DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 9, 2016

Ansell Healthcare Products, LLC
Vasudev Dobariya
Regulatory Specialist
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K151694
Trade/Device Name: Gammex PI Hybrid Surgical Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: February 3, 2016
Received: February 8, 2016

Dear Vasudev Dobariya:

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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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)*
K151694

Device Name
Gammex PI Hybrid Surgical Glove

Indications for Use *(Describe)*
Gammex PI Hybrid Surgical Glove is 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The assigned 510(k) number is: **K151694**

Submitter

Ansell Healthcare Products LLC.
111 Wood Avenue South, Suite 210
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Contact Person:

Vasudev Dobariya
Regulatory Affairs Specialist
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Vasudev.dobariya@ansell.com

Date Prepared

March 7, 2016

Name of Device

Trade Names:	Gammex PI Hybrid Surgical Glove (also marketed as Encore PI Hybrid 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 – Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves

Device Description

The subject device is single-use disposable powder-free surgical glove that is supplied sterile and made of synthetic rubber blend of polyisoprene and neoprene.

Indications for Use

Gammex PI Hybrid Surgical Glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.

Technological Characteristics

Gammex PI Hybrid Surgical Glove have the following technological characteristics as compared to ASTM or equivalent standards:

Technological Characteristics	**Standard/Test/FDA Guidance**	**Result Summary**
Dimensions	ASTM D3577-09	Meets ASTM D3577-09 requirements for length, width and thickness
--Length	Minimum 265mm	Average 305mm
--Palm Width(size)	(mm)	Average value in mm
5.5	70±6	73
6.0	76±6	80
6.5	83±6	86
7.0	89±6	91
7.5	95±6	97
8.0	102±6	103
8.5	108±6	110
9.0	114±6	117
--Thickness	(mm)	Average value in mm
Finger	Minimum 0.10	0.22
Palm	Minimum 0.10	0.20
Cuff	Minimum 0.10	0.17
Physical Properties	ASTM D3577-09	Meets ASTM D3577-09 requirements for tensile strength and elongation at break before and after accelerated aging
Freedom from holes	ASTM D3577-09 ASTM D5151-06	Meets ASTM D3577-09 and ASTM D5151-06 requirements of AQL 1.5
Powder-Free	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 Skin Irritation Study	ISO 10993-10:2010	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

Substantial Equivalence

Substantial Equivalence Comparison Table

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Trade Name	Derma Prene PI or Isotouch Green Sterile Powder-Free Polyisoprene Surgical Gloves	Gammex PI Hybrid Surgical Glove	Not applicable
510(k) Number	K071746	K151694	Not applicable
Submitter	Ansell Healthcare Products LLC	Ansell Healthcare Products LLC	Yes

	Predicate Device	**Subject Device**	**Substantial Equivalence**
Product Code	KGO	KGO	Yes
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Yes
Regulation Name	Surgeon's glove	Surgeon's glove	Yes
Indications for Use	These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination.	This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.	Yes
Prescription or Over-The Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Yes
Materials	Synthetic polyisoprene rubber	Synthetic rubber blend of polyisoprene and neoprene	Yes with difference
Coating	Polyurethane polymer inner coating to aid donning	Polyurethane polymer inner coating to aid donning	Yes
Design	Single use	Single use	Yes
	Sterile	Sterile	Yes
	Powder-free	Powder-free	Yes
	Hand specific	Hand specific	Yes
	Beaded cuff	Beaded cuff	Yes
Color	Green	White	Yes with difference
Sterilization method	Radiation	Radiation	Yes
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	Yes
Shelf Life	3 years	3 years	Yes
Dimensions and physical properties	Meets ASTM D3577-09 requirements	Meets ASTM D3577-09 requirements	Yes
Freedom from holes	Meets ASTM D3577-09 requirements of AQL 1.5	Meets ASTM D3577-09 requirements of AQL 1.5	Yes
Powder-Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Yes
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"	Yes

The subject device is manufactured from synthetic rubber blend of polyisoprene and neoprene with polyurethane polymer inner coating to aid donning. The predicate device is manufactured from synthetic

polyisoprene rubber with polyurethane polymer inner coating to aid donning. Though the materials of construction differ, 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 with regard to dimensions and sizes, physical properties, freedom from holes, powder residues, and protein content as found in the following standards: ASTM D3577-09, ASTM D5151-06 and ASTM D6124-06. 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 Hybrid Surgical Glove is substantially equivalent to the predicate device with respect to design, technological characteristics, intended use and conformance to standard requirements.

Conclusion:
The Gammex PI Hybrid Surgical Glove is substantially equivalent to the Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves. Based on the performed nonclinical tests, the subject device performs as safely and as effectively as the legally marketed predicate device, Derma Prene PI or Isotouch Green sterile Powder-Free Synthetic Polyisoprene Surgical Gloves, previously cleared under K071746, Class I (21 CFR 878.4460, Product code KGO).