November 24, 2021

String King Lacrosse, LLC
% Sharon Morrow
Regulatory Affairs Consultant
Medical Device Academy Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K212633
Trade/Device Name: Disposable Isolation Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: August 3, 2021
Received: August 19, 2021

Dear Sharon Morrow:

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 Clarence W. Murray III, 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)*
K212633

Device Name
Disposable Isolation Gown

Indications for Use *(Describe)*
The StringKing Disposable Isolation Gown is intended to protect health care personnel and health care patients from the transfer of microorganisms, body fluids and particulate material. These gowns are not intended for use in the operating room. The StringKing Isolation Gown 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). The String King Disposable Isolation Gown is a single use, disposable medical device and is 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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K212633
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

String King Lacrosse, LLC
19100 S Vermont Ave.
Gardena, CA, 90248 USA
Tel: +1.508.654.1988
Fax: N/A

Contact Person: Thomas Frasca
Date Prepared: November 23, 2021

II. DEVICE

Name of Device:	Disposable Isolation Gown
Classification Name:	Surgical Isolation Gown
Regulation:	21 CFR § 878.4040
Regulatory Class:	Class II
Product Classification Code:	FYC

III. PREDICATE DEVICE

Predicate Manufacturer:	Wildcat PPE, LLC
Predicate Trade Name:	Wildcat PE Surgical Isolation Gown Full Back
Predicate 510(k):	K202310

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Disposable, single-use isolation gown. The StringKing Disposable Isolation Gown is made of blue polyethylene and serves as a barrier to the transfer of microorganisms, body fluids and particulate material. The gowns feature hook and loop neck closure with a strap for fastening the back of the gown. The gown sleeves have thumb-loops to keep sleeves from sliding when donning the gown. The gowns are available in Large and X-Large sizes. The gowns are non-sterile, single-use devices.

V. INDICATIONS FOR USE

The StringKing Disposable Isolation Gown is intended to protect health care personnel and health care patients from the transfer of microorganisms, body fluids and particulate material. These gownsare not intended for use in the operating room. The StringKing Disposable Isolation Gown 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). The String King Disposable Isolation Gown is a single use, disposable medical device and is provided non-sterile.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device to demonstrate substantial equivalence in Table 1 below.

Table 1 – Comparison of Technological Characteristics

Device	Proposed Device - Disposable Isolation Gown	Predicate Device - Wildcat PE Surgical Isolation Gown Full Back	Result
Manufacturer	StringKing	Wildcat PPE, LLC	N/A
510K Number	K212633	K202310	N/A
Product Common Name	Disposable Isolation Gown	Surgical Isolation Gown	N/A
Product Code	FYC	FYC	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use/Indications for Use	The StringKing Disposable Isolation Gown is intended to protect health care personnel and health care patients from the transfer of microorganisms, body fluids and particulate material. These gownsare not intended for use in the operating room. The StringKing Disposable Isolation Gown 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). The String King Disposable Isolation Gown is a single use, disposable medical device and is provided non-sterile. .	Wildcat PE Surgical Isolation Gown Full Back 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 Wildcat PE Surgical Isolation Gown Full Back meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Wildcat PE Surgical Isolation Gown Full Back is a single use, disposable medical device provided non-sterile.	Same
Material Composition	Polyethylene LDPE CAS # 9002-88-4	Linear Low-Density Polyethylene (LLDPE)	Same
Design Features	Hook and Loop Neck Closure Closed back – tie at waist Thumb Loops	Tabs Tie in the Middle of Back Thumbhole at Cuff	Similar; predicate device has ties at neck while subject device has hook and loop

Color	Blue CAS # 147-14-8	Blue (CAS unknown)	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same

VII. NON-CLINICAL PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Device	Proposed Device - Disposable Isolation Gown	Predicate Device - Wildcat PE Surgical Isolation Gown (K202310)	Result
ANSI/AAMI PB70:2012	Level 3	Level 3	Same
Water Resistance HydrostaticPressure Test - AATCC 127:2017 (cm)	Fabric (body) Mean 170.33 Min 128.87 Max 196.87 Sleeve Mean 126.60 Min 54.83 Max 189.40 Armhole Each lot tested had less than 4 failures in the armhole region; thus meeting the requirement of AQL 4.0.	Chest: Mean = >151 Min = 155 Max = >155 Sleeve Seam: Mean = >165 Min = 171 Max = >173	Both the subject and predicate device passed at ≥50cm
Water Resistance Impact Penetration Test AATCC 42	Fabric (body) Mean 0.01 Min 0.00 Max 0.11 Sleeve Mean 0.03 Min 0.01 Max 0.38 Armhole Mean 0.02 Min 0.00 Max 0.16	Chest: Mean = <0.1 Min = <0.1 Max = .5 Sleeve Seam: Mean = <0.1 Min = <0.1 Max = <0.1	Both the subject and predicate device passed at ≤1.0g
Flammability of Clothing Textiles - 16 CFR Part 1610 (a)	Mean 5.41 Min 1.63 Max 7.87	Class I	Class 1: average > 3.5 seconds. Both the subject and predicate device passedwith an average of ≥3.5 seconds.

