable medical devices and ethylene oxide (EO) sterilized. They are available in six sizes: S, M, L, XL, XXL and XXXL.

The proposed surgical gowns are constructed of a Spunbond, Meltblown, Supunbond (SMS) nonwoven material, with cuffs made of polyester and elastic, offered in standard (non-reinforced) and reinforced surgical gowns, in blue color.

**8. Comparison of technological characteristics with the Predicate**

The following table compares the subject device to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

**Table 1 – Comparison of Technological Characteristics**

| **Attribute** | **Subject Gown K213844** | **Predicate Gown K202706** | **Reference Device K190950** | **Comparison** |
|---|---|---|---|---|
| **Product Code** | FYA | FYA | FYA | Same |
| **Regulation Number** | 878.4040 | 878.4040 | 878.4040 | Same |
| **Class** | II | II | II | Same |
| **Intended Use** | To protect both patients and healthcare personnel from the | To protect both patients and healthcare personnel from the transfer of | To protect both patients and healthcare personnel | Same |

| Attribute | Subject Gown K213844 | Predicate Gown K202706 | Reference Device K190950 | Comparison |
|---|---|---|---|---|
| | transfer of microorganisms, body fluids, and particulate material. | microorganisms, body fluids, and particulate material. | from the transfer of microorganisms, body fluids, and particulate material. | |
| **Indication for Use** | Surgical gowns are 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. This device is provided sterile. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the standard (non-reinforced) surgical gowns meet Level 2 classification and the reinforced surgical gowns meet 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 meet the requirements for Level 3 classification. | The [multiple named gowns] are sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The [gowns] meet the respective level requirements of ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities. The [gowns] have been validated using an ethylene oxide (EtO) sterilization process. The [gowns] are also sold as bulk single use, non-sterile, to repackager/relabeler establishments for further packaging and sterilization using the validated EtO sterilization method according to ISO 11135-1 prior to being provided to the end user. | Similar |
| **Prescription or OTC** | OTC | OTC | OTC | Same |
| **Barrier Level (per ANSI/AAMI PB70)** | Standard: Level 2<br>Reinforced: Level 3 | Level 3 | Standard: Level 2<br>Reinforced: Level 3 | Similar |

| Attribute | Subject Gown K213844 | Predicate Gown K202706 | Reference Device K190950 | Comparison |
|---|---|---|---|---|
| **Device Materials** | SMS Polypropylene nonwoven, Polyester | SMS Polypropylene nonwoven, Polyester | SMS Polypropylene nonwoven, Polyester | Same |
| **Device Design** | Standard (nonreinforced) & Reinforced | Standard (nonreinforced) | Standard (nonreinforced) & Reinforced | Similar |
| **Durability** | Single-Use (Disposable) | Single-Use (Disposable) | Single-Use (Disposable) | Same |
| **Sizes** | Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), Extra Extra Extra Large (XXXL) | Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), Extra Extra Extra Large (XXXL) | Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), Extra Extra Extra Large (XXXL) | Same |
| **Color** | Blue | Blue | Blue | Same |
| **Flammability 16 CFR Part 1610** | Class I | Class I | Class I | Same |
| **Hydrostatic Pressure AATCC 127** | Level 2 > 20 cm<br>Level 3 > 50 cm | > 50 cm | - | Similar |
| **Impact Penetration AATCC 42** | <1.0 g water | <1.0 g water | - | Same |
| **Tear Strength ASTM D 5587 (Trapezoid Procedure)** | Length Direction > 20 N<br>Width Direction > 20 N | > 20 N | - | Same |
| **Tensile Strength ASTM F 2407 (ASTM D 5034)** | Length Direction ≥ 115N<br>Width Direction ≥ 115N | > 20 N | - | Same |
| **Seam Strength ASTM D1683** | ≥ 20 N | > 20 N | - | Same |
| **Linting ISO 9073-10** | $Log_{10}$ <4 | $Log_{10}$ <4 | - | Same |
| **Sterilization Method** | Ethylene Oxide | Ethylene Oxide Sterilized and Non-Sterile Versions | - | Similar |
| **EO and ECH Residuals** | EO: not detected<br>ECH: not detected | Passed | - | Same |
| **Biocompatibility Cytotoxicity ISO 10993-5** | Non-cytotoxic | Non-cytotoxic | - | Same |

| Attribute | Subject Gown K213844 | Predicate Gown K202706 | Reference Device K190950 | Comparison |
|---|---|---|---|---|
| **Biocompatibility Irritation ISO 10993-10** | Non-irritating | Non-irritating | - | Same |
| **Biocompatibility Sensitization 10993-10** | Non-sensitizing | Non-sensitizing | - | Same |

## 9. Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrate that the proposed device complies with the following standards by passing all applicable acceptance criteria.

**Table 2 – Summary of Performance Testing**

| Test Method | Purpose | Acceptance Criteria | Result |
|---|---|---|---|
| AATCC 127 | Hydrostatic pressure | Level 2 > 20 cm<br>Level 3 > 50 cm | Pass |
| AATCC 42 | Impact penetration | ≤1g | Pass |
| ASTM F 2407 (ASTM D 5034) | Tensile Strength | Length Direction ≥ 115N<br>Width Direction ≥ 115N | Pass |
| ASTM D 5587 | Tearing strength by Trapezoid Procedure | Length Direction > 20 N<br>Width Direction > 20 N | Pass |
| ASTM D 1683 | Seam strength | ≥ 20 N | Pass |
| 16 CFR Part 1610 | Flammability of Textiles | Class 1 | Class 1 |
| ISO 10993-7 | Ethylene oxide residues | EO residual ≤ 4 mg/device<br>ECH residual ≤ 9 mg/device | Pass |
| ISO 9073-10 | Linting | Log10 <4 | Pass |
| Biocompatibility | Cytotoxicity | ISO 10993-5:2009 | ISO 10993-5; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic |
| | Irritation | ISO 10993-10:2010 | ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-irritating |
| | Sensitization | ISO 10993-10:2010 | ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-sensitizing |

## 10. Clinical Performance Data

No clinical study is included in this submission.

**11. Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202706.