October 24, 2021

Hubei Wanli Protective Products Co. Ltd
Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500#Century Ave
Shanghai, Shanghai 200122
China

Re: K211509
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 24, 2021
Received: September 24, 2021

Dear Eva Li:

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,

For 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)*
K211509

Device Name
Surgical Gown
（Model: WLG1002-L3）

Indications for Use *(Describe)*
Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Surgical Gowns are single use, disposable medical devices; provided non-sterile.

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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Hubei Wanli Protective Products Co.ltd.
Tangwan Street ,Xiliuhe Town,Xiantao ,Hubei,China

510(K) Summary **K211509**

A. Applicant

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Prepared Date： Oct 22nd , 2021 Submission

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B. Device

Trade Name: Surgical Gown
Common Name: Surgical Gown
Model: WLG1002-L3

Regulatory Information
Classification Name: Gown, Surgical
Classification: Class II
Product code: FYA
Regulation Number: 878.4040
Review Panel: Surgical Apparel

C. Predicate device:

K170762
Cardinal Health™ Non-Reinforced Surgical Gown
Cardinal Health 200, LLC

D. Intended use of the device:

Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to

protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Surgical Gowns are single use, disposable medical devices; provided non-sterile.

E. Device Description:

Surgical Gown is designed for the medical personnel using in operation. The employed material is SMS compound non-woven fabric. The material has many good properties，such as soft， clean, good filtration and uniformity and waterproof, they are not sensitive to human beings，difficult to fluff，they don't have any peculiar smell，other matters. The Surgical gowns are for safe use in the operating room environment, i.e., lint free, free of toxic ingredients and non-fast dyes. It is a kind of Non- Reinforced surgical gown.

The chest front and sleeve critical zone of the Surgical Gown are constructed from a blue PE SMS (spun-bond, melt-blown, spun-bond) and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown. The Surgical Gown is a single use, disposable medical device that will be provided of non-sterile packaging configurations.

F. Technological Characteristics Comparison with predicate device

Table 1 General Comparison

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	Hubei Wanli Protective Products Co.ltd.	Cardinal Health™	—
510(K) number	K211509	K170762	—
Model Name	Surgical Gown	Cardinal Health™ Non-Reinforced Surgical Gown	—
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	Same
Intend use	Surgical Gown are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70).	Surgical Gown are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for	same

	The Surgical Gowns are single use, disposable medical devices; provided non-sterile.	use in health care facilities (AAMI PB70). The Surgical Gowns are single use, disposable medical devices; provided non-sterile.	
Material Composition	Sleeve/body（polyethylene SMS Nonwoven）	Polyolefin (Polypropylene) SMS nonwoven	Same
Color	Blue	Blue	same
Size	S,M,L,XL,XXL	M-S, M, L, XL, XXL	Similar
Sterility	Non-Sterile	Non-Sterile	same
Use	Single Use; Disposable	Single Use; Disposable	same
Weight per square(g)	45.9 g/m^2	31g/m^2 (1.32 oz/yd2)	Similar
Resistance to blood and liquid penetration	Level 3 AAMI PB70	Level 3 AAMI PB70	same
Biocompatibility	Under the conditions of the study, the device extract was not cytotoxic. Under the conditions of the study, the non-polar and polar device extracts were not found to be an irritant. Under conditions of the study, the non-polar and polar device extracts were not found to be a sensitizer.	Under the conditions of the study, the device extract was not cytotoxic. Under the conditions of the study, the non-polar and polar device extracts were not found to be an irritant. Under conditions of the study, the non-polar and polar device extracts were not found to be a sensitizer.	same
Sterilization Modality	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same

Table 2 performance test

Performance		Lot#20210110	Lot#20210112	Lot#20210114
Impact penetration AATCC42-2017 （≤1.0g）	Front	0.2	0.1	0.2
	Back	0.2	0.2	0.1
	Sleeve seams	0.2	0.1	0.2
	Side seams	0.2	0.2	0.1
	Belt Seam	0.1	0.1	0.1
hydrostatic pressure AATCC 127-2018 (⩾50 cmH2o)	Front	74.10	73.08	73.15
	Back	70.19	71.66	71.53
	Sleeve seams	70.95	70.34	70.89
	Side seams	73.99	75.72	77.10
	Belt Seam	56.10	56.62	58.98

Testing Item	Shoulder	Armhole	Sleeve
Seam strength(mean)	71.8N	66.0N	77.0N

Testing Item	Mean
Tensile strength, MD*	27.8 IBS
Tensile strength, CD*	19.1 IBS
Tear strength, MD*	10.7 IBS
Tear strength, CD*	6.24 IBS
Weight per Unit Area	45.9g/m2

Evaporative Resistance Of Clothing Materials	Mean
Evaporative Resistance (Ret)	0.0052 kPa.m^2/W
Intrinsic Evaporative Resistance (Ref)	0.0018 kPa.m^2/W

Flammability	Class I

Lint And Other Particles Generation In The Dry State	A:Face	B: Face
Material(Md)	2.2	2.4
Material(Uq)	2.3	2.5
Sleeve seam(Md)	2.2	2.4
Sleeve seam(Uq)	2.3	2.4

Table3 Biocompatibility Comparison

Item	**Proposed device**	**Acceptance Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.	Non-Cytotoxic	No cytotoxic
Irritation	Under the conditions of the study, the device is non-irritating.	Non-Irritating	No irritating
Sensitization	Under the conditions of the study, the device is non-sensitizing	Non-Sensitizing	No sensitizing

G. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoint safe levels using the following standards:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And

Skin Sensitization

- CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;
- ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D5587-15, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities.
- ASTM F1868-17 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate
- ISO9073-10-2003 Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state
- ASTM D1683/D1683M-17（2018）Standard Test Method for Failure in Sewn Seams of Woven Fabrics

Test Methodology	Purpose	Acceptance Criteria	Result
AATCC42-2017	Water Resistance：Impact penetration	≤1.0g	Pass
AATCC 127-2018	Water Resistance：hydrostatic pressure	≥50 cmH2o	Pass
ASTM D1683/D1683M-2017(R2018)	Seam strength (sleeve seam)	≥20N(4.5lbf)	Pass
ASTM D5587-15(2019), Tensile Testing Machine, CR	Tensile strength	≥20N(4.5lbf)	Pass
ASTM D5034-09(2017), 1-in Grab Test, Tensile Testing Machine, CRE	Tear strength	≥20N	Pass
ASTM F 1868-2017, Procedure Part B	Evaporative Resistance Of Clothing Materials	≥30cmH2O (0.00294Kpa)	Pass
ISO 9073-10:2004	Lint and other particles generation in the dry state(material)	Critical area≤4.0 Less critical area≤4.0	Pass
16 CFR Part 1610	Flammability	Class I	Pass

H. Summary of Clinical Performance Test

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn fromthe nonclinical tests performed demonstrate thatthe subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Cardinal Health™ Non-Reinforced Surgical Gown cleared under K170762.