April 20, 2026

Hubei Xinxin Non-woven Co., Ltd
Nicole Jin
Quality Manager
Taizihu Industrial Park, Pengchang Town
Xiantao, Hubei 433018
China

Re: K253003
Trade/Device Name: Non-sterile Level 3 Surgical Gown (4025); Sterile Level 3 Surgical Gown (M4025); Non-sterile Reinforced Level 4 Surgical Gown (G4025); Reinforced Sterile Level 4 Surgical Gown (GM4025)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: September 19, 2025
Received: March 23, 2026

Dear Nicole Jin:

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)*
K253003

Device Name
Non-sterile Level 3 Surgical Gown (4025);Sterile Level 3 Surgical Gown (M4025);
Non-sterile Reinforced Level 4 Surgical Gown (G4025);Reinforced Sterile Level 4 Surgical Gown(GM4025)

Indications for Use *(Describe)*
Surgical Gowns are intended to be worn by operation room personnel during surgical procedures or other invasive procedures tests to protect both the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This is single use, disposable device, provided non-sterile and sterile. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end users.

Per ANSI/AAMI PB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns meet the requirements for Level 3 classification, and the reinforced surgical gowns meet the requirements for Level 4 classification.

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.

510K Summary K253003

Prepared by 2026/4/14

A. Applicant

Name: Hubei Xinxin Non-woven Co.,Ltd.
Address: Taizihu Industrial Park, Pengchang Town, Xiantao, China.
Contact Person: Nicole Jin
Position: QA Manager
Tel: +86-728-2618155
Email: nicole_jin@xtxfsl.com

B. Device

Product Name: Surgical Gowns Model: Non-sterile
Level 3 Surgical Gown (4025)
Sterile Level 3 Surgical Gown (M4025)
Non-sterile Reinforced Level 4 Surgical Gown (G4025)
Reinforced Sterile Level 4 Surgical Gown (GM4025)

Regulatory Information
Classification: Class II
Product code: FYA (Class 2) - Gown, Surgical
Regulation Number: 21 CFR 878.4040
Review Panel: General & Plastic Surgery

C. Predicate Device

510(k) Number: K212869
Fugou County Shenxiang Manufacturing Co., LTD.
Product Name: Disposable Surgical Gown, Disposable Reinforced Surgical Gown

D. Indications for use

Surgical Gowns are intended to be worn by operation room personnel during surgical procedures or other invasive procedures to protect both the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This is single use, disposable device, provided non-sterile and sterile. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end users.

Per ANSI/AAMI PB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns meet the requirements for Level 3 classification, and the reinforced surgical gowns meet the requirements for Level 4 classification.

E. Device Description

The main components of 4025 & M4025:
The body and arm of the Basic Gown, which is blue and the material is SMS (Spunbond + Meltblown + Spunbond). Belt, used to close the back of the gown, which is blue and the material is SMS.
Cuff, sewn to the end of sleeves, which is made of PET (polyethylene terephthalate).
Hood-and-loop Velcro, used to adjust the size of the neck and close the neck.
Necktie, which is white and made of SPP (Spunbond Polypropylene).
This proposed device can meet the requirements for Level 3 in accordance with ANSI/AAMI PB70:2022.
4025 provided in non-sterile and M4025 provided in sterile.

The main components of G4025 & GM4025:
The body and arm of the Basic Gown, which is blue and the material is SMS.
Belt, used to close the back of the gown, which is blue and the material is SMS
Cuff, sewn to the end of sleeves, which is made of PET (polyethylene terephthalate).
Hood-and-loop Velcro, used to adjust the size of the neck and close the neck.
Necktie, which is white and made of SPP.
Reinforced piece, put in front chest and sleeves of the gown, made of PP/PE(Polypropylene/Polyethylene) laminated film. G4025 provided in non-sterile and GM4025 provided sterile.
The critical zone of this proposed device can meet the requirements for Level 4 in accordance with ANSI/AAMI PB70:2022 while the basic zone can meet Level 3.

Specification:

Models	Product Number	Size
Non-sterile Level 3 Surgical Gown	4025	S, M, L, XL, XXL, XXXL
Sterile Level 3 Surgical Gown	M4025	S, M, L, XL, XXL, XXXL
Non-sterile Reinforced Level 4 Surgical Gown	G4025	S, M, L, XL, XXL, XXXL
Reinforced Sterile Level 4 Surgical Gown	GM4025	S, M, L, XL, XXL, XXXL

