January 12, 2022

Xiantao Dingcheng Non-Woven Product Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212718
Trade/Device Name: Surgical gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: August 20, 2021
Received: August 27, 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,

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)*
K212718

Device Name
Surgical Gowns

Indications for Use *(Describe)*
The 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. 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 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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K212718 510(k) Summary

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

Name: XIANTAO DINGCHENG NONWOVEN PRODUCTS CO.,LTD
Address: LIUKOU INDUSTRIAL PARK,XIANTAO CITY,HUBEI PROVINCE,CHINA 433000
Contact: Mr. Cheng Qin
Phone Number: 86-18007229722
Date of Preparation: 02/08/2021

Designated Submission Correspondent

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2.0 Device information

Trade name: Surgical gowns
Common name: Surgical gown
Classification name: Gown, Surgical
Model(s): M, L, XL, XXL.

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 Indication for Use Statement

The 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. 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 Surgical gowns are single use, disposable medical devices, provided sterile.

6.0 Device description

The Surgical gowns is composed of collar, body, sleeve and tie. The back is full opening, the neck and waist are laced, the sleeve are made of cotton 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	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	Surgical gowns	Cardinal Health™ Non-Reinforced Surgical Gown	-
510(k) No.	Pending	K170762	-
Models	M, L, XL, XXL.	M-S, M, L, XL, XXL	Similar
Intended Use	The Surgical gowns 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 Surgical gowns are single use,	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 facilities (AAMI	Same

	disposable medical devices, provided sterile.	PB70). The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices; provided sterile and non-sterile.	
Composite	Neck Closure: Loop Belt Ties Knit Cuffs Transfer Tab	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Transfer Tab	Same
Material	Polyolefin (Polypropylene) SMS nonwoven Cotton	Polyolefin (Polypropylene) SMS nonwoven	Similar
Color	Blue	Blue	Same
Sterility	Sterile	Non-Sterile and sterile	* Gap 1
Sterilization method	EO	EO	Same
Shelf life	2 years	No identified	* Gap 2
Single Use	Yes	Yes	Same
Impact Penetration	<0.1g	0.0-0.10 g	Same
Hydrostatic Resistance	>50cmH_2O for critical zone	65-92 cm	* Gap 3
Tensile strength	Machine direction mean: 252N; Cross direction mean: 121N	MD mean: 21.57 lbf; CD mean: 13.6 lbs	* Gap 4
Tear resistance	Farbic direction A mean: 91N; Farbic direction B mean: 34.5N;	MD mean: 3.47 lbf; CD mean: 5.63 lbs	* Gap 5
Flame spread	Class 1, Non Flammable	Class 1, Non Flammable	Same
Resistance to blood and liquid penetration	Level 3 per PB70	Level 3 per PB70	Same
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-5	Same
Irritation	Comply with ISO 10993-10	Comply with ISO 10993-10	Same
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 2-4, the two devices have some small deviations in product performance, but the differences in the performance test results do 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.

Table 1 - Performance Testing

Items	Performance	Test methods
Impact Penetration	<0.1g	AATCC 42
Hydrostatic Resistance	>50cmH_2O for critical zone	AATCC 127
Resistance to blood and liquid penetration	Level 3	AAMI PB70
Tensile strength	Machine direction mean: 252N; Cross direction mean: 121N	ASTM D5034
Tear resistance	Farbic direction A mean: 91N; Farbic direction B mean: 34.5N;	ASTM D5733
Flame spread	Class 1, Non Flammable	16 CFR Pat 1610
SAL	10^{-6}	
Shelf life	2 years	

Table 2 - Biocompatibility Testing

Item	**Proposed Device**	**Result**
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

9.0 Clinical Test Conclusion

No clinical study implemented for the Surgical gowns.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.