May 26, 2023

Ansell Healthcare Products, LLC
Tammy McGriff
Manager
2301 Robb Drive
Reno, Nevada 89523

Re: K213289
Trade/Device Name: Gammex® PI Plus Glove-in-Glove System™ Tested For Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, OPJ
Dated: May 24, 2023
Received: May 26, 2023

Dear Tammy McGriff:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213289

Device Name
Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove system was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer-glove together. Please note that the following drugs have extremely low permeation times: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa.

Test Chemotherapy drug & Concentration	Average Breakthrough Detection Time (Minutes)
Bleomycin - 15.0 mg/ml	>240
Busulfan - 6.0 mg/ml	>240
Carboplatin - 10 mg/ml	>240
Carmustine - 3.3 mg/ml	35.0
Cisplatin - 1.0 mg/ml	>240
Cyclophosphamide - 20.0 mg/ml	>240
Cytarabine HCl - 100.0 mg/ml	>240
Dacarbazine - 10.0 mg/ml	>240
Daunorubicin HCl - 5.0 mg/ml	>240
Docetaxel - 10.0 mg/ml	>240
Doxorubicin HCl 2.0 mg/ml	>240
Epirubicin - 2.0 mg/ml	>240
Etoposide - 20.0 mg/ml	>240
Fludarabine - 25 mg/ml	>240
Fluorouracil - 50.0 mg/ml	>240
Gemcitabine - 38.0 mg/ml	>240
Idarubicin - 1.0 mg/ml	>240
Ifosfamide - 50.0 mg/ml	>240
Irinotecan - 20.0 mg/ml	>240
Mechlorethamine HCl - 1.0 mg/ml	>240
Melphalan - 5.0 mg/ml	>240
Methotrexate - 25.0 mg/ml	>240
Mitomycin C - 0.5 mg/ml	>240
Mitoxantrone - 2.0 mg/ml	>240
Oxaliplatin - 2.0 mg/ml	>240
Paclitaxel - 6.0 mg/ml	>240
Rituximab - 10.0 mg/ml	>240
Thiotepa - 10.0 mg/ml	67.0
Vincristine Sulfate - 1.0 mg/ml	>240

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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510KSummary

510(k) Number:

K213289

Submitter:

Ansell HealthcareProducts LLC.
2301 Robb Drive
Reno, NV 89523

Contact Person(s):

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Date Prepared

May 24, 2023

Name of Device

Trade Names:	Gammex® PI Plus Glove-in-Glove™ System 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, OPJ, LZC
Classification Panel:	General and Plastic Surgery

Legally Marketed Predicate Device

K190077 – Biogel® PI UltraTouch S Surgical Glove, Biogel® PI Ultra Touch S Indicator Underglove

Legally Marketed Reference Device

K190018 - Gammex® Non-Latex PI White Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs

Device Description

Gammex® PI Plus Glove-in-Glove™ System tested for use with Chemotherapy Drugs is a sterile and disposable device. This glove system ismade of synthetic polyisoprene rubber. Gammex® PI Plus Glove- in-Glove™ System Tested for Use with Chemotherapy Drugs is comprised of a single-use, sterile, white outer glove, which is a disposable, powder-free surgical glove made from synthetic polyisoprene and a single-use, sterile, green underglove which is a disposable, powder-free surgical glove made from synthetic polyisoprene. The Gammex® PI Plus Glove-in-Glove™ system Tested for Use with Chemotherapy Drugs is comprised of the underglove being mechanically inserted into the outer glove prior to packing and sterilization. There is no adhesive present between the two gloves. This results in quick double gloving with only one donning event.

Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs conforms to the following FDA recognized consensus standards: ASTM D3577-19, ASTM D6124-06, ASTM D5151-19, ASTM D412-16, ISO 11137-1:2006, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017, & ASTM D6978-05.

Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs is available in the following sizes: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

Indication for Use Statement

Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs

A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove system was tested for use with Chemotherapy Drugs as per ASTM D6978-05 *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer glove together. Please note that the following drugs have extremely low permeation times: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa.

