February 10, 2023

Sejong Healthcare Co., Ltd.
℅ Seohee Kwon
RA Manager
K-Bio Solutions
201 South 4th St, Suite 727
San Jose, California 95112

Re: K220435
Trade/Device Name: SEJONG Surgical Gown Soft
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: January 12, 2023
Received: January 19, 2023

Dear Seohee Kwon:

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
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)*
K220435

Device Name
SEJONG Surgical Gown Soft

Indications for Use *(Describe)*
The SEJONG Surgical Gown Soft is 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 SEJONG Surgical Gown Soft meets the Level 3 requirements of ANSI/AAMI PB70:2012. Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities. The SEJONG Surgical Gown Soft has been validated using ethylene oxide (EtO) sterilization process. The SEJONG Surgical Gown Soft is also sold as bulk single-use, non-sterile, to repackager/relabeler establishments for further packaging and sterilization using the validated EO sterilization method according to ISO 11135 prior to being provided to the end user.

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
K220435

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

I. Submitter's Information

- Company: Sejong Healthcare Co., Ltd. Address: 1502-1, Tongil-ro, Paju-eup,
- Paju-si, Gyeonggi-do, 10836, Republic of Korea
- Tel : 82-31-942-1700
- Fax: 82-31-942-1801

510(k) Submission Correspondent: Jian Park, RA Manager K-Bio Solutions
jian.park@kbiotechsolutions.com
Tel: 82-2-597-2700, USA: 408-750-7843

Date Prepared: January 25th, 2023

II. Device Information

- Trade Name of Device: Sejong Surgical Gown Soft
- Common Name of Device: Gown, Surgical
- Regulation Name: Surgical Apparel
- Review Panel: General Hospital
- Regulation Number: 21 CFR 878.4040
- Regulatory Class: Class II
- Product Code: FYA
- Model Number: GSGW971 (SEJONG Surgical Gown Soft, Size: Medium) GSGW972 (SEJONG Surgical Gown Soft, Size: Large) GSGW973 (SEJONG Surgical Gown Soft, Size: X-Large) GSGW975 (SEJONG Surgical Gown Soft, Size: XX-Large)

III. Predicate Device

- Medline Level 3 Surgical Gown (Sirus Non-Reinforced)
- 510(k) number: K190950
- Manufacturer: Medline Industries, Inc.
- Product Code: FYA
- Regulation Number: 21 CFR 878.4040
- The predicate device has not been subject to a design-related recall.

IV. Intended Use/Indications for Use

The SEJONG Surgical Gown Soft is 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 SEJONG Surgical Gown Soft meets the Level 3 requirements of ANSI/AAMI PB70:2012. Liquid barrier performance and classification of

protective apparel and drapes intended for use in healthcare facilities. The SEJONG Surgical Gown Soft has been validated using ethylene oxide (EtO) sterilization process. The SEJONG Surgical Gown Soft is also sold as bulk single-use, non-sterile, to re-packager /re-labeler establishments for further packaging and sterilization using the validated EO sterilization method according to ISO 11135 prior to being provided to the end user.

V. Device Description

The SEJONG Level 3 Surgical Gowns is a non-reinforced design and available in 4 sizes ranging from medium to XX-large. Below Table provides model number of the Sejong Surgical Gown Soft. The chest and sleeve critical zones, as well as the overall body, are constructed from a blue polyolefin/polypropylene SMMMS (Spunbound, meltblown, meltblown, meltblown, spunbound). Sejong Surgical Gown Soft has been tested according to ANSI/AAMI PB70:2012 and meets and AAMI Level 3 barrier level protection for a surgical gown. Sejong Surgical Gown Soft is non-reinforced, single use, disposable medical device that will be provided in both a sterile packaging configuration and a variety of sizes.

Device Names, Model Numbers of the Sejong Surgical Gown Soft

No.	Device Name	Model Number	Size
1	SEJONG Surgical Gown Soft	GSGW971	Medium
2	SEJONG Surgical Gown Soft	GSGW972	Large
3	SEJONG Surgical Gown Soft	GSGW973	X-Large
4	SEJONG Surgical Gown Soft	GSGW975	XX-Large

VI. Technological Characteristic Comparison Table

Category	<Proposed Device>	< Predicate Device > (K190950)	Comparison
Product Name	Sejong Surgical Gown Soft	Medline Level 3 Surgical Gown (Sirus Non-Reinforced)	N/A
510(k) Reference	K220435	K190950	N/A
Product Owner	Sejong Healthcare Co., Ltd.	Medline Industries, Inc.	N/A

