DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 28, 2016

Ansell Healthcare Products LLC
Mr. Robert Mahler
Director, Regulatory Affairs for the Americas
111 Wood Avenue South, Suite 210
Iselin, New Jersey 08830

Re: K160974
Trade/Device Name: Gammex (R) Cut Resistant Glove Liner
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: September 28, 2016
Received: September 30, 2016

Dear Mr. Mahler:

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)*
K160974

Device Name
Gammex (R) Cut Resistant Glove Liner

Indications for Use *(Describe)*
The Gammex(R) Cut Resistant Glove Liner is a single use glove liner intended to provide ANSI/ISEA 105 Cut Level Protection 2 against cuts when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.

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.

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

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1. 510(k) Summary

Submitter

Ansell Healthcare Products LLC
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Contact Person:

Robert Mahler
Director Regulatory Affairs for the Americas
Phone: (732) 345-2174
Email: rob.mahler@ansell.com

Date prepared:

October 25, 2016

Name of Device:

Trade name:	Gammex® Cut Resistant Glove Liner
Common name:	Glove Liners/Undergloves
Classification name:	Surgeon's Glove (accessory)
Classification regulation:	21 CFR 878.4460
Device class:	I
Product code:	KGO
Classification panel:	General and plastic surgery

Legally marketed predicate device:

K922407 – Wells Lamont Cut Resistant Surgical Glove Liners

Device description:

Cut resistant under glove liner is a white color liner knitted from an ultrahigh molecular weight polyethylene fiber (UHMWPE) that offers ANSI/ISEA 105 Cut Level Protection against cuts. The liner is knitted using the UHMWPE as the main strengthening component along with nylon and spandex for comfort. The device is a single use device.

Indications for use statement:

The Gammex(R) Cut Resistant Liner is a single use glove liner intended to provide ANSI/ISEA 105 Cut Level Protection 2 against cuts when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.

Technological characteristics:

Gammex® Cut Resistant Glove Liner has the following technological characteristics as compared to ASTM or equivalent standards

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Technological Characteristic	Standard	Result Summary
Cut level 2	ANSI/ISEA 105 Clause 5.1.1	Weight (g) needed to cut through material ≥ 500
ISO In Vitro Cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, not cytotoxic
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	Substantially Equivalent
Trade Name	Wells Lamont Cut Resistant Surgical Glove Liners	Gammex® Cut Resistant Glove Liner	As noted
510(k) Number	K922407	To be declared	As noted
Indications for use	A cut resistant glove liner for improved protection from cuts, slashes, and sharp instrument. For optimum barrier protection, it is suggested that a latex surgical glove be worn over and under the glove liner. The liner may be reused	Cut Resistant Liner is a single use glove liner intended to provide ANSI/ISEA 105 Cut Level Protection 2 against cuts when used with an inner and outer surgical glove. The glove liner should be worn between two surgical gloves.	As noted
Material	Ultra-high molecular weight polyethylene fibre	Ultra-high molecular weight polyethylene fibre	Equivalent
Color	White	White	Equivalent
Design	Knitted glove, ambidextrous, straight fingers	Knitted glove, ambidextrous, straight fingers	Equivalent
Cuff feature	Coloured coded and a label attached on cuff to note number of reusable.	Coloured coded and a label attached on cuff to note number of reusable.	Equivalent
Cut level	ANSI Cut Level 2 according to ASTM F1790-97	ANSI Cut Level 2 according to ASTM F1790-97	Equivalent
Reusable	Laundry up to the readable guide on the cuff edge label. Washing, drying and disinfection with sodium hypochlorite or alkaline glutaraldehyde. Re-sterilisation via auto clave or ethylene oxide gas.	Single use only	As noted

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	Predicate Device	**Subject Device**	**Substantially Equivalent**
Sterilization	Ethylene Oxide gas Meeting sterility assurance level, SAL 10^{-6}	Gamma Irradiation Meeting sterility assurance level, SAL 10^{-6}	As noted
Glove Length	XS – 6 3/8” S - 7 1/2” M - 8” L - 8 3/8” XL – 8 ¾”	XS – 6 3/8” S - 6 7/8” M - 7 1/8” L - 7 1/8” XL – 7 1/2 ”	As noted.

The cut resistant under glove liner is a white color glove liner knitted from an ultrahigh molecular weight polyethylene (UHMWPE) fibers that offers cut resistance. The glove liner is knitted using UHMWPE yarn as the main strengthening component along with Nylon and Spandex for comfort.

The cut resistance under glove is designed to provide ANSI/ISEA 105 Cut Level Protection 2 against cuts for the hands of surgeons, nurse or any personal involving in surgeries by giving cut protection level 2 during the surgeries. The glove to be worn between two surgical glove inner and outer as a under glove.

The glove is manufactured from similar type materials to provide equivalent material, color, design, cuff feature and cut level performance as the predicate. The sterilization process though differs but achieves the required sterility. Biocompatibility was done on the subject device to show that the product was not cytotoxic, an irritant or a sensitizer consistent with the ISO 10993 series of standards.

Performance Data

A clinical study was not conducted on the subject device or the predicate device.

Substantial Equivalence Statement

The Gammex® Cut Resistant Glove Liner is substantially equivalent to the predicate device with respect to the design, technological characteristics, and conformance to standards requirements. The device differs from the predicate in that it is a single use device.