



February 4, 2026

YADU Medical (Henan) Co., Ltd.
Peilong Shi
General Manager
66 Yangze Road, Nanpu District, Changyuan, Xinxiang,
He Nan, Henan Province PEOPLE'S 453400
China

Re: K252301

Trade/Device Name: Henan Yadu Level 4 Surgical Gowns (Reinforced)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 30, 2025
Received: December 30, 2025

Dear Peilong Shi:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

DHT4C: Division of Infection

Control Devices

OHT4: Office of Surgical and

Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K252301

Device Name
Henan Yadu Level 4 Surgical Gown (Reinforced)

Indications for Use (Describe)

Henan Yadu Level 4 Surgical Gown (Reinforced) are sterile, single-use surgical apparel intended to be used by operating room personnel during surgical operations and other invasive examinations to provide a liquid and microbial barrier for patients and medical staff.

These products meet the Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2022 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."

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 K252301

I. 510(k) Submitter

Device YADU Medical (Henan) Co., Ltd.
Submitter: 66 Yangze Road, Nanpu District, 453400 Changyuan,
Xinxiang, Henan Province PEOPLE'S REPUBLIC OF CHINA
Contact Person: Shi PeiLong
General Manager
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E-mail: winnie.li@yadugroup.com

II. Device Information

Trade Name of Device: Henan Yadu Level 4 Surgical Gown (Reinforced)
Regulation Number: 878.4040
Classification Name: General & Plastic Surgery
Product Code: FYA
Regulatory Class 2
Review Panel General Hospital

III. Predicate Device Information

510k Number K182172
Trade Name of Device: Surgical Apparel
Regulation Number: 878.4040
Classification Name: General & Plastic Surgery
Regulatory Class 2
Product Code: FYA

IV. Device Description

Henan Yadu Level 4 Surgical Gowns (Reinforced) are sterile, single-use surgical apparel intended to be worn by healthcare professionals during surgical procedures to provide barrier protection against the transfer of microorganisms, body fluids, and particulate matter in critical surgical zones for both patients and healthcare personnel. These products meet the Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2022 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities. Gowns have six different sizes: Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), Extra extra extra Large (XXXL).

V. Indications for use

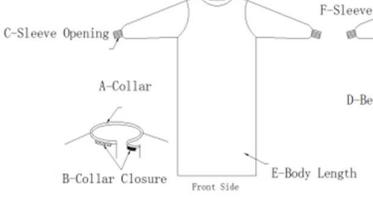
Henan Yadu Level 4 Surgical Gown (Reinforced) are sterile, single-use surgical apparel intended to be used by operating room personnel during surgical operations and other invasive examinations to provide a liquid and microbial barrier for patients and medical staff.

These products meet the Level 4 liquid barrier performance requirements of

ANSI/AAMI PB70:2022 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."

VI Technological Characteristics Comparison

Device Characteristic	Subject Device	Predicate Device (K182172)	Discussion
Trade name	Henan Yadu Level 4 Surgical Gown (Reinforced)	Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora)	N/A
Product code	FYA	FYA	Same
Regulation Number	878.4040	878.4040	Same
Manufacturer	YADU Medical (Henan) Co., Ltd.	Medline Industries, Inc.	N/A
Device Classification	General & Plastic Surgery	General & Plastic Surgery	Same
Indications for Use	Henan Yadu Level 4 Surgical Gown (Reinforced) are sterile, single-use surgical apparel intended to be used by operating room personnel during surgical operations and other invasive examinations to provide a liquid and microbial barrier for patients and medical staff. These products meet the Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2022 "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities"	The Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) is a sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter. The Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), and Medline Level 4 Surgical Gown (Aurora) meets the Level 4 requirements of ANSI/AAMI PB70:2012 Liquid barrier performance	similar

Device Characteristic	Subject Device	Predicate Device (K182172)	Discussion
		and classification of protective apparel and drapes intended for use in health care facilities.	
Color	Blue	Blue	Same
Design Features	 <p>A. Collar; B. Collar Closure; C. Sleeve Opening; D. Belt; E. Body; F. Sleeve</p>	Neck Closure: Hook and Loop Belt Ties Knit Cuffs Reinforced Material Raglan or Set-in/Standard Sleeves	Similar
Sizes	Small to XXX-Large	Small to XXXX-Large	Similar
Materials	47gSSMMMS+35g protective film	Nonwoven SMS polypropylene Anti-Static, Repellency Poly-Reinforcement Film White Knitted Cuffs	Different Comment 1
Performance Specifications	Level 4 barrier protection	Level 4 barrier protection	Same
Prescription vs. OTC	OTC	OTC	Same
Contact classification	Surface contacting, < 24 hours	Surface contacting, < 24 hours	Same
Single Use	Yes	Yes	Same
Biocompatibility	Met requirements per: ISO 10993-5 Cytotoxicity ISO 10993-23 Irritation ISO 10993-10 Sensitization	Met requirements per: ISO 10993-5 Cytotoxicity ISO 10993-23 Irritation ISO 10993-10 Sensitization	Same
Disposable vs Non Disposable	Disposable	Disposable	Same
Sterile vs Non Sterile	Sterile	Sterile	Same
Sterilization	EO Sterilization	EO Sterilization	Same

