October 22, 2022

WRP Asia Pacific SDN. BHD.
℅ Michael Scaglione
U.S. Agent
WRP USA Inc
3700 Massillon Road
Suite 340
Uniontown, Ohio 44685

Re: K222058
Trade/Device Name: Polyisoprene Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistant
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, OPJ, QDO
Dated: July 6, 2022
Received: July 12, 2022

Dear Michael Scaglione:

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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222058

Device Name
POLYISOPRENE SURGICAL GLOVE, POWDER FREE, STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE

Indications for Use *(Describe)*
A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug	Concentration	Average Breakthrough Detection Time (Minutes)
*Carmustine (BCNU)	(3.3 mg/ml)	24.0
Cisplatin	(1.0 mg/ml)	> 240
Cyclophosphamide (Cytoxan)	(20.0 mg/ml)	> 240
Dacarbazine	(10.0 mg/ml)	> 240
Doxorubicin Hydrochloride	(2.0 mg/ml)	> 240
Etoposide	(20.0 mg/ml)	> 240
Fluorouracil	(50.0 mg/ml)	> 240
Ifosfamide	(50.0 mg/ml)	> 240
Methotrexate	(25.0 mg/ml)	> 240
Mitomycin C	(0.5 mg/ml)	> 240
Mitoxantrone	(2.0 mg/ml)	> 240
Paclitaxel	(6.0 mg/ml)	> 240
*ThioTepa	(10.0 mg/ml)	23.1
Vincristine Sulfate	(1.0 mg/ml)	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 24.0 minutes and Thiotepa: 23.1. Do not use with Carmustine and Thiotepa

Fentanyl Resistance	Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100mcg/2mL)	No breakthrough up to 240 minutes

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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510(k) SUMMARY

K222058

1.0 Submitter:

Name	:	Saravanan Ramasamy
Address	:	WRP Asia Pacific Sdn. Bhd. Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.	:	+60 3 8706 1486
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Date of Summary Prepared	:	10/20/2022

2.0 Identification of the subject device:

Trade Name	:	Polyisoprene Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance
Common Name	:	Surgical Gloves
Classification Name	:	Surgeon's Gloves
Device Classification	:	I
Regulation Number	:	21 CFR 878.4460
Product Code	:	KGO, LZC, OPJ , QDO

3.0 Predicate Device:

	Predicate
Manufacturer	WRP Asia Pacific Sdn. Bhd.
Device name	Powder Free Polymer Coated Polyisoprene Surgical Glove, Sterile
510(k) Number	K032942
Regulatory Class	I
Product Code	KGO

4.0 Reference Device:

	Reference
Manufacturer	WRP Asia Pacific Sdn. Bhd.
Device name	Powder Free Nitrile Surgical Glove, Sterile, Tested for Use with Chemotherapy Drugs
510(k) Number	K203030
Regulatory Class	I
Product Code	KGO, LZC

510(k) SUMMARY

5.0 Description of The Device:

Powder Free Polyisoprene Surgical Glove, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance meets all the requirements of ASTM standard D3577, ASTM D6978-05 and FDA 21 CFR 878.4460.

The powder free polyisoprene surgical glove is manufactured from 100% synthetic polyisoprene latex. Inner surface of gloves undergoes surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is hand specific. The physical properties of glove, i.e., tensile strength meets ASTM standard D3577. Device is intended for single use.

The powder free polyisoprene surgical glove, sterile is supplied in the following sizes: 5½, 6, 6½, 7, 7½, 8, 8½ and 9. This glove comes in natural color and powder free.

