December 15, 2021

Cadillac Products, Inc.
% Dennis Gucciardo
Partner
Morgan Lewis & Bockius LLP
1111 Pennsylvania Ave
Washington, District of Columbia 20004-2541

Re: K210405
Trade/Device Name: ProTEC-USA EZDoff Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QPC
Dated: November 15, 2021
Received: November 15, 2021

Dear Dennis Gucciardo:

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)*
K210405

Device Name
ProTEC-USA EZDoff Gown

Indications for Use *(Describe)*
ProTEC-USA EZDoff Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The ProTEC-USA EZDoff Gown is a single use, disposable gown provided non-sterile. The back of the gown is open and non-protective. The gown is not intended for use in the operating room.

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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K210405

510(k) SUMMARY

Cadillac Product Inc.'s ProTEC USA EZDoff Gown

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Cadillac Products, Inc.
5800 Crooks Road
Suite 100
Troy, MI 48098

Phone: (248) 813-8200
Fax: (248) 813-8282

Contact Person: Andrew Stone
Date Summary Prepared: December 11, 2021

Application Correspondent

Dennis C. Gucciardo, Partner

Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Ave. NW
Washington, DC 20004-2541

Phone: (202) 739-5278

Name of Device and Name:

ProTEC-USA EZDoff Gown

Common or Usual Name:

Singe Use/Non-Sterile Open Back Protective Gowns

Classification Name:

Class II, 21 CFR § 878.4040; Product Code QPC

Predicate Device

ValueCare®Open Back Protective Gown (K160337)

Intended Use / Indications for Use

ProTEC-USA EZDoff Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The ProTEC-USA EZDoff Gown is a single use, disposable gown provided non-sterile. The back of the gown is open and non-protective. The gown is not intended for use in the operating room.

Device Description

The ProTEC-USA EZDoff Gown is constructed of 41 gsm blue polyolefin (Polyethylene) film offered in one universal size. The body of the gown is provided with belt ties that are constructed of the same 41 gsm blue polyolefin (Polyethylene) film. The sleeves of the gown are sealed using a heat-sealing method.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the ProTEC-USA EZDoff Gown are nearly identical to the cleared ValueCare®Open Back Protective Gown (K160337). Both devices are made from extruded plastic film and include sleeves that are sealed with a heat treatment. A summary of the technologies and characteristics between the predicate device and the ProTEC-USA EZDoff Gown are provided in the table below.

	Predicate Device: ValueCare® Open Back Protective Gown (K160337)	**Proposed Device:** ProTEC-USA EZDoff Gown (K210405)	**Comparison**
Intended Use / Indications for Use	These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room.	ProTEC-USA EZDoff Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The ProTEC-USA EZDoff Gown is a single use, disposable gown provided non-sterile. The back of the gown is open and non-protective. The gown is not intended for use in the operating room.	Same
Design	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Same
Material Composition	Made from extruded plastic film	Made from extruded plastic film (Polyolefin (Polyethylene) film)	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single use; disposable	Single use; disposable	Same
Color	Blue	Blue	Same
Labeling Claims	These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room. - Non-Sterile	These gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. The back of the gown is open and non- protective. They are not intended for use in the operating room. - Non-Sterile	Same

	- Not Made with Natural Rubber Latex - Meets ANSI/AAMI PB70: 2012 Level 3 - Open Back Non-protective - SingleUse, Disposable	- Not Made with Natural Rubber Latex - Meets ANSI/AAMI PB70: 2012 Level 3 - Open Back Non-protective - Single Use, Disposable	
Flammability 16 CFR 1610	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Meets Class 1 "normal flammability " in accordance to 16 CFR Part 1610	Same
Liquid Barrier Performance Classification Properties	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for an isolation gown.	Device was tested in accordance with AAMI PB70:2012 and meets Level 3 requirements for an isolation gown.	Same
Biocompatibility	Pass ISO 10993-1	Pass ISO 10993-1	Same
Tearing Strength / Resistance	*Not Reported*	8N (Machine Direction) 22N (Transverse Direction)	Not reported for comparison
Lint	*Not Reported*	$Log_{10}<4$	Not reported for comparison
Air Permeability	*Not Reported*	0 $ft^3/min/ft^2$	Not reported for comparison
Tensile Strength	*Not Reported*	52N (Machine Direction) 41N (Transverse Direction)	Not reported for comparison
Sterilization Modality	None (Non-Sterile)	None (Non-Sterile)	Same