Comment 1

The material of this product is composed of multi-layer non-woven fabric (Spunbond-

Spunbond-Meltblown-Meltblown-Meltblown-Spunbond: multi-layer Meltblown (M) enhanced filtration, double spunbond(S) internal and external reinforcement). Whereas the predicate device apparatus is composed of three layers of nonwoven fabric (Spunbond-Meltblown-Spunbond: outer spunbond (S) provides strength, middle meltblown (M) filtration, inner spunbond (S)) although the material composition is slightly different. However, the products are all composed of nonwoven fabrics and have the same intended use.

VII. Summary of Non-clinical Testing (Bench)

The product meets the Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2022 and ASTM F2407/F2407M-23a.

Test items	Test methods	Acceptance criteria	Test result.
Water resistance: Impact Penetration	AATCC TM42-2017e	Critical area $\leq 1.0g$	Meet the requirements
Water resistance: Hydrostatic Pressure	AATCC TM127-2017 (2018) e	$\geq 50cmH_2O$	Meet the requirements
Flame Spread	16 CFR Part 1610	class 1	Meet the requirements
Lint generation testing	ISO 9073 part 10	Coefficient of linting < 4	Meet the requirement
Tensile strength (longitudinal and transverse)	ASTM D5034-21	$\geq 30N.$	Meet the requirements
Tear strength (longitudinal and transverse)	ASTM D5587-15 (2019)	$\geq 10N.$	Meet the requirements
Seam strength	ASTM D1683/D1683M-17	$\geq 30N.$	Meet the requirements
Resistance to Phi-X174 Bacteriophage	ASTM F1671/F1671M-22	No penetration	Meet the requirements
Sterility	ISO 11737-2:2019	The surgical gown should be sterile after sterilization.	Meet the requirements
Bacterial endotoxins	ISO 11737-3:2023	Bacterial endotoxin content $\leq 20 EU$	Meet the requirements

Ethylene oxide residue	ISO 10993-7:2008/and 1:2019	EO residue not greater than 4mg/ For the device, the residual ECH content should not exceed 9 mg/device.	Meet the requirements
Biocompatibility test			
The proposed device is classified as a surface device with a limited duration of contact (<24 hours) on surfaces.			
In vitro cytotoxicity	ISO 10993-5:2009	No in vitro cytotoxicity	Meet the requirements
Skin sensitization	ISO 10993-10:2021	No skin sensitization	Meet the requirements
Irritation	ISO 10993-23:2021/and 1:2025	No irritation	Meet the requirements

VIII. Clinical Test Conclusion

No clinical study is included in this submission.

IX. Predetermined change control plan

Planned Modification	Test Methods and Validation Activities	Communication to users, as needed
Addition of shelf life	<p>Performance testing will be conducted on accelerated aged device to establish provisional shelf life of the gown and real time aging performance testing will be conducted concurrently for validation. The following performance testing will be conducted:</p> <p><u>Barrier property testing (ANSI/AAMI PB70:2022)</u></p> <ul style="list-style-type: none"> • Water resistance: Impact Penetration: AATCC TM42-2017e • Water resistance: Hydrostatic Pressure: AATCC TM127-2017 	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding device's shelf life.

	<p>(2018) e</p> <ul style="list-style-type: none"> • Resistance to Phi-X174 Bacteriophage: ASTM F1671/F1671M-22 <p><u>Physical property testing (ASTM F2407/F2407M-23a)</u></p> <ul style="list-style-type: none"> • Tensile Strength: ASTM D5034-21 • Tear Strength: ASTM D5587-15 • Seam Strength: ASTM D1683/D1683M-22 • Lint testing: ISO 9073-10:2003 • Flammability: 16 CFR Part 1610-2008 <p><u>Packaging performance</u></p> <ul style="list-style-type: none"> • Sealing strength: ASTM F88-2015 • Dye leakage: ASTM F1929-2015 • Sterility: ISO 11737-1:2018 	
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X. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that Henan Yadu Level 4 Surgical Gown (Reinforced) is as safe as, as effective, and performs as well as or better than the legally marketed device, Medline Level 4 Surgical Gown (Sirus), Medline Level 4 Surgical Gown (Eclipse), Medline Level 4 Surgical Gown (Aurora).