6.0 Indication for use:

A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn on the hands of healthcare personnel as a barrier for protection against cross-contamination between the healthcare personnel and patient.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug	**Concentration**	**Breakthrough Detection Time (Minutes)**
*Carmustine (BCNU)	3.3 mg/ml	24.0
Cisplatin	1.0 mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml	> 240
Dacarbazine	10.0 mg/ml	> 240
Doxorubicin Hydrochloride	2.0 mg/ml	> 240
Etoposide	20.0 mg/ml	> 240
Fluorouracil	50.0 mg/ml	> 240
Ifosfamide	50.0 mg/ml	> 240
Methotrexate	25.0 mg/ml	> 240
Mitomycin C	0.5 mg/ml	> 240

Mitoxantrone	2.0 mg/ml	> 240
Paclitaxel	6.0 mg/ml	> 240
*ThioTepa	10.0 mg/ml	23.1
Vincristine Sulfate	1.0 mg/ml	> 240

***WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 24.0 and ThioTepa: 23.1. Do not use with Carmustine and Thiotepa.**

Fentanyl Resistant	**Concentration**	**Breakthrough Detection Time in Minutes**
Fentanyl Citrate Injection	100mcg/2mL	No breakthrough up to 240 minutes

7.0 Summary of the Technological Characteristics of the Device:

The Powder Free Polyisoprene Surgical Glove, Sterile, Tested for use with Chemotherapy Drugs and Fentanyl Resistance are summarized with the following technological characteristics compared to ASTM D3577 or equivalent standards as shown in Table 1.

510(k) SUMMARY

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
Manufacturer(s)	-	WRP Asia Pacific Sdn. Bhd.	WRP Asia Pacific Sdn. Bhd.	WRP Asia Pacific Sdn. Bhd.	Same
Material	ASTM D3577	Polyisoprene Rubber	Nitrile	Polyisoprene Rubber	Different
Color	-	Cream	Natural	Natural White	Different
Texture	-	Micro roughened	Bisque Finish	Bisque Finish	Different
Physical Properties **Before Aging** **Tensile Strength:** **Ultimate Elongation:** **Stress at 500% Elongation:**	ASTM D3577	Meets Min. 17MPa Min. 650% Max. 7.0MPa	Meets	Meets Min. 17MPa Min. 650% Max. 7.0MPa	Same
After Aging **Tensile Strength:** **Ultimate Elongation:** **Stress at 500% Elongation:**		Meets Min. 12MPa Min. 490% N/A	Meets	Meets Min. 12MPa Min. 490% N/A	Same

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
Thickness: **- Finger** **- Palm** **- Cuff**	ASTM D3577	Meets Min. 0.10 mm Min. 0.10 mm Min. 0.10 mm	Meets	Meets Min. 0.10 mm Min. 0.10 mm Min. 0.10 mm	Same
Dimension, Length	ASTM D3577	Meets 5½: Min. 245mm 6.0: Min. 265 mm 6½: Min. 265 mm 7.0: Min. 265 mm 7½: Min. 265 mm 8.0: Min. 265 mm 8½: Min. 265 mm 9.0: Min. 265 mm	Meets 5½: Min. 245 mm 6.0: Min. 265 mm 6½: Min. 265 mm 7.0: Min. 265 mm 7½: Min. 265 mm 8.0: Min. 265 mm 8½: Min. 265 mm 9.0: Min. 265 mm	Meets 5½: Min. 245 mm 6.0: Min. 265 mm 6½: Min. 265 mm 7.0: Min. 265 mm 7½: Min. 265 mm 8.0: Min. 265 mm 8½: Min. 265 mm 9.0: Min. 265 mm	Same
Dimension, Width	ASTM D3577	Meets 5½: 70 ± 6 mm 6.0: 76 ± 6 mm 6½: 83 ± 6 mm 7.0: 89 ± 6 mm 7½: 95 ± 6 mm 8.0: 102 ± 6 mm 8½: 108 ± 6 mm 9.0: 114 ± 6 mm	Meets 5½: 70 ± 6 mm 6.0: 76 ± 6 mm 6½: 83 ± 6 mm 7.0: 89 ± 6 mm 7½: 95 ± 6 mm 8.0: 102 ± 6 mm 8½: 108 ± 6 mm 9.0: 114 ± 6 mm	Meets 5½: 70 ± 6 mm 6.0: 76 ± 6 mm 6½: 83 ± 6 mm 7.0: 89 ± 6 mm 7½: 95 ± 6 mm 8.0: 102 ± 6 mm 8½: 108 ± 6 mm 9.0: 114 ± 6 mm	Same

