October 28, 2022

Xiantao Rhycom Non-woven Products Co., Ltd
℅ Jet Li
Regulation Manager
PureVision Ai, Inc.
Contact Address

Re: K211060
Trade/Device Name: Disposable Surgical Gown Rk-3011C
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: October 26, 2022
Received: October 27, 2022

Dear Jet 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 (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.

Submission Number *(if known)*

K211060

Device Name

Disposable Surgical Gown (Rk-3011C)

Indications for Use *(Describe)*

The Disposable Surgical Gown Rk-3011C is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of 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, the Disposable Surgical Gown Rk-3011C surgical gowns met the requirements for Level 3 classification.

This is a single use, disposable device(s), provided non-sterile. The Surgical Gowns is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.

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."

K211060

510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirements of 21 CFR 870.92.

This summary was prepared on October 17, 2022.

1. Submitter Information

Sponsor Company Name: Xiantao Rhycom Non-woven Products Co., Ltd

Address: Chuangye Road, Longhuashan Sub-district, Xiantao City, Hubei, China

Phone: 86-15271157850

Contact Person (including title): Liu Yang (Operational position)

E-mail: Yang@chinarhycom.com

Application Correspondent: PureVision Ai, Inc.

Address: 111 Town Square Place Suite 1203, Jersey City, NJ, 07310-2784, USA

Contact:

Name: Mr. Bryan Wong

Title: Associate

Tel: +1 201-371-3083

Email: bryan@purefda.com

Alternate Contact Person: Mr. Jet Li

Tile: Regulation Manager

Tel: +86-18588874857

Email: jet@ne.purefda.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Classification/Common Name: Surgical Gown, Surgical Apparel
- Trade Name: Disposable Surgical Gown Rk-3011C
- Model: Rk-3011C
- Review Panel: General & Plastic Surgery
- Product Code: FYA
- Regulation Number: 21 CFR 878.4040
- Regulation Class: Class II

3. Predicate Device Information

- 510(k) number: K172987
- Sponsor: Wuhan Dymex Healthcare Co., Ltd.
- Classification/Common Name: Surgical Gown, Surgical Apparel
- Trade Name: Surgical Gown (AG1001, AG2001, AG3001)
- Model: AG1001, AG2001, AG3001
- Review Panel: General & Plastic Surgery
- Product Code: FYA
- Regulation Number: 21 CFR 878.4040
- Regulation Class: Class II

4. **Device Description**

The proposed surgical gown is a single use, disposable medical device provided as bulk, non-sterile items to repackagers/ relablers for further packaging and Ethylene Oxide (EO) sterilization.

The gown is manufactured with four layers: the inner and outer layers are made of spun-bond polypropylene and the middle layers are made of melt blown polypropylene. All gowns are reinforced with polypropylene and microporous reinforcement material. The proposed surgical gown is only available in the color blue. The available sizes of the proposed surgical gown are M, L, XL, and XXL.

The cuffs are composed of cotton and terylene. The back is open with ties to secure the gown.

5. Intended Use/Indications for Use

The Disposable Surgical Gown Rk-3011C is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of 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, the Disposable Surgical Gown Rk-3011C surgical gowns met the requirements for Level 3 classification.

The Surgical Gown is single use, disposable medical device provided non-sterile. The Surgical Gowns is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.

6. Comparison of technological characteristics with the predicate

The primary components of The Disposable Surgical Gown Rk-3011C are manufactured to identical or similar specifications of the predicated devices listed above. The intended use, basic design, function and materials used are identical or similar to the predicate devices.

Table 1 General Comparison

.