F. General Comparison with the predicate device

Device	Proposed Device	Predicate Device	Remark
Manufacturer	Xiantao Xinxin Non-woven Co.,Ltd.	Fugou County Shenxiang Manufacturing Co., LTD.	/
Model Name	Non-sterile Level 3 Surgical Gown, Sterile Level 3 Surgical Gown, Non-sterile Reinforced Level 4 Surgical Gown, Reinforced Sterile Level 4 Surgical Gown	Disposable Surgical Gown, Disposable Reinforced Surgical Gown	/
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	same
Intended Use /Indications for use	Surgical Gowns are intended to be worn by operation room personnel during surgical procedures or other invasive procedures to protect both the surgical patient and operating room personnel from the	Disposable Surgical Gown and Disposable Reinforced Surgical Gown 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	same

	transfer of microorganisms, body fluids and particulate material. This is single use, disposable device, provided non-sterile and sterile. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end users. Per ANSI/AAMI PB70:2022 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the surgical gowns meet the requirements for Level 3 classification, and the reinforced surgical gowns meet the requirements for Level 4 classification.	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, Disposable Surgical Gown ML515M45U met the requirements for Level 3 classification, Disposable Surgical Gown GD524ME65 and Disposable Reinforced Surgical Gown met the requirements of Level 4 classification.	
Style	Non-reinforced/Reinforced	Non-reinforced/Reinforced	same
Use	Single Use; Disposable	Disposable	same
Color	Blue	Blue	same
Size	S, M, L, XL, XXL, and XXXL	S, M, L, XL, XXL, and XXXL	same
Labelling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	same

Technical Comparison with the predicate device

Table 1 Comparison for Level 3 Surgical Gowns

Item	**Proposed Device**	**Predicate Device K212869**	**Remark**
Weight per square(g)	36 g/m^2	45 g/m²	different
Flammability	Class I	Class I	same
Hydrostatic pressure	>50 cm	>50 cm	same
Water impact	≤1.0 g	≤1.0 g	same
Breaking strength	>20N Longitude:94.9N Latitude:63.5N	>20N	same
Tearing strength	>20N Longitude:48.3N Latitude:21.6N	>20 N	same
Seam Strength	74.5N	No found in the summary	/
Linting	Log_{10}＜4	Log_{10}＜4	same
Sterilization	Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	same
Ethylene oxide residues	EO <4mg/device ECH <9mg/device	No found in the summary	/
Shelf Life	3 years	No found in the summary	/
Barrier protection level	Level 3 per AAMI PB70	Level 3 per AAMI PB 70	Same

Material	SMS non-woven, SPP fabric, PET	SMS, Polyester, Blue masterbatch	different
Sterility	Sterile/Non-Sterile	Sterile	different
Biocompatibility	Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non sensitizing.	Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non-sensitizing.	same

Discussion

Different - Weight per square

The weight per square of the proposed device is different from the predicate devices. The weight per of the proposed device is 36g/m^2 for the body, arm and belt ; 30g/m^2 for the neck tie; while the predicate device is 45 g/m^2. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrate that the proposed surgical gown can meet the barrier protection level 3 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different- Material

The material for the proposed surgical gowns is different from the predicated device. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Sterility

The proposed product is available in sterile or non-sterile form, the non-sterile model shall be terminal sterilized, so none of the proposed devices can be used before sterilization, which is essentially the same as the predicated device.

Table 2 Comparison for reinforced Level 4 Surgical Gowns

Item	**Proposed Device**	**Predicate Device K212869**	**Remark**
Weight per square(g)	36 gsm Blue SMS Fabric + 30 gsm white SPP + 45gsm White Laminated Fabric (reinforced film)	Level 4 Reinforced Surgical Gown: 45g/m^2 and 25g/m^2 PE film reinforced film	different
Flammability	Class I	Class I	same
Hydrostatic pressure	>50 cm	>50 cm	same
Water impact	≤1.0 g	≤1.0 g	same
Breaking strength	Reinforced area: Latitude: 150.25N Longitude:201.62N	Level 4 Reinforced Surgical Gown: Latitude:109N Longitude:122N	different
Tearing strength	Reinforced area: Latitude: 44.8N Longitude:100.1N	Level 4 Reinforced Surgical Gown: Latitude:80N Longitude:137N	different
Seam Strength	62.5N	No found in the summary	/

Linting	Log_{10}＜4	Log_{10}＜4	same
Sterilization	Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	Method: Ethylene Oxide (EO); Sterilization Assurance Level (SAL): 10^{-6}	same
Ethylene oxide residues	EO <4mg/device ECH <9mg/device	No found in the summary	
Shelf Life	3 years	No found in the summary	/
Barrier protection level	Level 4 per AAMI PB70	Level 4 per AAMI PB 70	Same
Barrier Penetration	No detectable transfer of the Phi-X174 Bacteriophage	No detectable transfer of the Phi-X174 Bacteriophage	same
Material	SMS non-woven, SPP fabric, PET, laminated fabric reinforced film	SMS nonwoven, Polyester, PE film reinforced film and Blue masterbatch	different
Sterility	Sterile/Non-Sterile	Sterile	different
Biocompatibility	Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non sensitizing.	Under the conditions of the study, the device is non-cytotoxic, non-irritating, and non-sensitizing.	same

Discussion:

Different - Weight per square

The weight per square of the proposed device is different from the predicate devices. The weight per of the proposed device is 36g/m^2 for the body, arm and belt ; 30g/m^2 for the neck tie; 45 g/m^2 for the reinforced piece, while the predicate device is 45 g/m^2 plus 25g/m^2 PE film reinforced film. However, the difference in the weight per square will not affect the intended use. In addition, the performance testing results demonstrate that the proposed surgical gown can meet the barrier protection level 4 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Breaking Strength