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
Powder Free	ASTM D6124	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Meets requirements of ≤2.0 mg/glove for Powder-Free designation per ASTM D3577	Same
Biocompatibility	Primary Skin Irritation – ISO 10993-10 (E) & Consumer Product Safety Commission Title 16, Chapter II, Part 1500	Passes (Not a primary skin irritant).	Passes (Not a primary skin irritant).	Passes (Not a primary skin irritant).	Similar
	Dermal Sensitization - ISO 10993-10 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Passes (Not a contact sensitizer).	Passes (Not a contact sensitizer).	Passes (Not a contact sensitizer).	Similar

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
	Acute Systemic Toxicity, ISO 10993-11 (E)	N/a	It is concluded that the product did not induce any systemic toxicity	It is concluded that the product did not induce any systemic toxicity	Different
	Material Mediated Pyrogenicity, ISO 10993-11 (E)	N/a	It is concluded that the product is considered to be non-pyrogenic	It is concluded that the product is considered to be non-pyrogenic	Different
Watertight (1000ml)	ASTM D5151	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level 1, AQL 1.5.	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level I, AQL 0.65	Meets 21 CFR 800.20 and ASTM D3577 when tested in accordance with ASTM D5151 Inspection Level I, AQL 0.65	Similar (AQL was subsequently lowered after FDA cleared the predicate)
Intended use / Indications for Use	-	A powder free, polymer coated polyisoprene surgical glove, sterile, is made of synthetic rubber latex and intended to be worn on the hand of healthcare personnel,	A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn on the hands of healthcare personnel as a	A powder-free sterile surgeon's glove is a disposable device made of synthetic rubber intended to be worn on the hands of healthcare personnel as a	Same with additional characteristics.

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
		operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.	barrier for protection against cross-contamination between the healthcare personnel and patient. These gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	barrier for protection against cross-contamination between the healthcare personnel and patient. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
Size	Medical Glove Guidance Manual - Labeling	5½ 6.0 6½ 7.0 7½ 8.0 8½ 9.0	5½ 6.0 6½ 7.0 7½ 8.0 8½ 9.0	5½ 6.0 6½ 7.0 7½ 8.0 8½ 9.0	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single use	Single use	Single use	Same
Sterility Status	Medical Glove Guidance Manual - Labeling	Sterile	Sterile	Sterile	Same
Sterility Method	ISO 11137-1 ISO 11137-2	Gamma Radiation	Gamma Radiation	Gamma Radiation	Same

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
Chemotherapy Drug Permeation Test	ASTM D6978-05	**Minimum Breakthrough Detection Time (Minutes)**			
* Carmustine (BCNU) (3.3 mg/ml)		N/A	27.3	24.0	Different
Cisplatin (1.0 mg/ml)		N/A	> 240	> 240	Different
Cyclophosphamide (Cytoxan) (20.0 mg/ml)		N/A	> 240	> 240	Different
Dacarbazine (10.0 mg/ml)		N/A	> 240	> 240	Different
Doxorubicin Hydrochloride (2.0 mg/ml)		N/A	> 240	> 240	Different
Etoposide (20.0 mg/ml)		N/A	> 240	> 240	Different
Fluorouracil (50.0 mg/ml)		N/A	> 240	> 240	Different
Ifosfamide (50.0 mg/ml)		N/A	> 240	> 240	Different
Methotrexate (25.0 mg/ml)		N/A	> 240	> 240	Different
Mitomycin C (0.5 mg/ml)		N/A	> 240	> 240	Different
Mitoxantrone (2.0 mg/ml)		N/A	> 240	> 240	Different
Paclitaxel (6.0 mg/ml)		N/A	> 240	> 240	Different

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
510(k) Number	-	**K032942**	**K203030**	**K222058**	-
* ThioTepa (10.0 mg/ml)		N/A	26.9	23.1	Different
Vincristine Sulfate (1.0 mg/ml)		N/A	> 240	> 240	Different
Warning Statement		N/A	CAUTION: Testing showed an average breakthrough time of 27.3 minutes for Carmustine and an average breakthrough time of 26.9 minutes for ThioTepa	WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 24.0 minutes and Thiotepa: 23.1. Do not use with Carmustine and Thiotepa	Different
Fentanyl Resistant	ASTM D6978-05	N/A	N/A	> 240	Different

There are no significant differences between the devices and are identical in terms of intended use, material, color and size. Both devices meet the applicable requirements for surgical gloves regarding physical properties, freedom from holes, and powder residues.

