May 23, 2019

Ansell Healthcare Products, LLC.
Don Cronk
Director, Regulatory Affairs for the Americas
2301 Robb Drive
Reno, Nevada 89523

Re: K190018
Trade/Device Name: Gammex Non Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I
Product Code: KGO
Dated: April 16, 2019
Received: April 17, 2019

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

For David Krause, PhD
Acting 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190018

Device Name
Gammex Non Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
Gammex Non Latex PI White Surgical Gloves Tested for Use with Chemotherapy Drugs are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Times(Minutes)
Blenoxane, 15 mg/ml	>240
Busulfan, 6 mg/ml	>240
Carmustine (BCNU), 3.3 mg/ml	10.2
Cisplatin , 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	>240
Cytarabine , 100 mg/ml	>240
Dacarbazine (DTIC), 10.0 mg/ml	>240
Daunorubicin , 5 mg/ml	>240
Docetaxel, 10.0 mg/ml	>240
Doxorubicin Hydrochloride, 2.0 mg/ml	>240
Etoposide (Toposar), 20.0 mg/ml	>240
Fludarabine , 25 mg/ml	>240
Fluorouracil , 50.0 mg/ml	>240
Gemcitabine (Gemzar), 38 mg/ml	>240
ldarubicin , 1 mg/ml	>240
lfosfamide , 50.0 mg/ml	>240
Irinotecan , 20.0 mg/ml	>240
Mechlorethamine HCI, 1.0 mq/ml	>240
Melphalan, 5 mg/ml	>240
Methotrexate , 25 mg/ml,	>240
Mitomycin C, 0.5 mg/ml	>240
Mitoxantrone, 2.0mq/ml	>240
Oxaliplatin , 2.0 mq/ml	>240
Paclitaxel (Taxol), 6.0 mq/ml	>240
Paraplatin , 10 mg/ml	>240
Thiotepa , 10.0 mg/ml	11.5
Vincristine Sulfate, 1.0 mg/ml	>240
Ellence 2 mg/ml	>240
Rituximab 10 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 10.2 minutes and Thiotepa: 11.5 minutes.
Warning: Do not use with Carmustine and Thiotepa

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
K190018

Submitter:
Ansell Healthcare Products LLC.
2301 Robb Drive
Reno, NV 89523
USA

Contact Person:
Don Cronk
Director of Regulatory Affairs
Phone: 775-470-7106
don.cronk@ansell.com

Date Prepared:
April 16th, 2019

Name of Device

Trade Names:	Gammex Non Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs
Common Name:	Surgeon's Gloves
Classification Name:	Surgeon's Gloves
Classification Regulation:	21 CFR 878.4460
Device Class:	I
Product Code:	KGO
Classification Panel:	
510k:	General and Plastic Surgery K190018

Legally Marketed Predicate Device
K111139 – Derma Prene lsotouch Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs.

Device Description
Gammex Non Latex PI White Surgical Gloves are sterile and disposable devices. Gloves are made of synthetic polyisoprene rubber. A polyurethane polymer coating is applied to the inner surface of the glove to make donning easy. Ansell has performed independent laboratory testing on the already cleared device to support a labeling modification for the subject device that the gloves are safe and effective for handling chemotherapy agents

Indication for Use Statement
Gammex Non Latex PI White Surgical Gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy drug Permeation
(Average breakthrough detection time in minutes) (ASTM D6978-05)

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)
Blenoxane (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carmustine (BCNU) (3.3 mg/ml)	10.2
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240
Cytarabine (100 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240
Daunorubicin (5 mg/ml)	>240
Docetaxel (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (Toposar) (20.0 mg/ml)	>240
Fludarabine (25 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Gemcitabine (Gemzar) (38 mg/ml)	>240
Idarubicin (1 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Irinotecan (20.0 mg/ml)	>240
Mechlorethamine HCl (1.0 mg/ml)	>240
Melphalan (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oxaliplatin (2.0 mg/ml)	>240

Paclitaxel (Taxol) (6.0 mg/ml)	>240
Paraplatin (10 mg/ml)	>240
Thiotepa (10.0 mg/ml)	11.5
Vincristine Sulfate (1.0 mg/ml)	>240
Ellence (2 mg/ml)	>240
Rituximab (10 mg/ml)	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 10.2 minutes and Thiotepa: 11.5 minutes.
Warning: Do not use with Carmustine and Thiotepa

Technological Characteristics

<table>
<tr><th colspan="4">Technical Characteristic Comparison Table</th></tr>
<tr><th></th><th>Predicate Device</th><th>Subject Device</th><th>Comparison</th></tr>
<tr><td>Trade Name</td><td>Derma Prene lsotouch Green Sterile Powder-Free Polyisoprene Surgical Gloves, Tested for Use with Chemotherapy Drugs.</td><td>Gammex® Non-Latex PI White</td><td>Different</td></tr>
<tr><td>510(k) Number</td><td>K111139</td><td>K190018</td><td>Different</td></tr>
<tr><td>Submitter</td><td>Ansell Healthcare Products LLC</td><td>Ansell Healthcare Products LLC</td><td>Same</td></tr>
<tr><td>Product Code</td><td>KGO</td><td>KGO</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 878.4460</td><td>21 CFR 878.4460</td><td>Same</td></tr>
<tr><td>Regulation Name</td><td>Non-powdered Surgeon's glove</td><td>Non-powdered Surgeon's glove</td><td>Same</td></tr>
<tr><td>Indications for Use</td><td>Indications For Use:
These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination, and are tested for use with chemotherapy drugs.