The breaking strength for the proposed device is different from the predicate device. Breaking strength is one of the indicators to evaluate the ability of the gown to withstand destructive force. The greater the breaking strength value, the stronger the ability to withstand destructive force. The breaking strength of the proposed device are larger than the predicate device. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Tearing strength

The tearing strength for the proposed device is different from the predicate device.Although the tearing strength of the proposed device is smaller than that of the predicated device, according to ASTM F2407/F2407M-2023, the acceptance criteria of tearing strength shall be more than 10N and the test result of the proposed device can meet this acceptance criteria. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Material

The material for the proposed surgical gowns is different from the predicated device. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Sterility

Except for sterilized model, the proposed devices will also be released in non-sterile state, but the non-sterile model shall be terminal sterilized, so none of the proposed devices can be used before sterilization, which is essentially the same as the predicated device.

Analysis

The subject surgical gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, and configuration. The weight per square (g) , breaking strength, tearing strength, material and Sterility are slightly different from those of the predicate device.

The proposed device has been tested according to ASTM F1671/F1671M-2022, AATCC 127-2018e , AATCC TM42-2017, ASTM D5034-2021, ASTM D5587-2015(2024), ASTM D1683/D1683M-2022, ISO 9073-10-2003, , US 16 CFR Part 1610, AAMIPB70:2022, ASTMF2407/F2407M-2023 respectively, and met the requirements of these standards.

Difference of the materials will not raise safe and effectiveness concerns. The biocompatibility and performance tests have been conducted to verify the safety and effectiveness of the gowns. Under the conditions of each study, the subject surgical gowns are non-cytotoxic, non-sensitizing and negligibly irritating per ISO-10993 and have met the requirements of ANSI/AAMI PB70:2022 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities for AAMI Level 3 and Level 4 surgical gowns.

G. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications.The subject surgical gown was assessed for performance using the following Standards and Test Methods.

The test results demonstrated that the proposed device met its acceptance criteria or testing endpoints.

Test Item	**Test standard**	**Acceptance Criteria**	**Result Level 4**	**Result Level3**
Seam strength	The test was performed in accordance with ASTM D1683/D1683M-22 Standard. Test Method for Seam Strength of Textile Fabrics (Grab Test) to evaluate Failure in Sewn Seams of the test sample.	≥30N(7lbf) per standard F2407/F2407M-23	PASS Average 62.5 N	PASS Average 74.5N

Breaking strength	The test was performed In accordance with D5034-2021. Standard. Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	≥30N(7lbf) per standard F2407/F2407M-23	PASS Reinforced area: Latitude: 150.25N Longitude:201.62N	PASS Latitude:63.5N Longitude:94.9N

Tear strength (N)	The test was performed in accordance with ASTM D5587: 2015(2024) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure to evaluate the tearing strength of the test sample.	≥10N(2.3lbf) per standard F2407/F2407M-23	PASS Reinforced area: Latitude: 44.8N Longitude:100.1N	PASS Latitude:21.6N Longitude:48.3N
Lint and other generation in the dry state	The test was performed in accordance with ISO 9073-10: 2003 Textiles Test Methods for Nonwovens - Part 10: Lint and Other Particles Generation in the Dry State to evaluate the linting of the test sample.	Log_{10}(particle count) < 4	PASS	PASS
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.	Class I	PASS Class I	PASS Class I

Water Impact	The test was performed in accordance with AATCC TM42-2017 Water Resistance: Impact Penetration Test to evaluate the water impact of the test sample.	≤1.0g per standard ANSI/AAMI PB70:2022 for level 3 AQL: 4%	PASS ≤1.0g	PASS ≤1.0g
Static hydrostatic resistance	The test was performed in accordance with AATCC 127- 2018e Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≥50 cmH_2O per standard ANSI/AAMI PB70:2022 for level 3 AQL: 4%	PASS ≥50 cmH_2O	PASS ≥50 cmH_2O
Pathogens Penetration	The test was performed in accordance with ASTM F1671/F1671M-2022 to measure the resistance of materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact	No detectable transfer of the Phi-X174 Bacteriophage per ANSI AAMI PB70:2022	PASS	Not evaluated
EO and ECH sterilization residual	The test was performed in accordance with ISO 10993-7:2008+A1:2019 Ethylene oxide sterilization residuals to determine the EO and ECH residuals of the test sample.	EO ⩽ 4mg/d ECH ⩽ 9mg/d	PASS	PASS

Cytotoxicity	The test was performed in accordance with ISO 10993-5 to determine cytotoxicity of the test sample	Non-Cytotoxic	PASS	PASS
Irritation	The test was performed in accordance with ISO 10993-10 to determine Irritation of the test sample	Non-Irritating	PASS	PASS
Sensitization	The test was performed in accordance with ISO 10993-10 to determine skin sensitization of the test sample	Non-Sensitizing	PASS	PASS

H. Summary of Clinical Test

No clinical study is included in this submission.

I. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device under K212869.