DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 4, 2016

priMED Medical Products Inc.
Mr. Richard Roy
Vice President Quality and Product Development
#301, 1259 91 Street SW
Edmonton, Alberta, Canada T6X 1E9

Re: K160361
Trade/Device Name: PRIMAGARD Isolation Gown (AAMI PB70 Level 3)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: October 5, 2016
Received: October 7, 2016

Dear Richard Roy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known): K160361*

Device Name:

PRIMAGARD Isolation Gown (AAMI PB70 level 3)

Indications for Use *(Describe)*

PRIMAGARD Level 3 Isolation Gowns, are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for healthcare personnel and patients from transfer of microorganisms, body fluids, and particulate material.

The PRIMAGARD Isolation Gowns, meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.

PRIMAGARD Isolation Gowns (AAMI PB70 level 3) are available in 5 models as below:
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Apron Neck Closure (Universal),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Tape Tab Neck Closure (Universal, XL),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Hook and Loop Closure (Universal, XL),
- PRIMAGARD Overhead Isolation Gown, AAMI PB70 Level 3, Apron Neck Closure (Universal, XL),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Tie Neck Closure (Universal, XL)

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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priMED Medical Products Inc.
3rd Floor, 1259-91 Street SW
Edmonton, Alberta, Canada
T6X 1E9

T 1.877.877.4633
P 780.497.7600
F 780.497.7670
www.primed.ca

510(K) Summary

Summary Date:	November 3, 2016 (Revised)
Manufacturer:	priMED Medical Products Inc.
Address:	# 301, 1259 91 St. SW, Edmonton, AB, Canada T6X 1E9
Phone Number:	1 780 497 7600
Fax Number:	1 780 497 7670
Contact person:	Richard Roy richard.roy@primed.ca
Product Common Name:	Non-Sterile Isolation gown
Trade or proprietary name:	PRIMAGARD Isolation Gown (AAMI PB70 level 3)
Classification Regulation:	21 CFR 878.4040: Surgical Apparel
Class:	II
Product code:	FYC (Gown, Isolation, Surgical)
Primary Predicate:	Kimberly-Clark MicroCool Isolation Gown (K981393)
Reference Predicate:	XuChang Surgical Gown (K141467)
510(k) number:	K160361

Product Description

PRIMAGARD AAMI PB70:2012 Level 3 gowns are non-sterile, single use isolation gowns intended to be worn by healthcare professionals in isolation applications. These gowns are made of SMS non woven material, contain ultrasonic seams, provide full coverage (level 3 as per PB70) and are not made with natural rubber latex. The proposed isolation gowns come in 5 different models as described in the *Indications for Use*.

Indications for Use

PRIMAGARD Level 3 Isolation Gowns are intended to be worn by healthcare personnel in isolation applications to provide moderate barrier protection for health care personnel and patients from the transfer of microorganisms, body fluids, and particulate material.

The PRIMAGARD Isolation Gowns of this 510(k) meet the requirements of level 3 Liquid Barrier Performance as per AAMI PB70:2012 and are provided non-sterile and are single use only.

PRIMAGARD Isolation Gowns (AAMI PB70 level 3) are available in 5 models as below:
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Apron Neck Closure (Universal),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Tape Tab Neck Closure (Universal, XL),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Hook and Loop Closure (Universal, XL),
- PRIMAGARD Overhead Isolation Gown, AAMI PB70 Level 3, Apron Neck Closure (Universal, XL),
- PRIMAGARD Isolation Gown, AAMI PB70 Level 3, Tie Neck Closure (Universal, XL)

Summary of the Technological Characteristics of PRIMAGARD Isolation Gowns, the Predicate and Reference Product

As per FDA guidance documents: "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" and "Premarket Notification [510(K)] Submissions for Surgical Gowns and Surgical Drapes", performance, safety and physical properties were tested according to the following standards to ensure the proposed isolation gown meet the applicable requirements.

ASTM F2407:2013	Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
AAMI PB70:2012	Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
AATCC 42: 2013	Water Resistance: Impact Penetration Test
AATCC 127: 2014	Water Resistance: Hydrostatic Pressure Test
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
16 CFR PART 1610	Standard for the Flammability of Clothing Textiles
ASTM D5034:2009 (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
NWSP 160.1R0 (15)	Standard Test Method for Resistance to Linting of Nonwoven Fabrics (Dry) (considered equivalent to IST 160.1 and ISO 9073-10)
ASTM E96:2015	Standard Test Methods for Water Vapor Transmission of Materials
ASTM F1868 part C: 2014	Standard Test Method for Thermal Resistance of Clothing Materials Using a Sweating Hot Plate – Heat Loss
ASTM D737: 04 (2012)	Standard Test Method for Air Permeability of Textile Fabrics (tested as per equivalent standard for nonwoven material: NWSP 070.1.R0 (15))
ASTM D5035:11 (2015)	Standard Test Method for Breaking Force and Elongation of Textile Fabrics (Strip Method)
ASTM D3776: 2009 (2013)	Standard Test Methods for Mass Per Unit Area (Weight) of Fabric

