January 26, 2023

Guangzhou Fuzelong Hygiene Material Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161 Lujiazui East Rd.
Pudong, Shanghai 200120
China

Re: K222403
Trade/Device Name: Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 18, 2022
Received: January 9, 2023

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,

Allan Guan -S

For Bifeng Qian, M.D., 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)*
K222403

Device Name
Surgical Gown

Indications for Use *(Describe)*
The 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 4 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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510(k) Summary
K222403

The following information is provided in accordance with 21 CFR 807.92 for the premarket 510(k) summary:

1.0 Submitter's information

Name: Guangzhou Fuzelong Hygiene Material Co., Ltd
Address: #12, Guancun Road, Jiangpu Street, Conghua, Guangzhou, China 510900
Contact: Ms. Haiyan Zeng
Phone Number: 86-020-87993188
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Date of Preparation: Jan 13, 2023

Designated Submission Correspondent

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

2.0 Device information

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

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
Device: Disposable Surgical Gown
510(k) number: K214088
Product code: FYA
Regulation number: 21 CFR 878.4040

5.0 Intended Use/Indication for Use Statement

The 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 4 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 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 SMS nonwoven material, in a blue color. It has been tested according to AAMI PB70:2012 and meet AAMI Level 4 barrier level protection for a surgical gown. The proposed devices are single use, disposable medical devices and EO that sterilized. They are available in six sizes: S, M, L, XL, XXL and XXXL

7.0 Technological Characteristic Comparison Table

Table 3 - General Comparison

Item	Proposed device	Predicated device	Comparison
Product Code	FYA	FYA	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	Surgical Gown	Disposable Surgical Gown	Similar
510(k) No.	K222403	K214088	-
Sizes	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL, XXXL	Same
Intended Use/Indications for Use	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 4 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. It is single use, disposable medical devices, provided sterile.	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 4 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. It is single use, disposable medical devices, provided sterile.	Similar

Item	Proposed device	Predicated device	Comparison
Material	SMS nonwoven fabric polyester fiber	SMS nonwoven TPU membrane	Similar
Color	Blue	Blue	Same
Sterility	Sterile	Sterile	Same
Sterilization method	Ethylene Oxide	Ethylene Oxide	Same
EO and ECH Residuals	EO: < 0.076 mg/device ECH: < 0.396 mg/device	Pass	Same
Single Use	Yes	Yes	Same
Impact Penetration AATCC 42	≤1.0 g	≤1.0 g	Same
Hydrostatic Pressure Test AATCC 127	≥ 50cmH2O AQL: 4%	≥ 50cmH2O AQL: 4%	Same
Tensile strength ASTM D5034-09	Warp/Length ≥ 30N Weft/Width ≥ 30N	Machine direction mean≥30 lbf; Cross direction mean≥25 lbf	Similar
Tear resistance ASTM D5733-99	Warp/Length ≥ 10N Weft/Width ≥ 10N	Machine direction mean≥9 lbf; Cross direction mean≥18 lbf	Similar
16 CFR Part 1610 Flammability	Class 1	Class 1	Same
Linting	Log_{10}<4	Log_{10}<4	Same
Resistance to blood and liquid penetration	Level 4 per PB70	Level 4 per PB70	Same
Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage ASTM F1671	No viral penetration observed	No viral penetration observed	Same
Cytotoxicity ISO 10993-5	Non-cytotoxic	Non-cytotoxic	Same
Irritation ISO 10993-10	Non-irritating	Non-irritating	Same
Sensitization ISO 10933-10	Non-sensitizing	Non-sensitizing	Same

8.0 Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is equivalent to the predicate device. The test results demonstrate that the proposed device complies with the following standards by passing all applicable acceptance criteria and is equivalent to the predicate device.

Test Methodology	Purpose	Acceptance Criteria	Results
AATCC 42	Assess resistance to water impact penetration	Level 4, ≤1.0g	Pass

Test Methodology	Purpose	Acceptance Criteria	Results
AATCC 127	Assess hydrostatic resistance	Level 4, ≥50cm	Pass
ASTM D5034	Assess adequate tensile strength	Warp/Length ≥ 30N Weft/Width ≥ 30N	Pass
ASTM D5587	Assess adequate tear resistance	Warp/Length ≥ 10N Weft/Width ≥ 10N	Pass
ASTM D1683	Assess adequate seam strength	Sleeve Seam: ≥ 30N Armhole Seam: ≥ 30N Shoulder Seam: ≥ 30N	Pass
ASTM F1868	Assess evaporative resistance of fabrics	(Ref)≥0.06($kPa \cdot m^2/W$).	Pass
ASTM F1671	Resistance to Penetration by Blood-Borne Pathogens using Phi-X174 Bacteriophage	No penetration (Assay Titer < 1 PFU/ml)	Pass
ISO 9073-10	Assess acceptable lint and other particles generation in the dry state	$Log_{10} < 4$	Pass
16 CFR Part 1610	Flammability testing	Class 1	Pass
ISO 11737-2	Sterility assurance	10^{-6}	Pass
ISO 10993-5	Biocompatibility-cytotoxicity	Non-cytotoxic	Pass
ISO 10993-10	Biocompatibility-irritation	Non-irritating	Pass
ISO 10993-10	Biocompatibility-sensitization	Non-sensitizing	Pass
ISO 10993-7	Verify acceptable sterilant residuals	EO residual ≤ 4 mg/device ECH residual ≤ 9 mg/device	Pass

9.0 Clinical Test Conclusion

No clinical study is included in this submission.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K214088.