Unlike the predicate, the current device has been tested for Acute Systemic Toxicity and for use with Chemotherapy Drugs and Fentanyl Citrate in accordance to ASTM D6978-05, which is a recognized attribute claim in FDA's Glove Guidance Manual and in other cleared surgical gloves, such as K203030 which is included are a reference.

8.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this Powder Free Polyisoprene Surgical Glove, Sterile is summarized as per below.

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results	
			[redacted]	Before Aging	After Aging	Before Aging	After Aging
Physical Properties	ASTM D412 (Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers - Tension)	To evaluate the tensile (tension) properties of glove	**Tensile strength**	Min. 17MPa	Min. 12MPa	Pass	Pass
			Ultimate elongation	Min. 650%	Min. 490%	Pass	Pass
			Stress at 500% Elongation	Max. 7.0MPa	N/A	Pass	N/A

510(k) SUMMARY

Test Method	Standard	Purpose of Testing	Acceptance Criteria		Results
Dimension	ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions)	To measure the length, width and thickness of glove	**Length**	5½ - Min. 245 mm	Pass
				6.0 - Min. 265 mm	Pass
				6½ - Min. 265 mm	Pass
				7.0 - Min. 265 mm	Pass
				7½ - Min. 265 mm	Pass
				8.0 - Min. 265 mm	Pass
				8½ - Min. 265 mm	Pass
				9.0 - Min. 265 mm	Pass
			Width	5½ - 70 ± 6 mm	Pass
				6.0 - 76 ± 6 mm	Pass
				6½ - 83 ± 6 mm	Pass
				7.0 - 89 ± 6 mm	Pass
				7½ - 95 ± 6 mm	Pass
				8.0 - 102 ± 6 mm	Pass
				8½ - 108 ± 6 mm	Pass
				9.0 - 114 ± 6 mm	Pass
Test Method	**Standard**	**Purpose of Testing**	**Acceptance Criteria**		**Results**
Dimension	ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions)	To measure the length, width and thickness of glove	**Thickness**	Finger - Min. 0.10 mm	Pass
				Palm - Min. 0.10 mm	Pass
				Cuff - Min. 0.10 mm	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results
Watertight	ASTM D5151 (Standard Test Method for Detection of Holes in Medical Gloves)	To detect holes that leak water and thereby compromise the usefulness of the glove	Sample size: 125 pcs Inspection level: GI AQL:0.65, Acceptance No. 2, Found 1	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results
Residual Powder	ASTM D6124 (Standard Test Method for Residual Powder on Medical Gloves)	To determine the amount of residual powder and non-powder solids found on gloves	Have a powder residue limit of 2.0 mg per glove	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results
Biocompatibility	Primary Skin Irritation – ISO 10993-10 (E) & Consumer Product Safety Commission Title 16, Chapter II, Part 1500	To assess the potential of glove to produce dermal irritation	Not a primary skin irritation	Pass
Biocompatibility	Dermal Sensitization- ISO 10993-10 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	To assess the potential of glove to cause a delayed hypersensitivity (Type IV) immunological response	Not a contact sensitizer	Pass
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11 (E)	To determine the acute systemic toxicity potential of glove	No biological reactivity shown	Pass
Biocompatibility	Material Mediated Pyrogenicity, ISO 10993-11 (E)	To determine any pyrogenic response induced by the glove	No increase of temperature	Pass

510(k) SUMMARY

8.0 Summary of Clinical Testing:

No clinical study is included in this submission.

9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject Polyisoprene Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance is as safe, as effective, and performs as well as or better than the legally marketed predicate device K032942.