Tested chemotherapy drugs are as follows:

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGEMINIMUM BREAKTHROUGH DETECTIONTIME (Minutes)
Bleomycin (15.0 mg/ml)	>240
Busulfan (6.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Carmustine (3.3 mg/ml)	35.0

Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Cytarabine HCl (100.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Daunorubicin HCl (5.0 mg/ml)	>240
Docetaxel (10.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fludarabine (25.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Gemcitabine (38.0 mg/ml)	>240
Idarubicin (1.0 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Irinotecan (20.0 mg/ml)	>240
Mechlorethamine HCl (1.0 mg/ml)	>240
Melphalan (5.0mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0mg/ml)	>240
Oxaliplatin (2.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Rituximab (10.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	67.0
Vincristine Sulfate (1.0 mg/ml)	>240

Technological Characteristics:

Technological Characteristics Comparison Table for Predicate Device

	Predicate Device	Proposed Subject Device	Comparison
Trade name	Biogel® PI UlltraTouch S Surgical Glove, Biogel® PI Ultra Touch S Indicator Glove	Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs	Different - New Product
510kNumber	K190077	K213289	Different -New 510(k)
Product Owner	Mölnlycke Health Care US, LLC	Ansell Healthcare Products LLC	Different – Separate Businesses
Product Code	KGO	KGO, OPJ, LZC	Different –OPJ,LZC product codes added for chemo
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulatory Class	I	I	Same
Regulation Name	Non-powdered Surgeon's Gloves	Non-powdered Surgeon's glove	Same
Indicationsfor Use	The Biogel PI UltraTouch S Surgical Glove is a disposable device made of polyisoprene, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminates. The Biogel PI UltraTouch S Indicator Underglove is a disposable device made of polyisoprene, blue in color, that is intended to be worn on the hands, usually in a surgical setting, to provide a barrier against potentially infectious material and other contaminants	A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove system was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer-glove together. Please note that the following drugs have extremely low permeation times: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa.	Different
Material Composition	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Same
Coating	Hydrogel Polymer Coating	Polyacrylic Polymer Inner Coating	Different
Design	Single use	Single use	Same
	Powder-free	Powder-free	Same
	Hand Specific	Ambidextrous	Different
	Beaded cuff	Beaded cuff	Same
Color	Under Glove- Blue OuterGlove–Straw (Natural)	Under Glove – Green Outer Glove - White	Different – Changed Color
Labeling	Surgeon's Gloves	Surgeon's Gloves	Same
Shelf Life	3 Years	No claimed shelf life	Different

	Predicate Device	Proposed Subject Device	Comparison
Performance a. **Dimensions**	Meets ASTM D3577-09 (2015) requirements	Meets ASTM D3577-19 requirements	Same
b. **Physical Properties**	Meets ASTM D3577-09 (2015) requirements	Meets ASTM D3577-19 requirements	Same
c. **Freedom from holes**	Meets ASTM D3577-09 (2015) AQL Meets CFR 800.20 Requirements	Meets ASTM D3577- 19 GI, AQL 1.5 Requirements	Same
d. **Powder Residual**	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Same
e. **Sterility**	Sterile	Sterile	Same
Biocompatibility Skin Irritation	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same
Biocompatibility Sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same
Biocompatibility Acute Systemic Toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Sterilization Information	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10-6 SAL.	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10-6 SAL.	Same
Prescription or Over the counter	Over the Counter	Over the Counter	Same

Itemized List of Differences Between Predicate and Proposed:

