HeNan YADU Industrial Co., Ltd.
% Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K220092
Trade/Device Name: YADU Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 7, 2022
Received: September 8, 2022

Dear Charles Shen:

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 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)*
K220092

Device Name
YADU Surgical Gowns

Indications for Use *(Describe)*
YADU Surgical Gowns are 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 surgical gowns meet the requirements for Level 2 and Level 3 classification Per ANSI/AAMI PB-70.

Model Number and details for gowns involved in K220092:

Model Number	Structure	Level of Protection	Size	Sterile/Non-Sterile	Color
SY0136	Non-Reinforced	Level-2	S	Sterile	Blue
SY0137	Non-Reinforced	Level-2	M	Sterile	Blue
SY0138	Non-Reinforced	Level-2	L	Sterile	Blue
SY0139	Non-Reinforced	Level-2	XL	Sterile	Blue
SY0172	Non-Reinforced	Level-2	XXL	Sterile	Blue
SY0173	Non-Reinforced	Level-2	XXXL	Sterile	Blue
SY0148	Reinforced	Level-3	S	Sterile	Blue
SY0149	Reinforced	Level-3	M	Sterile	Blue
SY0150	Reinforced	Level-3	L	Sterile	Blue
SY0151	Reinforced	Level-3	XL	Sterile	Blue
SY0178	Reinforced	Level-3	XXL	Sterile	Blue
SY0179	Reinforced	Level-3	XXXL	Sterile	Blue

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.

510(K) Number: K220092

510(k) Summary:

This summary of 510(k) safety and effectiveness information is being submitted In accordance with the requirements of 21CFR 807.92

1.0 Submitter Information

HeNan YADU Industrial Co., Ltd.
No.234, West Jianpu Road 453400 Changyuan,
Henan Province, CHINA
Tel: (086) 373-2157057

Submission Correspondent

Charles Shen
Manton Business and Technology Services
37 Winding Ridge,
Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

Date of Summary: October 6, 2022

2.0 Device Information

Proprietary Name:	YADU Surgical Gowns
Common Name:	Surgical Gown
Classification Name:	Gown, Surgical

3.0 Device Classification

Classification Regulation:	**21 CFR** 878.4040
Class:	Class 2
Panel:	General Hospital
Product Code:	FYA

4.0 Predicate Device Information:

Manufacturer: Jiangsu Medplus Non-woven Manufacturer Co., Ltd

Product Name: Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown
510(K) #: K211422

5.0 Device description:

YADU Surgical Gowns provide Level 2 and Level 3 protections per ANSI/AAMI PB70 standard.

YADU Surgical Gowns (Level 2) are made from SMMS material. They are full length, constructed with raglan sleeves, hook and loop neck closures, and tie waist closures. They provide AAMI Level-2 protection.

The Level 2 Gowns have six different sizes: Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), and Super Extra large (XXXL).

SMMS is a multi-ply material consisting of layers of spunbonded and meltblown polypropyle.

The body and sleeve is made from 35g Blue SMMS. Sleeve opening is made from pure polyester. The collar closure is made from dacron. The belt is made from 35g Blue SMMS.

YADU Surgical Gowns (Reinforced, Level 3) are made from SMMS material. They are full length, constructed with raglan sleeves, hook and loop neck closures, and tie waist closures. The chest area is reinforced with layer of PE+SPP material. They provide AAMI Level-3 protection.

The Level 3 Reinforced Gowns have six different sizes: Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), and Super Extra large (XXXL).

SMMS is a multi-ply material consisting of layers of spunbond and meltblown polypropyle.

The body and sleeve is made from 45g Blue SMMS. Sleeve opening is made from pure polyester. The collar closure is made from dacron. The belt is made from 45g Blue SMMS. The reinforced area is made from PE +SPP material.

All gowns are sterilized with ethylene oxide.

6.0 Indications for Use:

YADU Surgical Gowns are 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 surgical gowns meet the requirements for Level 2 and Level 3 classification Per ANSI/AAMI PB-70.

Model Number and details for gowns involved in K220092:

Model Number	Structure	Level of Protection	Size	Sterile/Non-Sterile	Color
SY0136	Non-Reinforced	Level-2	S	Sterile	Blue
SY0137	Non-Reinforced	Level-2	M	Sterile	Blue
SY0138	Non-Reinforced	Level-2	L	Sterile	Blue
SY0139	Non-Reinforced	Level-2	XL	Sterile	Blue
SY0172	Non-Reinforced	Level-2	XXL	Sterile	Blue
SY0173	Non-Reinforced	Level-2	XXXL	Sterile	Blue
SY0148	Reinforced	Level-3	S	Sterile	Blue
SY0149	Reinforced	Level-3	M	Sterile	Blue
SY0150	Reinforced	Level-3	L	Sterile	Blue
SY0151	Reinforced	Level-3	XL	Sterile	Blue
SY0178	Reinforced	Level-3	XXL	Sterile	Blue
SY0179	Reinforced	Level-3	XXXL	Sterile	Blue

7.0 Comparison to Predicate Devices

YADU Surgical Gowns are compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K211422, "Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown", manufactured by "Jiangsu Medplus Non-woven Manufacturer Co., Ltd" located in Siyang, Jiangsu, China.