Summary of Non-Clinical Testing Performed on the Proposed Device

Test Method	Purpose	Acceptance Criteria	Results
Flammability	Test performed in accordance with (CPSC),16 CFR Part 1610	Average burn time ≥ 3.5s	Pass Meets Class 1 Flammability.
Hydrostatic Pressure	Test performed in accordance with AAMI PB70:2012 utilizing three (3) nonconsecutive lots.	AATCC 127 ≥ 50 cm AQL of 4.0	Pass Meets Level 3 liquid barrier requirements.
Water Impact	Test performed in accordance with AAMI PB70:2012 utilizing three (3) nonconsecutive lots.	AATCC 42 ≤ 1.0g AQL of 4.0	Pass Meets Level 3 liquid barrier requirements.
Breaking strength	Test performed in accordance with ASTM D5034 utilizing three (3) nonconsecutive lots.	The standard does not include an acceptance criteria.	The test results reported values were 52N (Machine Direction), 41N (Transverse Direction).
Tearing strength	Test performed in accordance with ASTM D5587	The standard does not include an acceptance criteria.	The test results reported values were

	utilizing three (3) nonconsecutive lots.		8N (Machine Direction), 22N (Transverse Direction).
Linting	Test performed in accordance with ISO 9073-10 utilizing three (3) nonconsecutive lots.	The standard does not include an acceptance criteria.	The test results reported value was $Log_{10}<4$.
Air Permeability	Test performed in accordance with ASTM C522.	The standard does not include an acceptance criteria.	The test results reported value was 0 $ft^3/min/ft^2$

Biocompatibility Testing Performed on the Proposed Device

Test Method	Purpose	Acceptance Criteria	Results
Cytotoxicity	Test performed in accordance with ISO 10993-5:2009.	Under the conditions of the studies ISO 10993-5:2009, the proposed device is non-cytotoxic.	Pass
Sensitization	Test performed in accordance with ISO 10993-10:2010.	Under the conditions of the studies: ISO 10993-10:2010, the proposed device is non-sensitizing	Pass
Irritation	Test performed in accordance with ISO 10993-10:2010.	Under the conditions of the studies: ISO 10993-10:2010, the proposed device is non-irritating.	Pass

The EZDoff Gown was tested and conformed to the following standards and requirements:

Standard Number	Standards Organization	Standards Title	Version	Date
ASTM F2407	American Society for Testing & Materials	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	2013	May 2013
AAMI PB70:2012	American National Standard	Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities	2012	6/21/2012
(CPSC),16 CFR Part 1610	Consumer Product Safety Commission	Standard for Flammability of Clothing Textiles	2008	3/25/2008
ISO 10993-1:2009/(R)2013	International Organization of Standardization	Biological Evaluation of Medical Devices – Part 1: Evaluation and testing with a risk management process	2013	10/15/2009
ISO 10993-5:2009	International Organization of Standardization	Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity	2009	6/1/2009
ISO 10993-10:2010	International Organization of Standardization	Biological Evaluation of Medical Devices – Part 10: Tests for	2010	8/1/2010

		irritation and delayed-type of hypersensitivity		
ASTM D5587-15	American Society for Testing & Materials	Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	2019	7/1/2019
ASTM D5034-09	American Society for Testing & Materials	Standard Test Method for Breaking Strength and Elongation of Textile Fabrics	2017	7/15/2019
ASTM C522	American Society for Testing & Materials	Standard Test Method for Airflow Resistance of Acoustical Materials	2016	4/1/2016

Summary of Clinical Testing

No clinical testing was performed.

Conclusion:

The conclusions drawn from the nonclinical testing demonstrate that the ProTEC-USA EZDoff Gown is as safe, as effective, and performs as well as or better than the legally marketed device predicate.