August 23, 2023

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

Re: K230079
Trade/Device Name: Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, OPJ
Dated: July 20, 2023
Received: July 24, 2023

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/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,

Bifeng Qian -S

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)*
K230079

Device Name
Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential

Indications for Use *(Describe)*
These 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, have low dermatitis potential, and are non-pyrogenic. 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	Breakthrough Detection Time (Minutes)
Bleomycin (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carmustine (BCNU) (3.3 mg/ml)	12.6
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 HCI (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)	26.6
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) 12.6 minutes and Thiotepa: 26.6 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

K230079

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

Contact Person(s):
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Sr. Administrator, Quality
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Date Prepared:
August 23, 2023

Name of Device

Trade Names:	Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential
Common Name:	Surgeon's Gloves
Classification Name:	Non-Powdered Surgeon's Glove
Classification Regulation:	21 CFR 878.4460
Device Class: Product	I
Code: Classification	KGO, LZC, OPJ
Panel: 510k Number	General and Plastic Surgery
Assigned:	K230079

Legally Marketed Predicate Device
K190018 – Gammex Non-Latex PI White Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs

Device Description
Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential are sterile and disposable devices. Gloves are made of synthetic polyisoprene rubber, are white in color, and are available in sizes 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, and 9.0. A polyurethane polymer coating is applied to the inner surface of the glove to make donning easy.

Indication for Use Statement
These 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, have low dermatitis potential, and are non-pyrogenic. 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.

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 12.6 minutes and Thiotepa: 26.6 minutes. Warning Do not use with Carmustine and Thiotepa.

Chemotherapy Drug Permeation
(Minimum breakthrough detection time in minutes) (ASTM D6978-05 2019)

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH TIME (Minutes)
Blenoxane (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carmustine (BCNU) (3.3 mg/ml)	12.6
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)	26.6
Vincristine Sulfate (1.0 mg/ml)	>240
Ellence (2 mg/ml)	>240
Rituximab (10 mg/ml)	>240

<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>Gammex Non-Latex PI White Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs</td><td>Polyisoprene Surgical Glove Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential</td><td>Different</td></tr>
<tr><td>510(k) Number</td><td>K190018</td><td>K230079</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, LZC, OPJ</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>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:
<table>
<tr><th>TESTCHEMOTHERAPY DRUGAND CONCENTRATION</th><th>MINIMUM BREAKTHROUGH DETECTION TIME (Minutes)</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>
<tr><td>Cytarabine (100 mg/ml)</td><td>>240</td></tr>
<tr><td>Dacarbazine (DTIC) (10.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Daunorubicin (5 mg/ml)</td><td>>240</td></tr>
<tr><td>Docetaxel (10.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Doxorubicin Hydrochloride (2.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Etoposide (Toposar) (20.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Fludarabine (25 mg/ml)</td><td>>240</td></tr>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>>240</td></tr>
<tr><td>Gemcitabine (Gemzar) (38 mg/ml)</td><td>>240</td></tr>
</table></td><td>These 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, have low dermatitis potential, and are non-pyrogenic. 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 DRUGAND CONCENTRATION</th><th>MINIMUM BREAKTHROUGH TIME (Minutes)</th></tr>
<tr><td>Blenoxane (15 mg/ml)</td><td>>240</td></tr>
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<tr><td>Gemcitabine (Gemzar) (38 mg/ml)</td><td>>240</td></tr>
</table></td><td>Similar</td></tr>
</table>

	<table><tr><td>Idarubicin (1 mg/ml)</td><td>>240</td></tr><tr><td>Ifosfamide (50.0 mg/ml)</td><td>>240</td></tr><tr><td>Irinotecan (20.0 mg/ml)</td><td>>240</td></tr><tr><td>Mechlorethamine HCl (1.0 mg/ml)</td><td>>240</td></tr><tr><td>Melphalan (5 mg/ml)</td><td>>240</td></tr><tr><td>Methotrexate (25 mg/ml)</td><td>>240</td></tr><tr><td>Mitomycin C (0.5 mg/ml)</td><td>>240</td></tr><tr><td>Mitoxantrone (2.0 mg/ml)</td><td>>240</td></tr><tr><td>Oxaliplatin (2.0 mg/ml)</td><td>>240</td></tr><tr><td>Paclitaxel (Taxol) (6.0 mg/ml)</td><td>>240</td></tr><tr><td>Paraplatin (10 mg/ml)</td><td>>240</td></tr><tr><td>Thiotepa (10.0 mg/ml)</td><td>11.5</td></tr><tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>>240</td></tr><tr><td>Ellence (2 mg/ml)</td><td>>240</td></tr><tr><td>Rituximab (10 mg/ml)</td><td>>240</td></tr></table> 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	<table><tr><td>Idarubicin (1 mg/ml)</td><td>>240</td></tr><tr><td>Ifosfamide (50.0 mg/ml)</td><td>>240</td></tr><tr><td>Irinotecan (20.0 mg/ml)</td><td>>240</td></tr><tr><td>Mechlorethamine HCl (1.0 mg/ml)</td><td>>240</td></tr><tr><td>Melphalan (5 mg/ml)</td><td>>240</td></tr><tr><td>Methotrexate (25 mg/ml)</td><td>>240</td></tr><tr><td>Mitomycin C (0.5 mg/ml)</td><td>>240</td></tr><tr><td>Mitoxantrone (2.0 mg/ml)</td><td>>240</td></tr><tr><td>Oxaliplatin (2.0 mg/ml)</td><td>>240</td></tr><tr><td>Paclitaxel (Taxol) (6.0 mg/ml)</td><td>>240</td></tr><tr><td>Paraplatin (10 mg/ml)</td><td>>240</td></tr><tr><td>Thiotepa (10.0 mg/ml)</td><td>26.6</td></tr><tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>>240</td></tr><tr><td>Ellence (2 mg/ml)</td><td>>240</td></tr><tr><td>Rituximab (10 mg/ml)</td><td>>240</td></tr></table> Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 12.6 minutes and Thiotepa: 26.6 minutes. Warning Do not use with Carmustine and Thiotepa	
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
Design	Single use	Single use	Same
	Powder-free	Powder-free	Same
	Hand Specific	Hand Specific	Same
	Beaded cuff	Beaded cuff	Same
Color	White	White	Same
Sizes	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	Same
Dimensions and physical properties	Meets ASTM D3577	Meets ASTM D3577	Same
Sterility	Sterile	Sterile	Same
Sterilization method	Irradiation	Irradiation	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 1.5	Similar
Powder-Free	Meets ASTM D 6124-06. Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets ASTM D 6124-06. Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Same
Protein Content	Not Applicable	Not Applicable	Same
In Vitro Cytotoxicity	Failed. Cytotoxicity Grade 4.	Failed. Cytotoxicity Grade 4.	Same
Biocompatibility 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
Biocompatibility 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
Biocompatibility Acute Systemic Toxicity - ISO 10993-11: 2006	Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity	Under the conditions of the study, there was no mortality or evidence of acute systemic toxicity	Same
Material-Mediated Pyrogenicity	No pyrogenicity claims made	Under the conditions of the study, both inner and outer surface is non-pyrogenic	Different
Bacterial Endotoxin	No endotoxin claims	Under the conditions of the study, test results indicate low endotoxin level	Different
Low Dermatitis Potential	No low dermatitis potential claims made	Under the conditions of the study, the test results demonstrated low dermatitis potential for the subject glove.	Different