Tear Resistance - ASTM D1004*	N/A	Max Load (lbf): Mean = 1.04 Min = .95 Max = 1.17 Max Extension (in): Mean = 1.01 Min = .91 Max = 1.10	Subject device not tested as this method is not required by ANSI/AAMI PB70:2012 or ASTM F2407-20
General Tensile Testing - ASTMD882*	N/A	Breaking Factor (lbf/in): Mean = 6.66 Min = 4.87 Max = 9.20 Tensile (Max) (MPa): Mean = 24.8 Min = 19.7 Max = 33.4 Tensile (Break) (MPa): Mean = 21.5 Min = 15.9	Subject device not tested as this method is not required by ANSI/AAMI PB70:2012 or ASTM F2407-20
		Max = 33.4 Elongation (%): Mean = 1061 Min = 945 Max = 1327 Modulus (MPa): Mean = 91.1 Min = 2.58 Max = 117	
Trap Tear ASTM D5587-15	Length Mean 3.80 Min 3.18 Max 4.46 Width Mean 6.88 Min 6.26 Max 7.58	Mean = 5.10 Ind Min = 3.2 Ind Max = 7.0	Both the subject and predicate device passed at ≥2.3lbf
Grab Tensile CD ASTM D5034	Length Mean 23.75 Min 20.54 Max 25.91 Width Mean 19.63 Min 17.10 Max 21.59	Mean = 21.95 Ind Min = 20.60 Ind Max = 23.30	Both the subject and predicate device passed at ≥7lbf

ASTM D1683 Seam Strength	Sleeve Mean 11.95 Min 6.48 Max 18.18 Armhole Mean 12.30 Min 6.95 Max 17.41	Not included in 510k summary	The subject device passed at ≥7lbf; test data not provided in 510k summary for predicate device
Liquid Barrier Performance Classification Properties	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for a surgical gown.	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for a surgical gown.	Same
Biocompatibility			
Cytotoxicity: ISO 10993- 5:2009 [FR Recognition #2-245] Study # JN20I0831	Pass Test Articles: Grade 0 (non-cytotoxic)	Details not included in 510k summary; Summary states "Pass: ISO 10993-1"	Same
Skin Irritation: ISO 10993-10:2010(R)2014 [FR Recognition 2-174] Study #: JN20I0832	Negligible (pass) Specimen:0.0 non-irritating	Details not included in 510k summary; Summary states "Pass: ISO 10993-1"	Same
Skin Sensitization: ISO 10993-10:2010(R)2014 [FR Recognition 2-174] Study #: JN20I0833	No sensitization noted (pass) Specimen:0.0 – non- sensitizing	Details not included in 510k summary; Summary states "Pass: ISO 10993-1"	Same
Sterilization Modality	None (Non-Sterile)	None (Non-Sterile)	Same

**These tests are specifically for tear and tensile properties of thin plastic sheeting.*

The following standards were utilized in performance and biocompatibility testing of the StringKing Disposable Isolation Gown.

Table 2 – Use of Standards

	Standards Organization	Standards Title
PB70	AAMI	AAMI PB70 Liquid Barrier Performance Classification of Protective Apparel
TM 127	AATCC	Water Resistance: Hydrostatic Pressure Test
TM 42	AATCC	Water Resistance: Impact Penetration Test
F2407-20	ASTM	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
D5034	ASTM	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

D5587	ASTM	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure
D1683	ASTM	Standard Test Method for Failure in Sewn Seams of Woven Fabrics
Part 1610	CPSC	Standard for the Flammability of Clothing Textiles
10993-1	ISO	ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and
10993-5	ISO	Biological Evaluation of Medical Devices- Part 5: Tests for In-Vitro Cytotoxicity
10993-10	ISO	Biological Evaluation of Medical Devices- Part 10: Tests for irritation and delayed-type hypersensitivity

Sterilization & Shelf-life Testing

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

Table 3 - Biocompatibility Testing

Biocompatibility Testing Endpoints	Acceptance Criteria	Result
Cytotoxicity – ISO 10993-5	Non-Cytotoxic	Pass
Skin Sensitization – ISO 10993-10	Non- Sensitizing	Pass
Skin Irritation – ISO 10993-10	Non-Irritating	Pass

Software Verification and Validation Testing

Not Applicable (Passive Device)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Passive Device)

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K202310), manufactured by Wildcat PPE LLC.