- Trade Name
  - The difference is that the trade names are different due to the gloves being separate styles from sperate owners. There is no impact on the safety or effectiveness with the changing of device names.
- 510k Number
  - There are different 510k numbers because they are different devices with different owners. There is no impact on the safety or effectiveness with the predicate and proposed having different 510ks.
- Product Owner
  - There are different product owners for the proposed and predicate devices. There is no impact on safety or effectiveness with the predicate as this device has already been FDA cleared.
- FDA Product Code
  - The predicate device does not have chemotherapy testing so there is no OPJ or LZC product code.
- Indications for Use
  - There are different indications for use listed as the predicate device does not have chemotherapy data or indications for such use.
- Coating
  - The sum total of all performance safety and efficacy testing presented indicates that the proposed device is as safe and effective as the predicate and reference device.
- Design
  - The predicate device is listed as a hand specific glove, while the proposed is ambidextrous. There is no change to safety or efficacy as the gloves have different donning methods.
- Color
  - The predicate device is two gloves, the outer being straw colored and the under glove being blue.
  - The proposed device is two gloves, the outer being white and the under glove being green.
  - The sum total of all performance safety and efficacy testing presented indicates that the proposed device is as safe and effective as the predicate and reference device.
- Shelf Life
  - There is no claimed shelf life for the proposed device.

Technological Characteristics:

Technological Characteristics Comparison Table for Reference Device

	Reference Device	Proposed Subject Device	Comparison
Trade name	Gammex® Non-Latex PI White Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs	Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs	Different - New Product
510kNumber	K190018	K213289	Different - New 510(k)
Product Owner	Ansell Healthcare Products LLC	Ansell Healthcare Products LLC	Same
Product Code	KGO, OPJ	KGO, OPJ, LZC	Different –LZC added
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Regulatory Class	I	I	Same
Regulation Name	Non-powdered Surgeon's Gloves	Non-powdered Surgeon's Gloves	Same
Indicationsfor Use	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 Practices for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove system was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer-glove together. Please note that the following drugs have extremely low permeation times: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa.	Different
Material Composition	Synthetic polyisoprene rubber	Synthetic polyisoprene rubber	Same
Coating	Polyacrylic Polymer Inner Coating	Polyacrylic Polymer Inner Coating	Same
Design	Single use	Single use	Same
	Powder-free	Powder-free	Same
	Hand Specific	Ambidextrous	Different
	Beaded cuff	Beaded cuff	Same
Color	White	Under Glove – Green Outer Glove - White	Different – Changed Color
Labeling	Surgeon's Gloves	Surgeon's Gloves	Same
Shelf Life	3 Years	No claimed shelf life	Different

	Reference Device	Proposed Subject Device	Comparison
Performance a. **Dimensions**	Meets ASTM D3577-09 (2015) requirements	Meets ASTM D3577-19 requirements	Same
b. **Physical Properties**	Meets ASTM D3577-09 (2015) requirements	Meets ASTM D3577-19 requirements	Same
c. **Freedom from holes**	Meets ASTM D3577- 19 GI, AQL 1.5 Requirements	Meets ASTM D3577- 19 GI, AQL 1.5 Requirements	Same
d. **Powder Residual**	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Meet applicable definition for powder free per ASTM D3577-19; ≤ 2mg per glove	Same
e. **Sterility**	Sterile	Sterile	Same
Biocompatibility Skin Irritation	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Passes Primary Skin Irritation test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same
Biocompatibility Sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Passes Dermal Sensitization test per ISO 10993-10, Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization	Same
Biocompatibility Acute Systemic Toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Passes Acute Systemic Toxicity Test per ISO 10993-11, Biological Evaluation of medical devices, Part 11: Test for systemic toxicity	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same
Sterilization Information	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10-6 SAL.	Meets ANSI/AAMI/ISO 11137-1:2006 requirement of 10-6 SAL.	Same
Prescription or Over the counter	Over the Counter	Over the Counter	Same

Itemized List of Differences Between Reference and Proposed:

- Trade Name
    - The difference is that the trade names are different due to the gloves being separate styles. There is no impact on the safety or effectiveness with the changing of device names.
- 510k Number
    - There are different 510k numbers because they are different devices. There is no impact on the safety or effectiveness with the reference and proposed having different 510ks.
- Indications for Use
    - There are different indications for use listed as the predicate device does not have chemotherapy data or indications for such use.
- Design
    - The predicate device is listed as a hand specific glove, while the proposed is ambidextrous. There is no change to safety or efficacy as the gloves have different donning methods.
- Color
    - The sum total of all performance safety and efficacy testing presented indicates that the proposed device is as safe and effective as the predicate and reference device.

