October 11, 2022

Hubei Xinxin Non-woven Co.,Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K214116
Trade/Device Name: AAMI4 Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: September 8, 2022
Received: September 13, 2022

Dear Diana Hong:

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,

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)*

K214116

Device Name

AAMI4 Isolation Gown

Indications for Use *(Describe)*

The AAMI4 Isolation Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. The proposed AAMI4 Isolation Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB 70:2012, Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The AAMI4 Isolation Gown is a single use, disposable medical device provided non-sterile.

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.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K214116

1. Date of Preparation: 10/08/2022

2. Sponsor Identification

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3. Designated Submission Correspondent Ms.

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4. Identification of Proposed Device

Trade Name: AAMI4 Isolation Gown
Common Name: Surgical Isolation Gown

Regulatory Information

Classification Name: Surgical Isolation Gown
Classification: II
Product Code: FYC
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital;

Indications for Use:

The AAMI4 Isolation Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. The proposed AAMI4 Isolation Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB 70:2012, Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The AAMI4 Isolation Gown a single use, disposable medical device provided non-sterile.

Device Description:

The proposed device, AAMI4 Isolation Gown, is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. The proposed device is a single use, disposable medical device provided non-sterile.

There is one model of AAMI4 Isolation Gown: 4015T. And the proposed AAMI4 Isolation Gown is available in one product size: U. The barrier protection level for AAMI4 Isolation Gown meets AAMI Level 4. The proposed device consists of five components: 1) Basic Gown, 2) Belt, 3) Cuff, 4) Hook-and-loop Velcro and 5) Seam Sealing Tape. The gown is made of polypropylene and polyethylene laminating. The gown is blue in color.

5. Identification of Predicate Device

510(k) Number: K190306
Product Name: AMD Ritmed AssureWear™ VersaGown

6. Summary of Technological characteristics

Table 1 General Comparison

Item	Proposed Device K214116	Predicate Device K190306	Remark
Product Code	FYC	FYC	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indications for Use	The AAMI4 Isolation Gown is intended to protect health care personnel and patients from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. The proposed AAMI4 Isolation Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB 70:2012, Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities. The AAMI4 Isolation Gown a single use, disposable medical device provided non-sterile.	AMD Ritmed AssureWear™ VersaGown is intended to be worn by healthcare personnel to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. AMD Ritmed AssureWear™ VersaGown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). AMD Ritmed AssureWear™ VersaGown is a single use, non-sterile disposable medical device and not intended for use in operating rooms. The medical device will be available in 18 models in large and X-large sizes.	Similar
Design	Tape, Neck closure, Belt tie, Elastic cuffs	Thumb loop, Elastic cuffs, Extended cuff (Thumb loop), Flexneck™, Tie (neck), Straight sleeve, Inclined sleeve, Blue belt tie, Reinforced seams	Similar
Use	Single use; disposable	Single use; disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Safety and Effectiveness Comparison

Item	Proposed Device K214116	Predicate Device K190306	Remark
Weight per square (g)	43 g/m^2	39.97 ± 1.61 g/m^2 (1.17 oz/yd2 ± 0.05)	Different
Size	Universal (U)	Large and X-large	Different
Flammability	Class I	Class I	Same
Hydrostatic pressure	Gown sleeve: 188 cmH_2O Sleeve seam: 80 cmH_2O Body-sleeve seam: 65 cmH_2O Gown body: 199 cmH_2O Belt attachment: 74 cmH_2O	Chest: 109.34 ± 0.34 cmH_2O Sleeve seams: 110.67 ± 3.84 cmH_2O Belt attachments: 104 ± 5.19 cmH_2O Body/sleeve/belt mean: 108 ± 3.1 cmH_2O	Different
Water impact	Gown sleeve: 0g Sleeve seam: 0g Body-sleeve seam: 0g Gown body: 0g Belt attachment: 0g	Chest: <0.1 g Sleeve seams: <0.1 g Belt attachments: <0.1 g Body/sleeve/belt mean: <0.1 g	Different
Breaking strength	MD: Mean 87.3 N CD: Mean 66.7 N	MD: 18.17 ± 0.31 lbf (80.67 ± 1.38 N) CD: 11.78 ± 0.33 lbf (52.30 ± 1.47 N)	Different
Tearing strength	MD: Mean 31.6 N CD: Mean 22.9 N	MD: 11.01 ± 0.64 lbf (48.88 ± 2.84N) CD: 5.30 ± 0.35 lbf (23.53 ± 1.55 N)	Different
Linting	Log10(lint count): Mean 2.5	Particulate size range(μm): 1 to 25 Outside: Total linting >0.3: 2.07; >0.5: 1.97 Index for Particulate Matter (IPM): 1.50 Inside: Total linting >0.3: 2.16; >0.5: 2.00 Index for Particulate Matter (IPM): 1.35	Different
Seam strength	Mean 70.9 N	/	Different
Barrier protection level	Level 4 per AAMI PB 70	Level 3 per AAMI PB 70	Different
Viral barrier (resistance to bacteriophage Phi-X174)	Pass	/	Different
Material	Polypropylene and polyethylene laminating	PP SMS non-woven + PE	Same
Biocompatibility			
Cytotoxicity	Under the condition of the	Under the condition of the study, not	Same

	study, not cytotoxic	cytotoxic	
Irritation	Under the condition of the study, not an irritant.	Under the condition of the study, not an irritant.	Same
Sensitization	Under the condition of the study, not a sensitizer.	Under the condition of the study, not a sensitizer.	Same
Sterilization	Non-sterile	Non-sterile	Same