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.

The subject device meets the applicable requirements for surgeon'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, acute systemic toxicity, and material-mediated pyrogenicity in accord with the ISO 10993-10 and ISO 10993-11.

Summary of Non-clinical Testing

Technological Characteristics	Purpose	Standard/Test/FDA Guidance Criteria	Result Summary
Dimensions	To evaluate the dimension of the glove	ASTM D3577 Meets ASTM D3577 requirements for length, width and thickness	Pass
Length		Minimum 265mm	Pass
Palm Width (size)		(mm)	Pass
5.5		70±6	Pass
6.0		76±6	Pass
6.5		83±6	Pass
7.0		89±6	Pass
7.5		95±6	Pass
8.0		102±6	Pass
8.5		108±6	Pass
9.0		114±6	Pass
Thickness	To evaluate the thickness of the glove	(mm)	Pass
Finger		Minimum 0.10	Pass
Palm		Minimum 0.10	Pass
Cuff		Minimum 0.10	Pass
Physical Properties	To evaluate the tensile strength, ultimate elongation, and stress at 500% elongation	ASTM D3577-19 Meets ASTMD3577-19 requirements for tensile strength, ultimate elongation and stress at 500% elongation before and after accelerated aging for synthetic surgical gloves	Pass
Freedom from holes	To evaluate the presence of holes in the gloves	ASTM D3577-19 ASTM D5151-06 Meets ASTM D3577-19 and ASTM D5151-06 requirements AQL 1.5	Pass
Powder-Free	To evaluate the level of powder on the gloves	ASTM D3577-19 ASTM D6124-06 Meets applicable requirement for Powder Free; ≤ 2 mg per glove	Pass
Sterility	To demonstrate the sterilization performance	ANSI/AAMI/ISO 11137-1:2018 Meets ANSI/AAMI/ISO 11137-1:2018 requirement of 10^{-6} SAL	Pass

Technological Characteristics		**Standard/Test/FDA Guidance**	**Result Summary**
Biocompatibility:			
ISO in vitro cytotoxicity	To evaluate cytotoxicity	ISO 10993-5:2009 Non-cytotoxic	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 acute systemic response in the animal model.
ISO Skin Irritation Study	To demonstrate low skin irritation potential	ISO 10993-10:2010 Under the conditions of the study, not an irritant	Pass
ISO Maximization Sensitization Study	To demonstrate low sensitization potential	ISO 10993-10:2010 Under the conditions of the study not a sensitizer	Pass
ISO Acute Systemic Toxicity Study	To demonstrate no acute systemic toxicity	ISO 10993-11:2006 Under the conditions of the study, there was no morality or evidence of acute systemic toxicity	Pass
Chemotherapy Permeation Standard	To demonstrate chemotherapy drug barrier performance	ASTM D6978 - 05(2019) Under the conditions of the study the permeation is acceptable for the drugs tested for use with the subject gloves	Pass
Human Skin Sensitization	To demonstrate low dermatitis potential	Modified Draize-95 Test Under the conditions of the study, not a sensitizer.	Pass
Endotoxin Study	To demonstrate low endotoxin levels	Less than 20.0 EU/device	Pass
Material Mediated Pyrogenicity Study	To demonstrate low pyrogenicity potential	ISO 10993-11:2017 Under the conditions of the study, has met the material mediated pyrogenicity requirement	Pass

Clinical Summary:

Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis potential were tested in accordance with Modified Draize-95 Test, per FDA's guidance document "Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510k] Submissions for Testing Skin Sensitization Chemicals in Natural Rubber Products 1999". Both the inner and the outer surfaces of the subject glove were tested. The results showed low dermatitis potential for the human subject tested.

Conclusion

The conclusions drawn from the clinical and non-clinical tests performed demonstrate that the subject device, Polyisoprene Surgical Gloves Tested for Use with Chemotherapy Drugs and Low Dermatitis Potential, is as safe, as effective, and performs as well as or better than the predicate device K190018.