- Shelf Life
    - There is no claimed shelf life for the proposed device.

	Predicate Device	Proposed Subject Device	Comparison
Trade Name	Biogel® PI UlltraTouch S Surgical Glove, Biogel® PI Ultra Touch S Indicator Glove	Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs	Different Devices
Chemotherapy Claim	Tested chemotherapy drugs/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows	A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer glove together. Please note that the following drugs have extremely low permeationtimes: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa. Tested chemotherapy drugs/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows:	Different
	Not Available for Device	Busulfan (6.0 mg/ml) >240 min.	Different
	Not Available for Device	Carmustine (3.3 mg/ml) 35.0	Different
	Not Available for Device	Cisplatin (1.0 mg/ml) >240 min.	Different
	Not Available for Device	Cyclophosphamide (20.0 mg/ml) >240 min.	Different
	Not Available for Device	Cytarabine (100.0 mg/ml) >240 min.	Different

	Predicate Device	Proposed Subject Device	Comparison
	Not Available for Device	Dacarbazine (10.0 mg/ml) >240 min.	Different
	Not Available for Device	Daunorubicin HCl (5.0 mg/ml) >240 min.	Different
	Not Available for Device	Docetaxel (10.0 mg/ml) >240 min.	Different
	Not Available for Device	Doxorubicin HCl (2.0 mg/ml) >240 min.	Different
	Not Available for Device	Etoposide (20.0 mg/ml) >240 min.	Different
	Not Available for Device	Fludarabine (25.0 mg/ml) >240 min.	Different
	Not Available for Device	Fluorouracil (50.0 mg/ml) >240 min.	Different
	Not Available for Device	Gemcitabine (38.0 mg/ml) >240 min.	Different
	Not Available for Device	Idarubicin (1.0 mg/ml) >240 min.	Different
	Not Available for Device	Ifosfamide(50.0 mg/ml) >240 min.	Different
	Not Available for Device	Irinotecan (20.0 mg/ml) >240 min.	Different
	Not Available for Device	Mechlorethamine HCl (1.0 mg/ml) >240 min.	Different
	Not Available for Device	Melphalan (5.0 mg/ml) >240 min.	Different
	Not Available for Device	Methotrexate (25.0 mg/ml) >240 min.	Different
	Not Available for Device	Mitomycin C (0.5 mg/ml) >240 min.	Different
	Not Available for Device	Mitoxantrone (2.0 mg/ml) >240 min.	Different
	Not Available for Device	Oxaliplatin (2.0 mg/ml) >240 min.	Different
	Not Available for Device	Paclitaxel (6.0 mg/ml) >240 min.	Different
	Not Available for Device	Rituximab(10.0 mg/ml) >240 min.	Different
	Not Available for Device	Thiotepa (10.0 mg/ml) 67.0	Different
	Not Available for Device	Vincristine Sulfate (1.0 mg/ml) >240 min.	Different
	Not Available for Device	Bleomycin(15.0 mg/ml) >240 min.	Different
	Not Available for Device	Carboplatin(10.0 mg/ml) >240 min.	Different
	Not Available for Device	Epirubicin (2.0 mg/ml) >240 min.	Different

Itemized List of Chemotherapy Differences Between Predicate and Proposed:

- The predicate device was not tested for use with chemotherapy drugs. The safety and efficacy of the proposed device with respect to chemotherapy drugs is addressed through the performance testing and labeling of the device.

