August 7, 2026

Yadu Medical (Henan) Co., Ltd.
Winnie Li
Regulatory Affairs Manager
66 Yangze Rd., Nanpu District, Changyuan, Xinxiang
He Nan, Henan 453400
China

Re: K261028
Trade/Device Name: Surgical Gown Level2 (S, M, L, XL, XXL, XXXL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: July 8, 2026
Received: July 8, 2026

Dear Winnie 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

BIFENG QIAN -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261028

Device Name
Surgical Gown Level2 (S, M, L, XL, XXL, XXXL)

Indications for Use *(Describe)*
Level2 Surgical Gown is 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 material for both patients and healthcare personnel.
The product meets the Level 2 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
K261028

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:	Winnie Li Regulatory Affairs Manager Phone: +86 18637387159 E-mail: winnie.li@yadugroup.com
Summary Preparation Date	2026.08.06

II Device

Trade Name of Device:	Surgical Gown Level2 (S, M, L, XL, XXL, XXXL)
Regulation Number:	21 CFR 878.4040
Classification Name:	Surgical gown
Review Panel	General Hospital
Regulatory Class	2
Product Code:	FYA
Common Device name	Surgical gown
Size	S,M,L,XL,XXL,XXXL

III Predicate Devices

510k Number	K190950
Trade Name of Device:	Medline Level 2 Surgical Gown (Eclipse Non-Reinforced)
Regulation Number:	21 CFR 878.4040
Classification Name:	Surgical Gown
Review Panel	General Hospital
Regulatory Class	2
Product Code:	FYA
Common Device name	Surgical gown
Size	Small/Medium，Large，X-Large，XX-Large，XXX-Large，XXXX-Large

IV Device Description

Level 2 Surgical Gowns is made of non-woven fabric. This product is a disposable sterilized product. The product is composed of collar, body, sleeve and lanyard. It is

used to prevent transmission of infectious materials between patients and health care workers during surgical procedures and other invasive examinations.

Gowns have six different sizes: Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL), Extra extra extra Large (XXXL).

These products meet the Level 2 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”.

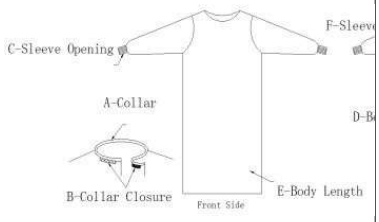
V Indication For Use

Level2 Surgical Gown is 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 material for both patients and healthcare personnel.

The product meets the Level 2 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 (K190950)	Discussion
Trade name	Surgical Gown Level2 (S, M, L, XL, XXL, XXXL)	Medline Level 2 Surgical Gown (Eclipse Non-Reinforced)	N/A
Product code	FYA	FYA	Same
Regulation Number	21 CFR 878.4040	21 CFR878.4040	Same
Manufacturer	YADU Medical (Henan) Co., Ltd.	Medline Industries, Inc.	N/A
Device Classification	2	2	Same

Device Characteristic	Subject Device	Predicate Device (K190950)	Discussion
Intended Use / Indications for Use	Level2 Surgical Gown is 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 material for both patients and healthcare personnel. The product meets the Level 2 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 2 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. The Medline Level 2 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.	Different Comment 1
Color	Blue	Blue	Same
Design Features	 A. Collar；B. Collar Closure；C. Sleeve Opening；D. Belt；E. Body；F. Sleeve	Available in Fabric non-Reinforced Hook and Loop Closure at neck Belt Ties Knit Cuffs Transfer Tab Raglan or Set-in/Standard Sleeves	Different Comment4
Sizes	Small to XXX-Large	Large，X-Large，XX-Large，XXX-Large，Small/Medium，XXXX-Large	Different Comment 2
Materials	35g blue anti-SMMS	Nonwoven SMS polypropylene/Polyolefin	Different Comment 3

Device Characteristic	Subject Device	Predicate Device (K190950)	Discussion
Performance Specifications	Level 2 PB70 Barrier Protection	Level 2 PB70 Barrier Protection	Same
Tensile strength	Meet the ASTM D5034-2021 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Meet the ASTM D5034-09 (2013) Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Same
Tear Strength	Meet the ASTM D5587-2015(2024) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Meet the ASTM D5587-15 Tearing Strength of Fabrics by Trapezoid Procedure	Same
Seam Strength	Meet the ASTM D1683/D1683M	None	Different Comment 5
Lint Generation	Meet the ISO 9073-10:2003	None	Different Comment 5
Package Test	Under the test conditions, the subject device was shown to be the seal strength compliant, No dye penetration, Microbial Barrier Properties meet the requirement, No bacteria growth and No leak per ASTM F88/F88M，ASTM F1929，DIN 58953-6，ISO11737-2& ASTM D3078-02.	Meet the ASTM F1929-15 Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Different Comment 6
Flammability	Meets requirements of Flame Resistant CFR Part 1610, Class 1	Meets requirements of Flame Resistant CFR Part 1610, Class 1	Same
Prescription vs. OTC	OTC	OTC	Same
Contact type and Durations	Surface, breached or compromised , < 24 ours	Surface, breached or compromised ,< 24 hours	Same
Single Use	Yes	Yes	Same