Element of Comparison	Subject Device (K211060)	Predicate Device (K172987)	Comparison
510(K)	K211060	K172987	--
Product Name	Disposable Surgical Gown Rk-3011C	Surgical Gown (AG1001, AG2001, AG3001)	--
Classification	Class II, FYA (21 CFR878.4040)	Class II, FYA (21 CFR878.4040)	Same
Intended Use/Indications for Use	Surgical gown is 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 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, the Rk-3011C surgical gowns met the requirements for Level 3 classification. The Surgical Gown is single use, disposable medical device provided non-sterile. The Surgical Gowns is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.	Surgical gown is 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 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, the AG series surgical gowns met the requirements for Level 3 classification.	Same. Additional statement added to intended use of Subject Device meets current requirements for FDA.
Style	Poly-reinforced	Non-reinforced/Fabric-reinforced/Poly-reinforced	Similar. Differences addressed by performance testing. No new issues of safety or effectiveness.
Size	M, L, XL, XXL	XL	No new issues of safety or effectiveness.
Color	Blue	Blue	Same
Durability	Disposable	Disposable	Same
Sterile	Sterile by packager	Sterile by packager	Same
Sterilization Method	EO	EO	Same
Ethylene oxide residuals	EO< 4 mg/device; ECH <9 mg/device Met requirements of ISO 10993-7:2008	Data not available, required to meet the requirements of ISO 10993-7: 2008	Same

Table 2 Performance Characteristic Comparison

Element of Comparison		Test results /Verdict	Subject Device (K211060)	Predicate Device (K172987)	Comparison
Physical Specification	**Barrier protection level**	Level 3	Level 3 per AAMI PB70	Level 2/Level 3 per AAMI PB70	Subject device provides higher level of barrier protection
	Tearing Strength	≥10N	>30N	>30N	Same
	Fire protection	Class I	Class I	Class I	Same
	Lint	Log10< 4	Log10=2.53	Log10< 4	Same
Mechanical Specifications	**Tensile Strength**	Head To Toe Peak Load (N) AVG was 138.8N, Cross Body AVG was 95.6N	>30N	≥20N	Same, both comply
	Seam Strength	≥30N	Min 59.0N	Not disclosed	Same, both comply
	Durability	Disposable	Disposable	Disposable	Same

Table 3 Biocompatibility Comparison

Element of Comparison	Subject Device (K211060)	Predicate Device (K172987)	Comparison
Material	SMMS, Microporous and polypropylene	SMMMS, Polypropylene, PE (Poly Ethylene), Polyester	Similar. Differences addressed by performance testing. No new issues of safety or effectiveness
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

7. Discussion of Non-Clinical Tests Performed:

The subject surgical gown was assessed for performance using the following Standards and Test Methods

Test Methodology	Test Methodology Purpose	Acceptance Criteria	Test Results	Pass/Fail
ASTM D5034-09	Tensile Testing	≥30N	Head To Toe Peak Load (N) AVG was 138.8N, Cross Body AVG was 95.6N	Pass
ASTM D5733	Tearing Strength of Fabrics by Trapezoid Procedure	≥10N	HEAD TO TOE AVG was 57.3N, CROSS BODY AVG was 37.5N.	Pass
ASTM D1683	Seam Strength	≥30N	Min 59.0N	Pass
AATCC 42	Water Resistance: Spray Impact	<0.1 g	<0.1 g	Pass
AATCC 127,ANSI/AAMI PB70:2012, and ISO 811:2018	Water Resistance: Hydrostatic Pressure	≥50 cm H_2O	50cmH_2O ≤ Chest: < 162cmH_2O 50cmH_2O ≤ Sleeve: <114cmH_2O 50cmH_2O ≤ Sleeve Seam: < 95.1cmH_2O	Pass
ISO 9073-10:2003	Determining Lint	<4	<4	Pass
16 CFR 1610	Flammability	Class I	Class I	Pass
ISO 10993-5: 2009	In Vitro Cytotoxicity	Under the condition of the test, the test article must be non-cytotoxic	Under the condition of the test, the test article was found to be non-cytotoxic	Pass
ISO 10993 -10: 2010	Skin Sensitization	Under the condition of the test, the test article must be non-sensitizing	Under the condition of the test, the test article was found to be non-sensitizing	Pass
ISO 10993 -10: 2010	Skin Irritation test	Under the conditions of the test, the test article must be non-irritating	Under the conditions of the test, the test article was found to be non-irritating	Pass
ISO 10993-7: 2008	Ethylene Oxide (EO)/ Ethylene Chlorohydrin (ECH) Residuals	Under the conditions of the test, the test article must meet with EO and ECH residual limit: EO< 4 mg/device; ECH <9 mg/device	Under the conditions of the study, the test article meets the allowable limits of Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH)	Pass

8. Summary of Clinical Test

Clinical testing is not needed for the subject devices.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device, the Disposable Surgical Gown Rk-3011C, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Surgical Gown cleared under K172987.