	Reference Device	Proposed Subject Device	Comparison
Trade Name	Gammex® Non-Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs.	Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs	Different Devices
Chemotherapy Claim	These gloves are intended to be worn by operating 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/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows	A powder-free surgeons' glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. The glove was tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Chemotherapy testing was carried out on the system as a whole, including both the under-glove & outer glove together. Please note that the following drugs have extremely low permeationtimes: Carmustine: 35.0 minutes and Thiotepa: 67.0 minutes. Warning: Do not use with Carmustine or Thiotepa. Tested chemotherapy drugs/concentration & Average Minimum Breakthrough Detection Time (Minutes) are as follows:	
	Busulfan (6.0 mg/ml) >240 min.	Busulfan (6.0 mg/ml) >240 min.	Same
	Carmustine (3.3 mg/ml) 10.2	Carmustine (3.3 mg/ml) 35.0	Different
	Cisplatin (1.0 mg/ml) >240 min.	Cisplatin (1.0 mg/ml) >240 min.	Same
	Cyclophosphamide (20.0 mg/ml) >240 min.	Cyclophosphamide (20.0 mg/ml) >240 min.	Same
	Cytarabine (100.0 mg/ml) >240 min.	Cytarabine (100.0 mg/ml) >240 min.	Same
	Dacarbazine (10.0 mg/ml) >240 min.	Dacarbazine (10.0 mg/ml) >240 min.	Same

	Reference Device	Proposed Subject Device	Comparison
	Daunorubicin HCl (5.0 mg/ml) >240 min.	Daunorubicin HCl (5.0 mg/ml) >240 min.	Same
	Docetaxel (10.0 mg/ml) >240 min.	Docetaxel (10.0 mg/ml) >240 min.	Same
	Doxorubicin HCl (2.0 mg/ml) >240 min.	Doxorubicin HCl (2.0 mg/ml) >240 min.	Same
	Etoposide (20.0 mg/ml) >240 min.	Etoposide (20.0 mg/ml) >240 min.	Same
	Fludarabine (25.0 mg/ml) >240 min.	Fludarabine (25.0 mg/ml) >240 min.	Same
	Fluorouracil (50.0 mg/ml) >240 min.	Fluorouracil (50.0 mg/ml) >240 min.	Same
	Gemcitabine (38.0 mg/ml) >240 min.	Gemcitabine (38.0 mg/ml) >240 min.	Same
	Idarubicin (1.0 mg/ml) >240 min.	Idarubicin (1.0 mg/ml) >240 min.	Same
	Ifosfamide(50.0 mg/ml) >240 min.	Ifosfamide(50.0 mg/ml) >240 min.	Same
	Irinotecan (20.0 mg/ml) >240 min.	Irinotecan (20.0 mg/ml) >240 min.	Same
	Mechlorethamine HCl (1.0 mg/ml) >240 min.	Mechlorethamine HCl (1.0 mg/ml) >240 min.	Same
	Melphalan (5.0 mg/ml) >240 min.	Melphalan (5.0 mg/ml) >240 min.	Same
	Methotrexate (25.0 mg/ml) >240 min.	Methotrexate (25.0 mg/ml) >240 min.	Same
	Mitomycin C (0.5 mg/ml) >240 min.	Mitomycin C (0.5 mg/ml) >240 min.	Same
	Mitoxantrone (2.0 mg/ml) >240 min.	Mitoxantrone (2.0 mg/ml) >240 min.	Same
	Oxaliplatin (2.0 mg/ml) >240 min.	Oxaliplatin (2.0 mg/ml) >240 min.	Same
	Paclitaxel (6.0 mg/ml) >240 min.	Paclitaxel (6.0 mg/ml) >240 min.	Same

	Reference Device	Proposed Subject Device	Comparison
	Rituximab(10.0 mg/ml) >240 min.	Rituximab(10.0 mg/ml) >240 min.	Same
	Thiotepa (10.0 mg/ml) 11.5	Thiotepa (10.0 mg/ml) 67.0	Different
	Vincristine Sulfate(1.0 mg/ml) >240 min.	Vincristine Sulfate (1.0 mg/ml) >240 min.	Same
	Bleomycin(15.0 mg/ml) >240 min.	Bleomycin(15.0 mg/ml) >240 min.	Same
	Carboplatin(10.0 mg/ml) >240 min.	Carboplatin(10.0 mg/ml) >240 min.	Same
	Epirubicin (2.0 mg/ml) >240 min.	Epirubicin (2.0 mg/ml) >240 min.	Same

Itemized List of Chemotherapy Differences Between Reference and Proposed:

- The proposed device has a longer breakthrough time for Carmustine. This show safety and efficacy as the reference device has already been cleared with lower breakthrough times.
- The proposed device has a longer breakthrough time for Thiotepa. This show safety and efficacy as the reference device has already been cleared with lower breakthrough times.

