July 7, 2021

Jiangsu Province Jianerkang Medical Dressing Co., Ltd
Tang Hongfang
Quality System Director
No.1 Jianerkang Road, Zhixi Industry Concentration Area,
Zhixi Town
Changzhou, Jiangsu 213251
China

Re: K210215
Trade/Device Name: Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 20, 2021
Received: June 24, 2021

Dear Tang Hongfang:

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,

Ryan Ortega, PhD
Acting 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)*
K210215

Device Name
Surgical Gown

Indications for Use *(Describe)*
Surgical gown are devices that 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.

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

K210215

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

Jiangsu Province Jianerkang Medical Dressing Co., Ltd
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Primary Contact Person: Hongfang Tang
Quality System Director
Jiangsu Province Jianerkang Medical Dressing Co., Ltd
Tel: (+86)-519-8244 4628
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Date prepared: June 20 , 2021

2. DEVICE

Device Name:	Surgical Gown
Common name:	Gown, Surgical
Classification Names:	Surgical apparel
Model:	
Regulation number	21 CFR 878.4040
Regulation Class:	2
Product Code:	FYA

3. PREDICATE DEVICE

K141467, Surgical gown XuChang ZhengDe Environstar Medical Products Co., Ltd

This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The surgical gown is 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. It is made of soft, air permeable SMS non-woven fabric.

The device description of the Jianerkang Surgical Gowns is in accordance with the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued on August 1, 1993 and Guidance for Industry and FDA Staff: Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings, issued on December 9, 2015.

The Jianerkang Surgical Gown is made of a laminate with adhesive taped seams and have a hook and loop closure at the back of the neck and a waist tie feature to secure the gown to the body of the user. The sleeves of the gown have knit cuffs sewn onto the end of the sleeve at the user's wrists to keep the sleeves in place on the wearer. The entire gown including the gown sleeves are made of the same material and utilize the same manufacturing processes.

5. INDICATIONS FOR USE

Surgical gown are devices that 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	**Predicate Device**	**Proposed**	**Conclusion**
K number	K141467	K210215	-
Manufacturer	XuChang ZhengDe Environstar Medical Products Co., Ltd	Jiangsu Province Jianerkang Medical Dressing Co., Ltd	-
Indication for Use	Surgical gown are devices that 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.	Surgical gown are devices that 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.	same
Material	SMS	SMS	same
Weight per square (g)	45	45	same
Durability	Disposable	Disposable	same
Size	M-S, M, L, XL, XXL	M-S, M, L, XL, XXL	same
Color	Blue	Blue	same
Style	Reinforced and non reinforced	non reinforced	similar

Specification	Predicate Device	Proposed	Conclusion
Hydrostatic pressure: AATCC 127	>50 cm	>50 cm	same
Impact penetration: AATCC 42	≤1	≤1	same
Biocompatibility	*under the conditions of the study, not an irritant; (ISO 10993-10:2010)*	*under the conditions of the study, not an irritant; (ISO 10993-10:2010)*	*same*
	under conditions of the study, not a sensitizer; (ISO 10993-10:2010)	*under conditions of the study, not a sensitizer; (ISO 10993-10:2010)*	*same*
	Under the conditions of the study the device is non-cytotoxic. (ISO 10993-5: 2009)	*Under the conditions of the study the device is non-cytotoxic. (ISO 10993-5: 2009)*	*same*
Tensile strength: ASTM D 5034	Length(Ibf): 17.7 Width(Ibf): 25.7	Length(Ibf): 17.1 Width(Ibf): 26.8	Similar
Tearing strength: ASTM D 5733	Length yarns torn(Ibf): 4.7 Width yarns torn(Ibf): 9.8	Length yarns torn(Ibf): 3.0 Width yarns torn(Ibf): 5.1	Similar-, the difference does not impact the product's safety and performance
Seam strength: ASTM D 1683	Armhole seam (Ibf) 17.6(F.B.) Shoulder seam (Ibf) 9.5(F.B.)	Armhole seam (Ibf) 19.4(F.B.) Shoulder seam (Ibf) 13.4(F.B.)	Similar
Flammability: 16 CFR Part 1610	Class 1	Class 1	same
Sterilization method	EO	EO	same
Resistance to blood and liguid penetration	Level 3 per AAMI PB70	Level 3 per AAMI PB70	same

7. Summary of non-clinical performance tests

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Surgical Gown was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity - (ISO 10993-5: 2009)
- Sensitization - (ISO 10993-10:2010)
- Skin Irritation - (ISO 10993-10:2010)

Performance testing

Performance testing was conducted on the Surgical Gown. All of the tested parameters met the predefined acceptance criteria.

Standards	Purpose	Acceptance Criteria	Results
AATCC 42	Spray Impact	Water Resistance	PASS
AATCC 127	Hydrostatic Pressure	Water Resistance	PASS
ANSI/AAMI PB70:2012 AAMI Level 3	Liquid Barrier Performance	Water Resistance	PASS
ASTM D 5733	Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure	Tearing Strength	PASS
ASTM D5034 –2017	Grab Tensile, Peak Stretch, and Peak Energy – Nonwovens	Tensile Strength	PASS
ASTM 1683-17 (2018)	Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics	Seam Strength	PASS

8. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210215, Jiangsu Province Jianerkang Medical Dressing Co., Ltd Surgical Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K141467.