Yanbian Pacific Textile Co., LTD
℅ Rafi Wong
Manager
Pacific Fortune Management Inc.
2350 Mission College BLVD, STE 475
Santa Clara, California 95054

Re: K203415
Trade/Device Name: Surgical Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC,
Dated: April 13, 2021
Received: April 19, 2021

Dear Rafi Wong:

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,

For Ryan Ortega
Acting 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)*

K203415

Device Name

Surgical Isolation Gown

Indications for Use *(Describe)*

The Surgical Isolation Gown is intended to protect patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4. Indications for Use Statement

The Surgical Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

The Surgical Isolation Gown is considered under the product code, FYC, under the classification of a surgical isolation gown per the new Guidance for Industry and FDA Staff - Premarket Notification Requirements Concerning Gowns Intended for Use in Healthcare Settings issued by the FDA on December 9, 2015 because this isolation gown has a moderate barrier protection.

The Surgical Isolation Gowns are non-sterile and provided in ONE product model in seven sizes to meet the needs of healthcare patients and health care personnel, Refer to Table 1 below. The medical device will be available in one model in S(160), M(165), L(170), XL(175), XXL(180), 3XL(185), 4XL(190) sizes.

The proposed Surgical Isolation Gown is constructed of Polypropylene SMS non-woven material with the color in blue. The Surgical Isolation Gowns consist of a one critical zone throughout the entire gown including seams but excluding cuffs, hems, and bindings. The product has been tested for barrier performance per ANSI/AAMI PB70:2012. Testing was performed according to the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued on August 1, 1993 and ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities. All results of testing met AATCC-42/AATCC-127, and meets AAMI PB70:2012 Level 3 requirements.

Table 1 Specifications and dimensions of proposed device

Product Name	**Model Number**	**Sterility**	Color	Dimensions	Size
Surgical Isolation Gown	12265	Non-sterile	Blue	105cm×125cm	S(160)
				110cm×130cm	M(165)
				115cm×135cm	L(170)
				120cm×140cm	XL(175)
				125cm×145cm	XXL(180)
				130cm×150cm	3XL(185)
				135cm×155cm	4XL(190)

510K SUMMARY

K203415

Date of Summary Prepared: May 20, 2021

1. Submitter Information

Submitter Contact:

Address: YANBIAN PACIFIC TEXTILE CO., LTD
Longjing industry concentration area, Longjing city,
Jilin, China, 133400

Submitter Contact Person:

Name: Juan Zhuang
Phone Number: (+86) 138-6397-7758
Email: zhuangjuan777@126.com

Designated Submission Correspondent:

Name: Rafi Wong
Phone Number: +1 (408) 646-6537
Email: rafi.wong@pfmfinance.com

2. Device Name: Surgical Isolation Gown

3. Regulatory Information

Classification Name:	Surgical Isolation Gown
Common Name:	Surgical Apparel
Classification:	Class II
Product Code:	FYC
Regulation Number:	21 CFR 878.4040

4. Predicate Device

510K Number:	K190306 - AMD Medicom Inc.
Device Name:	AMD Ritmed AssureWear™ VersaGown
Cleared date:	January 17, 2020

5. Intended Use/Indications for Use

The Surgical Isolation Gown is intended to protect patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

6. Device Description

The proposed Surgical Isolation Gown is constructed of Polypropylene SMS non-woven material with the color in blue. The melt-blown nonwovens are made of polypropylene. The Surgical isolation gown is different in size. The size of surgical isolation gown is divided into seven groups: S(160), M(165), L(170), XL(175), XXL(180), 3XL(185), 4XL(190).

The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.

The device description of the Surgical Isolation Gown is in accordance with the Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes, issued on August 1, 1993 and ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

7. Summary of Comparison and Technological Characteristics

Table I - General Comparison

Items	Proposed Device K203415	Predicate Device K190360	Result
Product Common Name	Surgical Isolation Gown	AMD Ritmed AssureWear™ VersaGown	Difference
Manufacturer	YANBIAN PACIFIC TEXTILE CO.,LTD	AMD Medicom Inc.	-
510K Number	K203415	K190306	-
Product Code	FYC	FYC	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use/Indication for Use	The Surgical Isolation Gown is intended to protect patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, the Surgical Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is 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. 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.	Similar
Materials	SMS PP + PE non-woven fabric material	PP SMS non-woven + PE	Same
Color	Blue	Blue	Same

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 for all designs except for the Flexneck patented design
OTC Use	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	No	No	Same
Level of barrier protection AAMI PB70	Level 3	Level 3	Same
Physical and mechanical performance			
Basic weight ASTM D3776	60.7 g/m2 (1.79 oz/yd2) Seam between areas C&D: <0.1g	39.97 ± 1.61 g/m2 (1.17 oz/yd2 ± 0.05)	Similar
Flammability 16 CFR Part 1610.7	Class 1	Class 1	Same
Breaking strength (MD) ASTM D5034	Mean: 175.5 N	18.17 ± 0.31 lbf	Similar
Breaking strength (CD) ASTM D5034	Mean: 118.0 N	11.78 ± 0.33 lbf	Similar
Tearing strength (MD) ASTM D5733-1999	Mean: 63.5 N	11.01 ± 0.64 lbf (ASTM D5587)	Similar
Tearing strength (CD) ASTM D5733-1999	Mean: 34.5 N	5.30 ± 0.35 lbf (ASTM D5587)	Similar
Linting (ISO 9073-10)	Particulate size range(µm): 3 to 25 A: Face: Measured value Coefficient of lingting log10 Min:2.2, Max:2.8, Mean: 2.5; B: Face: Measured value Coefficient of lingting log10 Min:2.5, Max:2.9, Mean:2.74	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	Similar
Biocompatibility			

Cytotoxicity ISO 10993-5: 2009	Non-Cytotoxic	Non-Cytotoxic	Same
Irritation ISO 10993- 10: 2010	Non-Sensitizing	Non-Sensitizing	Same
Sensitization ISO 10993- 10: 2010	Non-Irritating	Non-Irritating	Same

*The difference in the materials and colors does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

8. Summary of Non-clinical Tests Performed on the Proposed Device

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes on August, 1993 STANDARDS:

- AAMI PB70:2012, Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.
- ASTM D3776/D3776M-09 (2013), Test Methods for Mass Per Unit Area (Weight) of Woven Fabric.
- ASTM D5034-09(2013), Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test).
- ASTM D5587-2015, Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure.
- (CPSC), Part 1610, Standard For The Flammability Of Clothing Textiles.
- AATCC 42-2017, Water Resistance: Impact Penetration Test.
- AATCC 127-2018, Water Resistance: Hydrostatic Pressure Test.
- ISO 10993- 1: 2009/(R)2013, Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process.
- 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 9073-10:2004, Textiles-Test methods for nonwovens-Part 10: Lint and other particles generation in the dry state.

9. Clinical Test

There is no clinical study included in this submission.

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the proposed device Surgical Isolation Gown is as safe, as effective, and performs as well as or better than the predicate device, the AMD Ritmed AssureWear™ VersaGown (K190306) manufactured by AMD Medicom Inc.