The subject device meets the applicable requirements for surgeons's gloves with regards to 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, irritation, and acute systemic toxicity, in accord with the ISO 10993 series of standards.

Non-Clinical Testing

Gammex® PI Plus Glove-in-Glove™ System Tested for Use with Chemotherapy Drugs has the following technological characteristics as compared to ASTM or equivalent standards:

Results	Title of Test	Purpose of Test	Acceptance Criteria
PASS	ASTM D3767-03	Dimensions	Acceptance criteria in accordance with ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves*
PASS	ASTM D3577-19	Physical Properties	Acceptance criteria for tensile strength, ultimate elongation and stress at 500% elongation before and after accelerated aging for synthetic surgical gloves per ASTM D3577-19 : *Standard Specification for Rubber Surgical Gloves*
PASS	ASTM D5151-19	Freedom from holes	Acceptance criteria in accordance with ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves* with AQL requirements of 1.5
PASS	ASTM D6124	Powder-Free	Meets applicable acceptance criteria for powder free ≤ 2mg per glove per ASTM D3577-19: *Standard Specification for Rubber Surgical Gloves*
PASS	ANSI/AAMI/ISO 11137-1:2006	Sterility	Meets acceptancecriteria requirement of 10^{-6} SAL per ISO 11137-1: *Sterilization for health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
PASS	ASTM D6978-05(2019)	Chemotherapy Drug Permeation Test:	Acceptance Criteria in accordance with ASTM D6978-05(2019): *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.* *Please note that the following drugs have extremely low permeation times: Carmustine (35.0 min) and Thiotepa (67.0 min)

	ISO 10993-5	Biocompatibility:	Gammex®Non-Latex PI Surgical Glove (Outerglove)	Gammex®Non-Latex PI Underglove (Underglove)
FAIL	ISO 10993-5	ISO *in vitro* Cytotoxicity Study	Surfaces at undiluted and at the dilution of 1:2 was found to be cytotoxic (grade 4) to L-929 cells post 48 hour and non-cytotoxic at 1:4 dilution with grade 2 and with grade 0 at 1:8, :16, 1:32 and 1;64 dilutions. Acceptance criteria in accordance with ISO 10993-5: *Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity, 2009.*	Dilutions of 1:16, 1:32, and 1:64 were found to be non-cytotoxic (grade 0). Dilution 1:8 showed moderate cytotoxicity (grade 3). Undiluted, 1:2, and 1:4 dilutions showed severe positive cytotoxicity (grade 4). Acceptance criteria in accordance with ISO 10993-5: *Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity, 2009.*
PASS	ISO 10993-10:2010	ISO Skin Irritation Study	Passes Primary Skin Irritation test per ISO 10993-10, *Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization*. Under the conditions of the study, not an irritant.	
PASS	ISO 10993-10:2010	ISO Maximization Sensitization Study	Passes Dermal Sensitization test per ISO 10993-10, *Biological Evaluation of medical devices, Part 10: Test for irritation and skin sensitization*. Under the conditions of the study, not a sensitizer	
PASS	ISO 10993-11:2017	ISOAcute Systemic Toxicity Study – ISO10993-11:2017	Passes Acute Systemic Toxicity Test per ISO 10993-11, *Biological Evaluation of medical devices, Part 11: Test for systemic toxicity*. Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity	

Clinical Studies

A clinical study was not conducted on the subject device.

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.