Similar - Indications for Use

The indications for use of the proposed device and predicate device are not exactly the same, the main difference is that the proposed device is a level 4 isolation gown, while the predicate device is a level 3 isolation gown. However, the biocompatibility test for proposed device was performed and the results showed no adverse effect. And the performance testing for proposed device was also performed and the results demonstrated that the proposed AAMI4 Isolation Gown can meet the barrier protection level 4 requirement. Therefore, these differences will not affect the safety and effectiveness of the proposed device.

Similar - Design

The design of the proposed device and predicate device are not exactly the same. The proposed device does not have the Thumb loop and Flexneck™ patented design compared to the predicate device. However, this does not affect the intended use. In addition, the performance testing results demonstrated that the proposed AAMI4 Isolation Gown can meet the barrier protection level 4 requirement as required by PB70. Therefore, these differences will not affect the safety and effectiveness of the proposed device.

Different - Weight per square

The weight per square of the proposed device is different from the predicate device. The weight per of the proposed device is 43 g/m^2, and the predicate device is 39.97 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 isolation 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 - Size

The size for the proposed device is different from the predicate device. The proposed device is available in one size universal (U), while the predicate device is available in sizes large and X-large. However, the difference in the size will not affect the device performance. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Hydrostatic pressure

The hydrostatic pressure for the proposed device is different from the predicate device. However, the hydrostatic pressure results demonstrate that the proposed device meets the barrier protection level 4

requirement, i.e., at least 50cmH_2O, as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Water impact

The water impact for the proposed device is different from the predicate device. However, the water impact test was conducted on the proposed device and the results demonstrate that the proposed device meets the barrier protection level 4 requirement, i.e., no more than 1.0g, 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 isolation gown to withstand destructive force. The higher the breaking strength value, the stronger the ability to withstand destructive force. The MD and CD breaking strength of the proposed device are higher 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. The CD tearing strength of the proposed device is similar to the predicate device, while the MD tearing strength of the proposed device is smaller than the predicate device. However, the CD and MD tearing strength of the proposed device meets ASTM F2407-20's requirement of greater than 10N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Linting

The water linting for the proposed device is different from the predicate device. However, the linting test was conducted on the proposed device and the testing results demonstrate that the proposed device can meet the requirements of log10<4. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Seam strength

The seam strength was conducted on the proposed device and the testing results demonstrate that the seam strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

Different - Barrier protection level

The barrier protection level for the proposed device is different from the predicate device. The barrier protection level for the proposed device is level 4, while the barrier protection level for the predicate device is level 3. However, the performance testing results demonstrate that the proposed device 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 - Viral barrier (resistance to bacteriophage Phi-X174)
The viral barrier was conducted on the proposed device and the testing results demonstrate that the proposed device can prevent virus penetration, which meets the barrier protection level 4 requirement as required by PB70. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

7. Summary of Non-Clinical Tests

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrate that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- AATCC 127: 2018 Water Resistance: Hydrostatic Pressure Test;
- AATCC 42: 2017 Water Resistance: Impact Penetration Test;
- ISO 9073-10: 2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State;
- ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics;
- ASTM D5587: 2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D5034: 2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ISO 10993-1: 2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ASTM F1671/F1671M-13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System;

Table 3 Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of	Meets Class 1 requirements	Class 1

	Clothing Textiles to evaluate the flammability of the test sample.		
Hydrostatic pressure	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	>50 cm	Gown sleeve: 188 cmH_2O Sleeve seam: 80 cmH_2O Body-sleeve seam: 65 cmH_2O Gown body: 199 cmH_2O Belt attachment: 74 cmH_2O
Water impact	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≤1.0 g	Gown sleeve: 0g Sleeve seam: 0g Body-sleeve seam: 0g Gown body: 0g Belt attachment: 0g
Breaking strength	The test was performed in accordance with ASTM D 5034:2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	>20 N	MD: Mean 87.3 N CD: Mean 66.7 N
Tearing strength	The test was performed in accordance with ASTM D5587:2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure to evaluate the tearing strength of the test sample.	>20 N	MD: Mean 31.6 N CD: Mean 22.9 N
Linting	The test was performed in accordance with ISO 9073-10:2003 Textiles-Test Methods for Nonwovens-Pat 10: Lint and Other Particles Generation in the Dry State to evaluate the linting of the test sample.	Log10(particle count) < 4	Log10(lint count): Mean 2.5
Seam strength	The test was performed in accordance with ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics to	>50 N	Mean 70.9 N

	evaluate the seam strength of the test sample.		
Viral barrier (resistance to bacteriophage Phi-X174)	The test was performed in accordance with ASTM F1671/F1671M-13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System evaluate the resistance to bacteriophage penetration	No bacteriophage penetration	No bacteriophage penetration

Table 4 Summary of Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test sample.	The viability should be ≥ 70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability was ≥70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test sample.	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.
Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

	test sample.		

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and perform as well as or better than the legally marketed predicate device K190306.