Category	<Proposed Device>	< Predicate Device > (K190950)	Comparison
Intended Use/Indications for Use	The SEJONG Surgical Gown Soft 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 SEJONG Surgical Gown Soft meet the Level 3 requirements of ANSI/AAMI PB70:2012. Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities. The SEJONG Surgical Gown Soft have been validated using ethylene oxide (EtO) sterilization process. The SEJONG Surgical Gown Soft is also sold as bulk single-use, non-sterile, to re-packager /re-labeler establishments for further packaging and sterilization using the validated EO sterilization method according to ISO 11135 prior to being provided to the end user.	The Medline Level 2 Surgical Gown (Eclipse Non Reinforced) and Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirus Non-Reinforced & Sirus Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced) 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 Medline Level 2 Surgical Gown and the Medline Level 3 Surgical 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 Medline Level 2 Surgical Gown and the Medline Level 3 Surgical Gowns have been validated using an ethylene oxide (EtO) sterilization process. The Medline Level 2 Surgical Gown and the Medline Level 3 Surgical 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	Same
Regulation number	21 CFR 878.4040	21 CFR 878.4040	Same
Product Code	FYA	FYA	Same
Color	Blue	Blue	Same

Category	<Proposed Device>	< Predicate Device > (K190950)	Comparison
Design Features	Available in Fabric Non- Reinforced Neck and Belt Ties Knit Cuffs Set-in/Standard Sleeves	Available in Fabric Reinforced and Non-Reinforced, Hook and Loop Closure at neck Belt Ties Knit Cuffs Transfer Tab Raglan or Set-in/Standard Sleeves	Similar
Size	Medium to XX-Large	Small to XXXX-Large	Similar
Materials	Nonwoven SMMMS polypropylene/Polyolefin	Nonwoven SMS polypropylene/Polyolefin	Same
Performance Specifications	Level 3 PB70 Barrier Protection	Level 3 PB70 Barrier Protection	Same
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Surface, Intact, < 24 hours	Surface, Intact, < 24 hours	Same
Sterile vs. Non-Sterile	Sterile	Sterile	Same
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
EO and ECH Residuals	EO: not detectable ECH: not detectable	Pass	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Flammability	Meets requirements of Flame Resistant CPSC 1610 Class 1	Meets requirements of Flame Resistant CPSC 1610 Class 1	Same
Impact Penetration AATCC 42	≤1.0 g AQL: 4%	≤1.0 g AQL: 4%	Same
Hydrostatic Pressure Test AATCC 127	≥ 50cmH2O AQL: 4%	≥ 50cmH2O AQL: 4%	Same
Tensile strength ASTM D5034-09	Length ≥ 30N Width ≥ 30N	Length ≥ 30N Width ≥ 30N	Similar
Tear resistance ASTM D5587 ASTM D5733	Length ≥ 10N Width ≥ 10N	Length ≥ 10N Width ≥ 10N	Similar
Linting	Log_{10}<4	Log_{10}<4	Same
Cytotoxicity ISO 10993-5	Non-cytotoxic	Non-cytotoxic	Same
Irritation ISO 10993-10	Non-irritating	Non-irritating	Same
Sensitization ISO 10933-10	Non-sensitizing	Non-sensitizing	Same

VII. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is equivalent to the predicate device. The test results demonstrate that the proposed device complies

with the following standards by passing all applicable acceptance criteria and is equivalent to the predicate device.

Test Methodology	Purpose	Acceptance Criteria	Results
AATCC 42	Assess resistance to water impact penetration	Level 3, ≤1.0g	Pass
AATCC 127	Assess hydrostatic resistance	Level 3, ≥50cm	Pass
ASTM D5034	Assess adequate tensile strength	Length ≥ 30N Width ≥ 30N	Pass
ASTM D5587 ASTM D5733	Assess adequate tear resistance	Length ≥ 10N Width ≥ 10N	Pass
ASTM D1683	Assess adequate seam strength	Sleeve Seam: ≥ 30N Armhole Seam: ≥ 30N Shoulder Seam: ≥ 30N	Pass
Bursting Strength ASTM D3787 ISO 13938-1	Assess adequate bursting resistance	≥ 5.80 psi	Pass
ISO 9073-10	Assess acceptable lint and other particles generation in the dry state	Log10 < 4	Pass
16 CFR Part 1610	Flammability testing	Class 1	Pass
ISO 11737-2	Sterility assurance	10^{-6}	Pass
ISO 10993-5	Biocompatibility-cytotoxicity	Non-cytotoxic	Pass
ISO 10993-10	Biocompatibility-irritation	Non-irritating	Pass
ISO 10993-10	Biocompatibility-sensitization	Non-sensitizing	Pass
ISO 10993-7	Verify acceptable sterilant residuals	EO residual ≤ 4 mg/device ECH residual ≤ 9 mg/device	Pass

VIII. Clinical Test Conclusion

No clinical study is included in this submission.

IX. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K190950.