January 29, 2021

Wildcat PPE, LLC
Matthew Mcfarlane
General Counsel
301 S. Trade Center Pkwy
Conroe, Texas 77385

Re: K202310
Trade/Device Name: Wildcat PE Surgical Isolation Gown Full Back
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: January 25, 2021
Received: January 27, 2021

Dear Matthew Mcfarlane:

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: Elizabeth F. Claverie-Williams, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202320

Device Name
Wildcat PE Surgical Isolation Gown Full Back

Indications for Use *(Describe)*
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.

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 (K202310) Wildcat PE Surgical Isolation Gown Full Back

Manufacturer:
Wildcat PPE, LLC
26980 Decker Prairie Rosehill Rd
Magnolia, TX 77355

Regulatory Affairs Contact:
Matthew McFarlane
26980 Decker Prairie Rosehill Rd
Magnolia, TX 77355
Telephone Number: (346) 367-4299

Date Summary Prepared: June 15, 2020

Trade Name: Wildcat PE Surgical Isolation Gown Full Back

Regulation Number: 21 CFR §878.4040

Device Class: Class II

Regulation Name: Surgical Apparel

Common Name: Surgical Isolation Gown

Product Code: FYC

Classification Name: Surgical Isolation Gown

Predicate Device: Cardinal Health Isolation Gown, K160339

Indications for Use:
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.

Device Description:
The Wildcat PE Surgical Isolation Gown Full Back is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code FYC. Wildcat PE Surgical Isolation Gown Full Back is a single use, disposable medical device provided nonsterile. Wildcat PE Surgical Isolation Gown Full Back is offered in one color (blue) and one universal size. Each model is constructed of Linear Low- Density Polyethylene and has been tested according to ANSI/AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3.

Technological Characteristics Comparison Tables:

Side by Side Comparison Table: Predicate Device, Cardinal Health Isolation Gown and Proposed Device, Wildcat PPE Disposable PE Isolation Gown.

Element of Comparison	**Predicate Device: Cardinal Health Isolation Gown (K160339)**	**Proposed Device: Wildcat PE Surgical Isolation Gown Full Back (K202310)**	**Comparison Analysis**
Indications for Use	Cardinal Health 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 Cardinal Health Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB?0:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB?0). The Cardinal Health Isolation Gown is a single use, disposable medical device provided non-sterile.	Wildcat PE Surgical Isolation Gown Full Backis 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 Surgical Isolation Gown is a single use, disposable medical device provided non- sterile.	Similar

Element of Comparison	**Predicate Device: Cardinal Health Isolation Gown (K160339)**		**Proposed Device: Wildcat PE Surgical Isolation Gown Full Back (K202310)**		**Comparison Analysis**
Material Composition	Polyolefin (Polypropylene) SMS nonwoven		Linear Low-Density Polyethylene (LLDPE)		Material Composition
Design Features	Medical Tape Neck Closure White Belt Tie Elastic Cuffs		Tabs Tie in the Middle of Back Thumbhole at Cuff		Different
Sterility	Non-sterile		Non-Sterile		Same
Use	Single Use; Disposable		Single Use; Disposable		Same
Color	Blue and Yellow		Blue		Similar
	Test Results Mean (min/max)	**Specifications**	**Test Results Mean (min/max)**	**Specifications**	
Water Resistance Hydrostatic Pressure Test - AATCC 127:2017 (cm)	Body/Sleeve: Mean = 69 Ind Min = 56 Ind Max = 80	Target Mean = 67 Mean Min = 55 Ind Min = 52	Chest: Mean = >151 Min = 155 Max = >155 Sleeve Seam: Mean = >165 Min = 171 Max = >173	Target Mean = 67 Mean Min = 55 Ind Min = 52	Similar
Flammability of Clothing Textiles - 16 CFR Part 1610 (a)	Class I	Class I	Class I	Class I	Same
Tear Resistance - ASTM D1004*	NA	NA	Max Load (lbf): Mean = 1.04 Min = .95 Max = 1.17 Max Extension (in): Mean = 1.01 Min = .91 Max = 1.10	NA	NA
General Tensile Testing - ASTM D882*	NA	NA	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 Max = 33.4 Elongation (%): Mean = 1061 Min = 945 Max = 1327 Modulus (MPa): Mean = 91.1 Min = 2.58 Max = 117	NA	NA
Trap Tear ASTM D5587-15	Mean = 4.74 Ind Min = 3.67 Ind Max = 5.47	Target Mean = 5.40 Mean Min = 3.60	Mean = 5.10 Ind Min = 3.2 Ind Max = 7.0	Target Mean = 5.40 Mean Min = 3.60	Similar
Grab Tensile CD ASTM D5034	Mean = 14.54 Ind Min = 12.70 Ind Max = 16.45	Target Mean = 16.00 Mean Min = 14.00	Mean = 21.95 Ind Min = 20.60 Ind Max = 23.30	Target Mean = 16.00 Mean Min = 14.00	Similar
Water Resistance Impact Penetration Test - AATCC 42	Body/Sleeve: Mean = .07 Ind Min = .05	Target Mean = .1 Max = .5 Ind Max = 1.0	Chest: Mean = <0.1 Min = <0.1	Target Mean = .1 Max = .5 Ind. Max = 1.0	Similar

	Ind Max = .10		Max = .5 Sleeve Seam: Mean = <0.1 Min = <0.1 Max = <0.1		
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		
Biocompatibility	Pass: ISO 10993-1		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. As Wildcat's PPEs Surgical Isolation Gowns are made entirely of LLDPE, the tests applied to Cardinal Health's Isolation Gowns associated with tear and tensile properties are not applicable.

The Wildcat PE Surgical Isolation Gowns Full Back are similar to the predicate device, in terms of intended use, performance testing, material composition, and configuration/dimensions. The Wildcat PE Surgical Isolation Gowns passed biocompatibility studies per ISO-10993 and have met the requirements of AAMI PB70:2012 Liquid Barrier and Performance Classification of Protective Apparel and Surgical Drapes Intended for Use in Health Care Facilities for an AAMI Level 3 isolation gown.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective and performs as well as or better than the legally marketed device.