Device Characteristic	Subject Device	Predicate Device (K190950)	Discussion
Biocompatibility	Under the test conditions, the subject device was shown to be non-cytotoxic, non-irritating and non-sensitizing per ISO 10993-5, ISO 10993-23 & 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 Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
Ethylene Oxide (EtO) Residuals	The residual values are within the limits specified by ISO 10993-7 standard. EO < 4mg/device ECH < 9 mg/device	The residual values are within the limits specified by ISO 10993-7 standard.	Same

Comment 1
The indications for use statement is worded slightly differently and both have the same intended use when used. All achieved the effect of the intended protection
Comment 2
The only difference is that the subject gown does not have XXXX-Large size.
Comment 3
Although the product materials are different, biocompatibility and specification performance testing data demonstrate that the subject device is as safe, as effective and can perform as well as the predicate device.
Comment 4
The subject Surgical Gown adopts non-reinforced fabric construction. While the predicate device supplies optional reinforced zone material, the tested SMMS non-woven fabric of our device meets all ANSI/AAMI PB70-specified Level 2 liquid barrier, tensile strength and tear resistance performance requirements. The neck adopts hook and loop fastener closure; waist belt ties, knit cuffs, raglan cut sleeves and the overall structural layout are consistent with the predicate. The above mentioned structural difference will not affect the safety, barrier protection function and intended use performance of the device.
Comment 5
The predicate device 510(k) Summary does not include seam strength and Lint

Generation tests. The subject device conducts the above mentioned tests following ASTM D1683/D1683M and ISO 9073-10:2003. Test results meet standard specifications. The extra characteristic verification does not change core function, intended use or safety profile, and substantial equivalence is preserved.

Comment 6

Compared with the predicate device which carries out ASTM F1929-15 dye-leak test, our device implements multiple sterile-package tests under multiple standards. All indicators are qualified. The extra-test items only verify packaging reliability and will-not affect substantial equivalence.

VII Summary of Non-clinical Testing

Test Item		Test Standard	Level 2 Result	Acceptance Criteria	Pass/Fail
Surgical Gown	Impact Penetration	AATCC TM42-2017	0.8 g	≤ 1.0 g	Pass
	Hydrostatic Pressure	AATCC 127-2018e	25 cm H_2O	Level 2: ≥ 20 cm H_2O	Pass
	Lint Generation	IS09073-10:2003	Minimal linting	Minimal linting allowed	Pass
	Tensile Strength	ASTM D5034-2021	MD, CD > 95N	≥30N	Pass
	Tear Strength	ASTM D5587-2015(2024)	MD, CD > 30N	≥10N	Pass
	Seam Strength	ASTM D1683/D1683M-2022	> 70N	≥30N	Pass
	Flammability	US 16 CFR Part 1610	IBE	Class 1	Pass
	Skin Irritation Test	ISO 10993- 23	Under the test conditions, the subject device was non-irritating	The erythema and edema scores are ≤ 0.4	Pass
	Test for In vitro cytotoxicity	ISO 10993-5	Cell viability is 86.57%. There was no significant cytotoxicity.	Cell viability≥70%	Pass
	Skin Sensitization	ISO 10993- 10	Sensitization rate is 0. No Sensitization reactions.	GPMT sensitization rate<30%	Pass
	EtO residual testing	ISO 10993-7:2008	EO < 4mg/device ECH < 9 mg/device	EO < 4mg/device ECH < 9 mg/device	Pass
Package	Seal Strength	ASTM F88/F88M-2023	≥292.67N	≥80N/m	Pass

	Dye Penetration	ASTM F1929-2023	No penetration	No penetration was found	Pass
	Microbial Barrier Properties	DIN 58953-6:2023	Viable Count = 0	No penetration	Pass
	Sterility Test	ISO11737-2-2019	No bacteria growth	Should be sterile.	Pass
	Vacuum leak	ASTM D3078-02	No leak	No leak was found.	Pass

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

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