October 7, 2021

Wujiang Tutaike Textiles & Finishing Co., Ltd.
% Eva Li
RA
Microkn Business Consulting (Shanghai) Co., Ltd
Room 1215, Block A, No 3699, Gonghexin Road, Jingan District
Shanghai,
China

Re: K211077
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: March 23, 2021
Received: September 7, 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 Murray, 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)*
K211077

Device Name
Surgical Gown

Indications for Use *(Describe)*
The Surgical Gowns is intended to be worn by operating room personnel during surgical procedure 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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510K Summary

K211077

According to the requirements Per 21 CFR §878.4040, the following information is provided sufficient detail to understand the basis for a determination of substantial equivalence.

Applicant:	Wujiang Tutaike Textiles & Finishing Co., Ltd.
Address:	No.1599, South 3rd Ring Road, Shengze, Wujiang, Suzhou, Jiangsu
Contact Person:	Zhang Yanwen Mobile Phone: 15162512333 Email: evonzhang@szttk.com.cn
Common Name	Surgical Gown
510(k) Number:	K211077
Product Code：	FYA
Classification:	Class II
Regulation number:	21 CFR 878.4040
Legal Manufacturer:	Wujiang Tutaike Textiles & Finishing Co., Ltd. No.1599, South 3rd Ring Road, Shengze, Wujiang, Suzhou, Jiangsu
Predicate Device	
Predicate Device:	Medical Surgical Gowns
510(k) Number:	K202844
510(k) Preparation Date: 07/30/2021	

1. Indications for use

The Surgical Gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

2. Description of the Device

This product is a new type of SMS breathable non-woven fabric. It consists of collar, gown body and sleeves. The main components of proposed device are:

(1) One-piece non-woven fabric Surgical Gown:

(2) One-piece helps for better protection and good visuals;

(3) Lacing: It is used to tie the belt and fix the shape of the Surgical Gown.

3. Model specifications

See the table.1 below:

Table 1 Model specifications (unit: cm)

Size	Length	Bust	Sleeve Length
S	115	140	61
M	120	144	63
L	125	148	65
XL	130	152	67
XXL	135	156	69
Variation	±2	±2	±2

4. Comparison of the technological characteristics between the predicate and subject devices

Feature	Proposed Device	Predicate device	Remark
510(K)#	K211077	K202844	--
Manufacturer	Wujiang Tutaike Textiles & Finishing Co., Ltd.	Beijing Biosis Healing Biological Technology Co., Ltd	--
Common Name	Surgical Gown	Medical Surgical Gowns	--
Classification	Class II	Class II	Same
Product Code	FYA	FYA	Same

Intended Use	The Surgical Gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	The Medical Surgical Gowns is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same
Size	S, M, L, XL, XXL	S, M, L, XL, XXL,XXXL	Similar
Break strength	>20N	>20N	Same
Tear strength	>20N	>20N	Same
Air Permeability/ Evaporative Resistance	>0.14 kPa.m^2/W and <0.3 kPa.m^2/W	>15 cm3 /s/cm^2 (29 ft3/min/ft2)	Discussion 1
Lint	Log_{10}＜4.0	Log_{10}＜4.0	Same
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cmH_2O	>50 cmH_2O	Same

Water impact	<0.1 g	≤1.0 g	Discussion 2
Material	SMS breathable non-woven polyethylene	SMS nonwoven, polyethylene	Same
Level	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Skin Irritation	No Irritation	No Irritation	Same
Sensitization	No Sensitization	No Sensitization	Same
Sterile	Ethylene oxide sterilization	Ethylene Oxide (EO)	Same

Discussion 1:
The predicted device has passed the requirement of Air permeability according to ASTM D737-18:2018, while the proposed device has pass the ASTM F1868-2017 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate. Two standards have the same performance requirement. So, this can be seen as same and don't raise any problem.

Discussion 2:
The proposed device has higher performance acceptance criteria for water impact test than the predicate device.

5. Summary of non-clinical performance test results

The following performance data were provided in support of safe and effective use of the proposed device:

Test Item	**Test standard**	**Acceptance Criteria**	**Result**
Break strength	ASTM D5034	>30N	>30N in machine
Tear strength	ASTM D5587	>15N	>20N
Seam strength	ASTM D 1683/D1683M-17(2018)	>30N	>30N
Evaporative Resistance	ASTM F1868-17	N/A	>0.14 KPa.m^2/W
Lint	ISO 9073-10:2003	N/A	Log_{10}＜4.0
Flammability	16 CFR Part 1610.7	N/A	Class I
Hydrostatic pressure	AATCC Test Method 127	>50 cmH_2O	Average Failure Pressure >50 cmH_2O

Water impact	AATCC Test Method 42	<1.0 g	Average Amount of Penetration <0.1 g
Level	AAMI PB 70	N/A	Level 3

6. Clinical Test Conclusion

Clinical study is not applicable for the subject device and is not included in this submission.

7. Conclusion

The nonclinical tests performed demonstrate that the subject device, Disposable Medical Surgical Gown, is as safe, as effective, and performs as well as the legally marketed predicate device Medical Surgical Gowns under K202844.