August 12, 2021

Shandong Zhushi Pharmaceutical Group Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K210510
Trade/Device Name: Disposable Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: May 12, 2021
Received: May 12, 2021

Dear Boyle Wang:

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

For Clarence W. Murray III, 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)*
K210510

Device Name
Disposable Surgical Gown

Indications for Use *(Describe)*
The Disposable Surgical Gown is 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. In addition, 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 Disposable Surgical Gowns are single use, disposable medical devices, provided 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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510(k) Summary

K210510

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

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Contact: Mr. Junhui Zhu
Phone Number: 86-530-7150111
Fax number: 86-530-7150111 Date of
Preparation: Aug.01, 2021

Designated Submission Correspondent

Mr. Boyle Wang
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Email: Info@truthful.com.cn

2.0 Device information

Trade name: Disposable Surgical Gown
Common name: Surgical gown
Classification name: Gown, Surgical
Model(s): XS, S, M, L, XL, XXL, XXXL, XXXXL

3.0 Classification

Production code: FYA
Regulation number: 21CFR 878.4040
Classification: Class II
Panel: Surgical apparel

4.0 Predicate device information

Manufacturer: Cardinal Health 200, LLC
Device: Cardinal Health™ Non-Reinforced Surgical Gown
510(k) number: K170762

5.0 Intended Use/Indication for Use Statement

The Disposable Surgical Gown is 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. In addition, 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 Disposable Surgical Gowns are single use, disposable medical devices, provided sterile.

6.0 Device description

The Disposable Surgical Gown is composed of collar, body, sleeve and tie. The back is full opening, the neck and waist are laced, the sleeve are made of polyester elastic closure by sewing, and the rest are made of heat sealing. It has been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown

7.0 Technological Characteristic Comparison Table

Table 3 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	FYA	FYA	Identical
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Identical
Class	II	II	Identical
Product name	Disposable Surgical Gown	Cardinal Health™ Non-Reinforced Surgical Gown	Similar
510(k) No.	K210510	K170762	Different
Models	XS, S, M, L, XL, XXL, XXXL, XXXXL	M-S, M, L, XL, XXL	Similar
Intended Use/Indications for Use	The Disposable Surgical Gown is 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. In addition, 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 Disposable Surgical Gowns are single use, disposable medical devices, provided sterile.	Cardinal Health™ Non-Reinforced Surgical Gown is 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. In addition, 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	Similar

		facilities (AAMI PB70). The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices; provided sterile and non-sterile.	
Composite	Neck Closure: Hook and Loop	Neck Closure: Hook and Loop	Identical
	Belt Ties Knit Cuffs Transfer Tab	Belt Ties Knit Cuffs Transfer Tab	
Material	Polyolefin (Polypropylene) SMS nonwoven	Polyolefin (Polypropylene) SMS nonwoven	Identical
Color	Blue	Blue	Identical
Sterility	Sterile	Non-Sterile and sterile	* Gap 1
Sterilization method	EO	EO	Identical
Shelf life	2 years	No identified	* Gap 2
Single Use	Yes	Yes	Identical
Impact Penetration	<0.1g	0.0-0.10 g	Similar
Hydrostatic Resistance	>70 cm for critical zone	65-92 cm	* Gap 3
Tensile strength	Machine direction mean: 21.95 lbf; Cross direction mean: 14.41 lbf.	MD mean: 21.57 lbf; CD mean: 13.6 lbs	* Gap 4
Tear resistance	Fabric direction A mean: 5.09 lbf; Fabric direction B mean: 3.10 lbf;	MD mean: 3.47 lbf; CD mean: 5.63 lbs	* Gap 5
Flame spread	Class 1, Non Flammable	Class 1, Non Flammable	Identical
Resistance to blood and liquid penetration	Level 3 per PB70	Level 3 per PB70	Identical
Cytotoxicity	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity	Identical
Irritation	Under the condition of the test, no irritation and sensitization	Under the condition of the test, no irritation and sensitization	Identical
Sensitization			

* Gap analysis:
Gap 1: the proposed device is provided sterile, the predicate device has two types sterile and non sterile, this difference does not create additional risks to the device. Gap 2, the predicate device was not claimed clear shelf life, while the proposed device defined 2 years, the proposed device performed its shelf life study and verified its 2 years shelf life, the difference does not raise additional risk for safety and effectiveness. Gap 3-5, the two devices have some little deviation in product performance, but the difference in the performance test result does not raise additional questions for safety and effectiveness.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the related recognized standards and the requirements stated in the "Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes" dated on August, 1993.

Based on the 6-180 ASTM F2407-06 (Reapproved 2013), the subject device has been conducted the test as following:

AATCC 42-2013 Water Resistance: Impact Penetration Test

AATCC 127-2014 Water Resistance: Hydrostatic Pressure Test

ASTM D5034-09(2017) Standard Test Method for Breaking Strength and Elongation of Texile Fabrics (Grab Test)

ASTM D5587-15(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

ASTM D1683-17(2018) Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics

ASTM F1868-17(2017) Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

ISO 9073-10:2003 Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state

16 CFR Part 1610(a) Standard for The Flammability of Clothing Textiles

USP42-NF37 <85> Bacterial Endotoxins Test

ISO 11737-2:2019 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Test Methodology	Purpose	Acceptance Criteria	Results
AATCC 42	Impact Penetration	Level 3, ≤1.0g	<0.1g
AATCC 127	Hydrostatic Resistance	Level 3, ≥50cm	>70 cm for critical zone
ASTM D5034	Tensile strength	Machine direction mean: ≥18 lbf; Cross direction mean: ≥12 lbf.	Machine direction mean: 21.95 lbf; Cross direction mean: 14.41 lbf.
ASTM D5587	Tear resistance	Farbic direction A mean: ≥4.0 lbf; Farbic direction B mean: ≥2.5 lbf;	Farbic direction A mean: 5.09 lbf; Farbic direction B mean: 3.10 lbf;
ASTM D1683	Seam strength	Shoulder: ≥8.5 lbf; Arm opening: ≥5.5 lbf; Sleeve: ≥8.5 lbf;	Shoulder: 10.8 lbf; Arm opening: 6.4 lbf; Sleeve: 10.2 lbf;
ISO 9073-10	Side A (outside)	Index for Particulate Matter (IPM): ≤2.5	Index for Particulate Matter (IPM): 2.25
	Side B (inside)	Index for Particulate Matter (IPM): ≤3.0	Index for Particulate Matter (IPM): 2.85
	Side A&B	Index for Particulate Matter (IPM): ≤3.0	Index for Particulate Matter (IPM): 2.64
ASTM 2407	Evaporative resistance	Critical zone: ≥850 g/m^2/24hrs Non-critical zone: ≥850 g/m^2/24hrs	Critical zone: 953.8 g/m^2/24hrs Non-critical zone: 930.2 g/m^2/24hrs
16 CFR Pat	Flame spread	Class 1, Non Flammable	Class 1, Non Flammable

1610			
USP42-NF37 <85>	Bacterial Endotoxins	< 20EU	< 20EU
ISO 11737-2:2019	SAL	10^{-6}	10^{-6}
Cytotoxicity	Biocompatibility-cytotoxicity	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity
Irritation	Biocompatibility-irritation	Under the condition of the test, no irritation	Under the condition of the test, no irritation
Sensitization	Biocompatibility-sensitization	Under the condition of the test, no sensitization	Under the condition of the test, no sensitization

9.0 Clinical Test Conclusion

No clinical study implemented for the Disposable Surgical Gown.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210510, the Disposable Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device K170762.