



December 3, 2025

Yadu Medical (Henan) Co., Ltd.
Peilong Shi
General Manager
66 Yangze Rd., Nanpu District, Changyuan, Xinxiang
He Nan, Henan Province 453400
China

Re: K250564

Trade/Device Name: Surgical Gown (Level 3: S, M, L, XL, XXL, XXXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYA
Dated: October 31, 2025
Received: October 31, 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.

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)
K250564

Device Name
Surgical Gown
(Level 3: S, M, L, XL, XXL, XXXL)

Indications for Use (Describe)

Level 3 Surgical Gown (Standard & 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.

The products meet the respective liquid barrier performance requirements for Level 3 as specified in 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 (K250564)

I 510(k) Submitter

Device Submitter: YADU Medical (Henan) Co., Ltd.
66 Yangze Road, Nanpu District, 453400 Changyuan, Xinxiang, Henan
Province PEOPLE'S REPUBLIC OF CHINA

Contact Person:

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Phone: +86 18637387159
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II Device

Trade Name of Device: Surgical Gown (Level 3: S, M, L, XL, XXL, XXXL)
Regulation Number: 878.4040
Classification Name: Surgical Apparel
Product Code: FYA
Regulatory Class: Class 2
Review Panel: General Hospital

III Predicate Devices

510k Number: K190950
Trade Name of Device: Medline Level 2 Surgical Gown (Eclipse Non-Reinforced),
Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced),
Medline Level 3 Surgical Gown (Sirus Non-Reinforced &
Sirus Fabric Reinforced), Medline Level 3 Surgical Gown
(Aurora Non Reinforced & Aurora Fabric Reinforced)
Regulation Number: 878.4040
Classification Name: Surgical Apparel
Regulatory Class: Class 2
Product Code: FYA

IV Device Description

Surgical Gowns are class II medical devices under the FDA product code FYA, General & Plastic Surgery Panel, and Regulation 21 CFR 878.4040. The subject surgical gowns are single use, disposable and provided sterile. They are available as Standard or Reinforced at Critical areas of the gown to increase its resistance to fluid penetration. The gowns are designed for short to medium length procedures and procedures where there is moderate risk (AAMI PB70 level 3).

The subject gowns are single-use and provided sterile (Ethylene Oxide sterilization). The subject gowns provide barrier protection against the transfer of microorganisms, body fluids, and particulate matter in critical zones of the gowns for both patients and healthcare personnel.

V Indications for use.

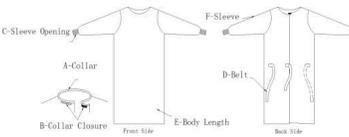
Level 3 Surgical Gown (Standard & Reinforced) are sterile, single-use surgical apparel intended to be worn by healthcare professionals during surgical procedures to provide barrier protection against the transfer of microorganisms, body fluids, and particulate matter in critical surgical zones for both

patients and healthcare personnel.

The products meet the respective liquid barrier performance requirements for Level 3 as specified in 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 (K190950)	Discussion
Manufacturer	YADU Medical (Henan) Co., Ltd.	Medline Industries, Inc.	N/A
Trade name	Surgical Gown (Level 3: S, M, L, XL, XXL, XXXL)	Medline Level 2 Surgical Gown (Eclipse Non-Reinforced), Medline Level 3 Surgical Gown (Eclipse Fabric Reinforced), Medline Level 3 Surgical Gown (Sirius Non-Reinforced & Sirius Fabric Reinforced), Medline Level 3 Surgical Gown (Aurora Non Reinforced & Aurora Fabric Reinforced)	N/A
Product code	FYA	FYA	Same
Regulation Number	878.4040	878.4040	Same
Classification Name	Surgical Apparel	Surgical Apparel	Same

Intended Use	<p>Level 3 Surgical Gown (Standard & 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.</p> <p>The products meet the respective liquid barrier performance requirements for Level 3 as specified in ANSI/AAMI PB70:2022</p>	<p>The Medline Level 2 Surgical Gowns and Medline Level 3 Surgical Gowns are 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.</p> <p>The Medline Level 2 Surgical Gowns and the</p>	Different Comment 1
	"Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities".	Medline Level 3 Surgical Gowns meets the respective level requirements of ANSI/AAMI PB70:2012 Liquid barrier performance 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>	<p>Available in Fabric Reinforced and NonReinforced Hook and Loop Closure at neck Belt Ties Knit Cuffs Transfer Tab Raglan or Set-in/Standard Sleeves</p>	Same
Sizes	Small to XXX-Large	Small to XXXX-Large	Different Comment 2
	Device Description	Materials	

Materials	Level3 Surgical Gown (Standard)	Non- woven fabrics 43g blue anti-SMMS	Nonwoven SMS polypropylene/Polyolefi n	Different Comment 3
	Level3	Non-		
	Surgical Gown (Reinforced)	woven fabrics 43g blue anti- SMMS+35g 35g white water repelled Laminated Material		
Performance Specifications	Level 3 PB70 Barrier Protection		Level 3 PB70 Barrier Protection	Same
Prescription vs. OTC	OTC		OTC	Same
Contact Durations	Surface, Intact, < 24 hours		Surface, Intact, < 24 hours	Same
Single Use	Yes		Yes	Same
Biocompatibility	Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.		Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5 & ISO 10993-10.	Same
Disposable vs Non Disposable	Disposable		Disposable	Same
Sterile vs Non Sterile	Sterile		Sterile	Same
Sterilization	Ethylene Oxide (EtO)		Ethylene Oxide (EtO)	Same

Comment 1

The intended use statement is worded slightly differently, and the model is LEVEL 3 only, but it has the same intended use.

Comment 2

The difference in sizes offered does not raise different questions of safety and effectiveness.

Comment 3

The differences in materials were assessed through testing and do not raise different questions of safety and effectiveness.

VII Summary of Non-clinical Testing (Bench)

Test Item	Acceptance Criteria	Pass/Fail
Impact Penetration (AATCC 42)	≤ 1.0 g	Pass
Hydrostatic Pressure (AATCC 127)	≥ 50 cm H ₂ O	Pass
Wet State Microbial Penetration	No penetration allowed	Pass
Dry State Microbial Penetration	No penetration allowed	Pass
Linting Test	Minimal linting allowed	Pass
Tensile Strength	≥ 30 N	Pass
Burst Strength	\geq Manufacturer Spec	Pass
Flammability	Class 1	Pass
Tear Strength	≥ 10 N	Pass
Seam Strength	≥ 30 N	Pass

VIII Summary of Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that Surgical Gown (Level 3: S, M, L, XL, XXL, XXXL) is as safe as effective and performs as well as or better than the legally marketed device.