Chemotherapy Drug Permeation (average breakthrough detection time in minutes) (ASTM D6978-05)

*Carmustine 15.5
Cyclophosphamide >240
Doxorubicm Hydrochloride >240
Etoposide (Toposar) >240
5-Fluorouracil >240
Paclitaxel (Taxol) >240
*ThioTEPA Methotrexate 15.5
Vincristine Sulfate >240</td><td>These gloves are intended to be worn by operating room personnel to protect a surgical wound from contamination. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Tested chemotherapy drugs are as follows:

<table>
<tr><th>TEST CHEMOTHERAPY DRUG AND CONCENTRATION</th><th>MINIMUM BREAKTHROUGH DETECTION TIME</th></tr>
<tr><td>Blenoxane (15 mg/ml)</td><td>>240</td></tr>
<tr><td>Busulfan (6 mg/ml)</td><td>>240</td></tr>
<tr><td>Carmustine (BCNU) (3.3 mg/ml)</td><td>10.2</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Cyclophosphamide (Cytoxan) (20.0 mg/ml)</td><td>>240</td></tr>
</table></td><td>Similar with the exception of added Chemoth-erapy drugs</td></tr>
</table>

	Please note that Carmustine and ThioTEPA have an extremely low permeation time of 15.5 minutes.	Cytarabine (100 mg/ml)	>240	
		Dacarbazine (DTIC) (10.0 mg/ml)	>240	
		Daunorubicin (5 mg/ml)	>240	
		Docetaxel (10.0 mg/ml)	>240	
		Doxorubicin Hydrochloride (2.0 mg/ml)	>240	
		Etoposide (Toposar) (20.0 mg/ml)	>240	
		Fludarabine (25 mg/ml)	>240	
		Fluorouracil (50.0 mg/ml)	>240	
		Gemcitabine (Gemzar) (38 mg/ml)	>240	

		Idarubicin (1 mg/ml) >240 Ifosfamide (50.0 mg/ml) >240 Irinotecan (20.0 mg/ml) >240 Mechlorethamine HCl (1.0 mg/ml) >240 Melphalan (5 mg/ml) >240 Methotrexate (25 mg/ml) >240 Mitomycin C (0.5 mg/ml) >240 Mitoxantrone (2.0 mg/ml) >240 Oxaliplatin (2.0 mg/ml) >240 Paclitaxel (Taxol) (6.0 mg/ml) >240 Paraplatin (10 mg/ml) >240 Thiotepa (10.0 mg/ml) 11.5 Vincristine Sulfate (1.0 mg/ml) >240 Ellence (2 mg/ml) >240 Rituximab (10 mg/ml) >240	
Prescription or Over-The Counter-Use	Over-The-Counter-Use	Over-The-Counter-Use	Same
Materials	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Same
Coating	Polyurethane polymer inner coating to aid donning	Polyurethane polymer inner coating to aid donning	Same
Performance	Meets ASTM D3577-09	Same	Same
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	White	Different
Dimensions and physical properties	Meets ASTM D3577	Meets ASTM D3577	Same
Sterility	Sterile	Sterile	Same

Sterilization method	Radiation	Radiation	Same
Sterility Assurance Level (SAL)	10-6 SAL	10-6 SAL	Same
Freedom from holes	Meets ASTM D3577-09(2015) Inspection level/AQL: GI/AQL 1.5	Meets ASTM D3577-09(2015) Inspection level/AQL: GI/AQL 0.65	Similar
Powder-Free	Meets ASTM D 6124-06. Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets ASTM D 6124-06 The averaged residual powder content for the glove during process validation is 0.16mg per glove	Same
Primary Skin Irritation ISO 10993-10:2010	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Same
Dermal Sensitization - ISO 10993-10:2010	Under the conditions of the study (per ISO 10993-10), not a sensitizer	Under the conditions of the study (per ISO 10993-10), not a sensitizer	Same
Acute Systemic Toxicity - ISO 10993-11: 2006	Under the conditions of the study, there was no mortality or evidence of systemic toxicity	Under the conditions of the study, there was no mortality or evidence of systemic toxicity	same
Shelf Life	3 years	3 years	Same

The subject device is manufactured from synthetic polyisoprene rubber 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.

Non-Clinical Testing Summary:

Non-clinical testing was performed to verify that the subject device will meet the acceptance criteria of the performance test shown below.

Technological Characteristics	**Standard/Test/FDA Guidance**	**Result Summary**
Dimensions	ASTM D3577	Meets ASTM D3577 requirements for length, width and thickness
Length	Minimum 265mm	Average 301mm
Palm Width (size)	(mm)	Average value in mm
5.5	70±6	74
6.0	76±6	80
6.5	83±6	86
7.0	89±6	92
7.5	95±6	97
8.0	102±6	103
8.5	108±6	111
9.0	114±6	119
Thickness	(mm)	Average value in mm
Finger	Minimum 0.10	0.233
Palm	Minimum 0.10	0.172
Cuff	Minimum 0.10	0.212
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-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

Technological Characteristics	Standard/Test/FDA Guidance	Result Summary
Biocompatibility:		
ISO in vitro cytotoxicity	ISO 10993-5:2009	Under the conditions of the study, the device was found to be cytotoxic and therefore the device extracts were evaluated by ISO 10993-11 – Test for systemic toxicity. From Acute Systemic Toxicity device extracts, the device extracts did not elicit a systemic response in the animal model.
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
ISO Systemic Toxicity Study	ISO 10993-11:2006	Under the conditions of the study, there was no mortality or evidence of systemic toxicity
Chemotherapy Permeation Standard	ASTM D6978 - 05(2013)	Under the conditions of the study, the permeation is acceptable

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, ASTM D5151 and ASTM D6124. The subject device passes biological reactivity testing for dermal sensitization, irritation, and acute systemic toxicity in accord with the ISO 10993-10 and ISO 10993-11.

Conclusion

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