Table: Summary of Comparison of Proposed Isolation Gown with Predicate Devices

Elements of comparison		Proposed: PRIMAGARD Isolation Gown (AAMI Level 3), Non-sterile		Predicate: MICROCOOL Isolation Gown, Non-sterile		Reference Predicate: Surgical Gown, Level 3, Sterile	
Manufacturer		priMED Medical Products Inc.		Kimberly-Clark Corporation		XuChang ZhengDe Environstar Medical Products Co., Ltd.	
510(K) Number		K160361		K981393		K141467	
Product Code		FYC		FYC		FYA	
Regulation Number		21 CFR 878.4040		21 CFR 878.4040		21 CFR 878.4040	
Intended Use		PRIMAGARD Isolation Gowns are non-sterile, single use isolation gowns intended to be worn by health care professionals to help protect both the patient and health care worker from the transfer of microorganisms, body fluids and particulate material		The MicroCool isolation gown (non sterile) is a single use item of surgical apparel intended to be worn by health care professionals to help protect both the patient and health care worker from the transfer of microorganisms, body fluids and particulate matter		Disposable surgical gowns are intended to be worn by operating room personnel during surgical procedures to protect both surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material.	
Material		Non woven Polypropylene (SMS)		Non woven polypropylene fabric		SMS Reinforced and non reinforced non-woven fabric	
Color		Blue, Yellow		Unknown		Unknown	
Sterility		Non-Sterile		Non-Sterile		Sterile	
Durability		Single use		Single use		Single use	
Size		Universal, XL		Various		Various	
Critical Zone		Entire gown		Met the Isolation gowns' requirements for critical zone		Critical zones as defined by AAMI PB70 (surgical gown)	
Level of Barrier Protection AAMI PB70		Level 3		Equivalent to level 4		Level 3	
Liquid barrier performance		Hydrostatic Pressure AATCC 127	≥ 50 cm	Fluid Penetration (ASTM 1670-97 and ASTM F903-96)	Met the requirement	Hydrostatic Pressure AATCC 127	≥ 50 cm
		Impact Penetration AATCC 42	≤ 1 g	Viral Penetration (ASTM F 1671-97a)	Met the requirement	Impact Penetration AATCC 42	≤ 1 g
Flammability	16 CFR Part 1610	Class 1		Class 1		Class 1	
Physical Specification	Breaking Strength	Tested to ASTM D5034. Met acceptance criteria		Unknown		Met Acceptance Criteria	

Elements of comparison		Proposed: PRIMAGARD Isolation Gown (AAMI Level 3), Non-sterile	Predicate: MICROCOOL Isolation Gown, Non-sterile	Reference Predicate: Surgical Gown, Level 3, Sterile
	Tearing Strength	Tested to ASTM D5587. Met acceptance criteria	Unknown	Met Acceptance Criteria to ASTM D5733
	Resistance to Linting	Tested to NWSP 160.1.R0. Met acceptance criteria	Unknown	Unknown
	Heat Loss	Tested to ASTM F1868 PART C. Met acceptance criteria	Unknown	Unknown
	Seam Strength	Tested to ASTM D5035. Met acceptance criteria	Unknown	Met Acceptance Criteria to ASTM D1683
	Water Vapor Transmission	Tested to ASTM E96. Met acceptance criteria	Unknown	Unknown
	Air Permeability	Tested to ASTM D737. Met acceptance criteria	Unknown	Unknown
Bio-compatibility	Irritation ISO 10993-10	Under the conditions of the study, not an irritant	No evidence of dermal irritation	Under the conditions of the study, not an irritant
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer	No evidence of component sensitizer	Under conditions of the study, not a sensitizer
	Cytotoxicity ISO 10993-5	Under the conditions of the study the device is non-cytotoxic	No evidence of component sensitizer (met USP XXIII requirements)	Under the conditions of the study the device is non-cytotoxic

Note: "unknown" above indicates performance values were not available in predicate 510(k) submissions

The PRIMAGARD AAMI PB70 Level 3 Isolation Gowns (non sterile, single use) are substantially equivalent with the MicroCool Isolation gowns (Non-Sterile). PRIMAGARD isolation gowns have been tested for biocompatibility, flammability, and other physical performance as documented above and meet or exceed the applicable requirements of the recognized and other related standards and therefore the proposed product is as safe and as effective for its intended use. The predicate isolation gown references testing to ASTM F1671 (and ASTM F1670) and therefore would be considered a level 4 barrier protection gown (moderate/high barrier protection category as per guidance). The proposed priMED gown follows AAMI PB70 and is a level 3 barrier protection (also considered in the moderate/high barrier protection category).

To additionally support the safety and effectiveness of barrier performance characteristics of the PRIMAGARD Level 3 isolation gowns, the proposed gown has been compared to a reference AAMI Level 3 surgical gown, as described in the above table. The reference surgical gown also falls under 21 CFR 878.4040 but has different indication for use (i.e., the isolation gowns are devices to be worn by health care personnel in isolation applications and shall provide full coverage, whereas the surgical gowns are devices to be worn by operating room personnel during surgical procedures and have distinct critical zones).

As described in detail in the comparison table, both proposed and reference devices provide moderate barrier protection (AAMI PB70 level 3) with the exception that the PRIMAGARD Level 3 Isolation Gown provides full barrier coverage compared to the reference surgical gown as the whole entire isolation gown is considered the critical zone. Therefore the proposed PRIMAGARD level 3 isolation gowns are as safe and effective as the predicate for their intended use.

Conclusion:

Based on the test results and comparison of PRIMAGARD isolation gowns with the predicate isolation gown and reference surgical gown, PRIMAGARD isolation gowns are as safe and as effective for their intended use as the legally marketed devices identified in this submission. PRIMAGARD isolation gowns are substantially equivalent to the legally marketed devices identified in this submission.