February 6, 2018

Ansell Healthcare Products LLC
Don Cronk
Sr Manager, QARA / Technical Services
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K171375
Trade/Device Name: Gammex PI Breach Detect Powder Free Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: December 20, 2017
Received: December 27, 2017

Dear Don Cronk:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171375

Device Name:
Gammex PI Breach Detect Powder Free Surgical Glove

Indications for Use *(Describe)*
Gammex PI Breach Detect Powder Free Surgical Gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination.

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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510k Summary

510(k): K171375

Submitter

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
Iselin, NJ 08830 USA

Contact Person:

Donald J. Cronk
Senior Manager QA/RA/Technical Services
Phone: (775) 470-7106
Email: don.cronk@ansell.com

Date Prepared

January 22, 2018

Name of Device

Trade Names:	Gammex PI Breach Detect Powder Free Surgical Glove
Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO
Classification Panel:	General and Plastic Surgery

Legally Marketed Predicate Device

K071746 – DermaPrene® PI or IsoTouch Green Sterile Powder-Free Polyisoprene Surgical Gloves

Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO
Classification Panel:	General and Plastic Surgery

Device Description

Gammex PI Breach Detect Powder Free Surgical Glove is a sterile, green in color, single use disposable powder free surgical glove. The glove is made of synthetic polyisoprene rubber. A polyurethane polymer is applied to the inner surface of the glove to make donning easy. The glove's outer surface is coated with a surface-active agent and when used as an under-glove, this coating and the glove's green color can improve visibility of a glove breach by promoting wetting of the glove surface and spreading of bodily fluid penetrating the breach.

Indication for Use Statement

Gammex PI Breach Detect Powder Free Surgical Gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination.

Technological Characteristics

Gammex PI Breach Detect Powder Free Surgical Gloves have the following technological characteristics as compared to ASTM or equivalent standards:

Characteristics	Standard/Test/FDA Guidance	Result Summary
Physical Characteristics:		
Dimensions	ASTM D3577-09	Meets ASTM D3577-09 requirements for length, width and thickness
Length	Minimum 265mm	Average value: Minimum 297 mm
Palm Width (mm)		Average value in mm:
Size 5.5	70 ± 6	76
Size 6.0	76 ± 6	82
Size 6.5	83 ± 6	86
Size 7.0	89 ± 6	91
Size 7.5	95 ± 6	98
Size 8.0	102 ± 6	100
Size 8.5	108 ± 6	112
Size 9.0	114 ± 6	120
Thickness (mm) – single wall		Average value in mm
Finger	Minimum 0.10	0.25
Palm	Minimum 0.10	0.21
Cuff	Minimum 0.10	0.17
Physical Properties:	ASTM D3577-09	Meets ASTM D3577-09 requirements for tensile strength, ultimate elongation and stress at 500% elongation before and after accelerated aging for synthetic surgical gloves
Freedom from holes	ASTM D3577-09 ASTM D5151-06	Meets ASTM D3577-09 and ASTM D5151-06 requirements of AQL 1.5
Powder Residual	ASTM D3577-09 ASTM D6124-06	Meets applicable requirement for powder free; ≤ 2 mg per glove
Sterility	ANSI/AAMI/ISO 11137-1:2006	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10^{-6} SAL.
Biocompatibility		
ISO In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, undiluted and 1:2 dilution were cytotoxic. 1:4, 1:8, 1:16, 1:32 and 1:64 are not cytotoxic
ISO Skin Irritation Study	ISO10993-10:2010	Under the conditions of the study, not an irritant
ISO Maximization Sensitization Study	ISO 10993-10:2010	Under the conditions of the study, not a sensitizer

ISO acute systemic toxicity	ISO 10993-11: 2006	Under the conditions of the study, no evidence of systemic toxicity

Substantial Equivalence

Substantial Equivalence Comparison Table

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Trade Name	*DermaPrene® PI or IsoTouch Green Sterile Powder-Free Polyisoprene Surgical Gloves*	*Gammex® PI Breach Detect Powder Free Surgical Glove*	Not applicable
510(k) Number	K071746	K171375	Not applicable
Submitter	Ansell Healthcare Products LLC	Ansell Healthcare Products LLC	Same
Product Code	KGO	KGO	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulation Name	Surgeon's Glove	Surgeon's Glove	Same
Regulatory Class	Class I	Class I	Same
Device Type	Type 2 *Gloves compounded primarily from rubber cement or synthetic rubber latex*	Type 2 *Gloves compounded primarily from rubber cement or synthetic rubber latex*	Same
Indications for use	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. When used as an underglove, the glove is intended to promote visibility of a fluid that breaches/enters the glove via an increased spreading rate.	Different
Prescription or Over-The Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Same
Material	Synthetic Polyisoprene Rubber	Synthetic Polyisoprene Rubber	Same
Coating (inner)	Polyurethane polymer inner coating to aid donning	Polyurethane polymer inner coating to aid donning	Same
Coating (outer)	None	Proprietary solution to aid in wetting/spreading of fluid when used as an underglove	Different

		and the outer surgeon's glove is breached.	
Design	Single use	Single use	Same
	Sterile	Sterile	Same
	Powder-Free	Powder-Free	Same
	Hand-specific	Hand-specific	Same
	Beaded cuff	Beaded cuff	Same
Color	Green	Green	Same
Dimension & physical properties	Meets ASTM D3577-09 requirements	Meets ASTM D3577-09 requirements	Same
Freedom from holes	Meets ASTM D3577-09 requirements of AQL 1.5	Meets ASTM D3577-09 requirements of AQL 1.5	Same
Powder-Free	Meets applicable definition for powder free; ≤ 2mg per glove	Meets applicable definition for powder free; ≤ 2mg per glove	Same
Sterilization method	Radiation	Radiation	Same
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	Same
Shelf life	3 years	3 years	Same
Biocompatibility	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	"Under the conditions of the study, not an irritant" and "Under the conditions of the study, not a sensitizer"	Same

The subject device is manufactured from polyisoprene with polyurethane polymer inner coating to aid donning. The glove's outer surface is coated with a surface-active agent and when used as an under-glove, this coating and the glove's green color can improve visibility of a glove breach by promoting wetting of the glove surface and spreading of bodily fluid penetrating the breach. Aside from the outer surface treatment, the subject device's materials are functionally equivalent to those of the cited predicate.

The subject device meets the applicable requirements for surgeon's gloves regarding dimensions and sizes, physical properties, freedom from holes, and powder residues as found in the following standards: ASTM D3577, ASTM D5151 and ASTM D6124. The subject device passes biological reactivity testing for dermal sensitization and irritation, in accord with the ISO 10993 series of standards.

Performance Data
A clinical study was not conducted on the subject or predicate devices.

Substantial Equivalence Statement

The Gammex PI Breach Detect Powder Free Surgeon's Glove are as safe and effective as the predicate device with respect to design, technological characteristics, intended use and conformance to standard requirements.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed device, K071746