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Subject Device (K220092)	Predicate Device (K211422)	Comparison
Product Code	FYA	FYA	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Classification	Class2	Class2	Same

Indication for Use	YADU Surgical Gowns are 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 surgical gowns met the requirements for Level 2 and Level 3 classification Per ANSI/AAMI PB-70	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. Per ANSI/AAMI PB70: 2012, Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Level 2 standard surgical gowns met the requirements for Level 2 classification, the Level 3 standard Surgical gowns and Level 3 Reinforced surgical gowns met the Requirements for Level 3 classification	Same
Basic Design	Full length, constructed with raglan sleeves, neck closures, and waist closures.	Full length, constructed with raglan sleeves, neck closures, and waist closures.	Same
Features	Regular and Reinforced	Regular and Reinforced	Same
Materials	SMMS nonwoven, Polyester, PE/SPP	SMS nonwoven, Polyester and Polyamide	Similar
Sizes	S,M,L,XL,XXL,XXXL	XS,S,M,L,XL,XXL,XXXL	Similar
Single Use	Yes	Yes	Same
Color	Blue	Blue	Same
Sterile	Sterile	Information not available	Same
Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same

The minor differences between the subject device and predicate device do not raise any concerns in terms of safety and effectiveness.

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards.

Table 5.2: Comparison of Biocompatibility and Performance Testing

Description	Subject Device (K220092)	Predicate Device (K211422)	Comparison
Cytotoxicity	Under conditions of the study, device extract is not cytotoxic (ISO10993-5)	Under conditions of the study, device extract is not cytotoxic (ISO10993-5)	Same
Skin Irritation and Sensitization	Under the conditions of the study, not an irritant or a sensitizer (ISO 10993-10)	Under the conditions of the study, not an irritant or a sensitizer (ISO 10993-10)	Same
Hydrostatic Pressure: Water Resistance	≥ 20cm (Level 2) ≥ 50cm (Level 3)	≥ 20cm (Level 2) ≥ 50cm (Level 3)	Same
Impact Penetration Test : Water Resistance	≤ 1.0g	≤ 1.0g	Same
Protection	Level 2 and Level 3 per ANSI/AAMI PB70	Level 2 and Level 3 per ANSI/AAMI PB70	Same
Tensile Strength	> 30 N	> 20 N	Similar
Tear Strength	> 10 N	> 20 N	Similar
Seam Strength	> 30 N	Data not available	Similar
Flammability	Class 1	Class 1	Same
Lint	< 10000 (Log particle < 4)	Log (particle count) < 4	Same
Ethylene Oxide and ECH residuals	EO: < 4 mg/device ECH: < 9 mg/device	EO: < 4 mg/device ECH: < 9 mg/device	Same

Both subject device and predicate device met the requirements of ANSI/AAMI PB70 and ASTM F2407. Their performance data are very similar.

8.0 Non-Clinical Study Summary

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- Protection Performance: ANSI/AAMI PB-70:2012
- Mechanical Performance: ASTMF2407-20
- In Vitro Cytotoxicity Test: ISO10993-5:2009
- Skin Irritation Test: ISO10993-10:2010
- Skin Sensitization Test: ISO10993-10:2010
- Sterilization Validation: ISO-11135-1:2014

Title of Test	Purpose of Test	Acceptance Criteria	Results (Level 2 gown)	Results (Level 3 gown)
AATCC127: 2018	Water resistance/ Hydrostatic Pressure	≥ 20 cm (Level 2) ≥ 50 cm (Level 3)	Passed	Passed
AATCC42: 2017	Water Resistance impact penetration	≤ 1.0 g	Passed	Passed
ASTM D5034-09	Tensile Strength	MD Mean ≥ 30 N; CD Mean ≥ 30 N	Passed	Passed
ASTM D5733-99	Tearing Strength	MD Mean ≥ 10 N; CD Mean ≥ 10 N	Passed	Passed
ISO 9073-10: 2003	Linting	Average ≤ 10000 (Log L < 4.0)	Passed	Passed
ASTM D1683-17	Seam Strength	≥ 30 N	Passed	Passed
ASTM F1868-17	Evaporative Resistance of Fabrics	No requirement	Passed	Passed
16 CFR 1610	Flammability testing	Meets Requirements Of Flame Resistant CPSC 1610 Class 1	Passed	Passed
ISO 10993-5: 2009	Tests for In vitro cytotoxicity	Under conditions of the study, device extract is not cytotoxic	Passed	Passed
ISO 10993-10: 2010	Tests for irritation And skin sensitization	Under the conditions of the study, not an irritant	Passed	Passed
ISO 10993-10: 2010	Tests for irritation and skin sensitization	Under conditions of the study, not a sensitizer	Passed	Passed
ISO 11135: 2014	Sterilization Validation	SAL level of 10^{-6}	Passed	Passed
ISO 11135: 2014 Annex B	Ethylene Oxide residuals	EO: < 4 mg/device ECH: < 9 mg/device	Passed	Passed

9.0 Clinical Study Summary

Clinical study is not performed for this product.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.