August 31, 2023

WRP Asia Pacific Sdn. Bhd.
% Michael Scaglione
U.S. Agent
WRP USA Inc
3700 Massillon Road, Suite 340
Uniontown, Ohio 44685

Re: K230578
Trade/Device Name: Polyisoprene Surgical Glove (Unified Double Layer), Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl
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 24, 2023
Received: August 1, 2023

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 -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

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)*
K230578

Device Name
Polyisoprene Surgical Glove (Unified Double Layer), Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl

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 Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug (Concentration)	Minimum Breakthrough Detection Time (Minutes)
*Carmustine (BCNU) (3.3 mg/ml)	67.6
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)	77.7
Vincristine Sulfate (1.0 mg/ml)	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 67.6 minutes and Thiotepa: 77.7. Do not use with Carmustine and Thiotepa.

Fentanyl	Concentration	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
K230578

Date of Preparation: August 31, 2023

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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2.0 Identification of the Subject Device:

Trade Name	:	Polyisoprene Surgical Glove (Unified Double Layer), Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl
Common Name	:	Surgical Gloves
Classification Name	:	Non-powdered Surgeon's Glove
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	Polyisoprene Surgical Glove, Powder Free, Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance
510(k) Number	K222058
Regulatory Class	I
Product Code	KGO, LZC, OPJ

4.0 Description of The Device:

This is a disposable polyisoprene surgical glove that is tested for use with chemotherapy drugs and fentanyl. The device is composed of two layers which are not attached in the fingers or palm/back of hand region, but are attached in the cuff area. The outer layer of the glove is white and the inner layer is green. The glove is supplied in the following sizes: 5½, 6, 6½, 7, 7½, 8, 8½ and 9, and is provided sterile. No shelf life is claimed.

5.0 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 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**	**Minimum Breakthrough Detection Time (Minutes)**
*Carmustine (BCNU)	3.3 mg/ml	67.6
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	77.7
Vincristine Sulfate	1.0 mg/ml	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 67.6 minutes and Thiotepa: 77.7. Do not use with Carmustine and Thiotepa.

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

6.0 Summary of the Technological Characteristics of the Device: *See table*

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE PREDICATE	DEVICE PERFORMANCE CURRENT	COMPARISON ANALYSIS
510(k) Number	-	**K222058**	**K230578**	-
Manufacturer(s)	-	WRP Asia Pacific Sdn. Bhd.	WRP Asia Pacific Sdn. Bhd.	Same
Material	ASTM D3577	Polyisoprene Rubber	Polyisoprene Rubber	Same
Color	-	Natural White	Green and White	Different
Texture	-	Bisque Finish	Bisque Finish	Same
Physical Properties	ASTM D3577	Meets	Meets	Same
Before Aging **Tensile Strength: Ultimate Elongation: Stress at 500% Elongation:**		Min. 17MPa Min. 650% Max. 7.0MPa	Min. 17MPa Min. 650% Max. 7.0MPa	
After Aging Tensile Strength: Ultimate Elongation: Stress at 500% Elongation:		Meets Min. 12MPa Min. 490% N/A	Meets Min. 12MPa Min. 490% N/A	Same
Thickness: **- Finger** **- Palm** **- Cuff**	ASTM D3577	Meets Min. 0.10 mm Min. 0.10 mm Min. 0.10 mm	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. 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	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	Same
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	Same
Biocompatibility	Primary Skin Irritation – ISO 10993-10 (E)	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Dermal Sensitization- ISO 10993-10 (E)	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
	Acute Systemic Toxicity, ISO 10993-11 (E)	Under the conditions of the study, no evidence of acute systemic toxicity observed	Under the conditions of the study, no evidence of acute systemic toxicity observed	Similar
	Material Mediated Pyrogenicity, ISO 10993-11 (E)	Under the conditions of the study, no evidence of material mediated pyrogenicity	Under the conditions of the study, no evidence of material mediated pyrogenicity	Similar
	Bacterial Endotoxins	Not available	≤ 20 EU/device	Different

	ANSI/AAMI ST72			
Watertight (1000ml)	ASTM D5151	ASTM D3577 when tested in accordance with ASTM D5151	ASTM D3577 when tested in accordance with ASTM D5151	Same
Intended use / Indications 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 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	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) Minimum Breakthrough Detection Time (Minutes) *Carmustine (BCNU) (3.3 mg/ml) 67.6 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) 77.7 Vincristine Sulfate (1.0 mg/ml) > 240 *WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 67.6 minutes and Thiotepa: 77.7. Do not use with Carmustine and Thiotepa. Fentanyl Breakthrough Detection Time in Minutes	Similar

			Fentanyl Citrate Injection No breakthrough up to 240 minutes	
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	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single use	Single use	Same
Sterility Status	Medical Glove Guidance Manual - Labeling	Sterile (SAL 10^{-6})	Sterile (SAL 10^{-6})	Same
Sterility Method	ISO 11137-1 ISO 11137-2	Gamma Radiation	Gamma Radiation	Same
Chemotherapy Drug Permeation Test	ASTM D6978-05			
* Carmustine (BCNU) (3.3 mg/ml)		24.0	67.6	Similar
Cisplatin (1.0 mg/ml)		> 240	>240	Same
Cyclophosphamide (Cytoxan) (20.0 mg/ml)		> 240	>240	Same
Dacarbazine (10.0 mg/ml)		> 240	> 240	Same
Doxorubicin Hydrochloride (2.0 mg/ml)		> 240	> 240	Same
Etoposide (20.0 mg/ml)		> 240	> 240	Same
Fluorouracil (50.0 mg/ml)		> 240	> 240	Same
Ifosfamide (50.0 mg/ml)		> 240	> 240	Same
Methotrexate (25.0 mg/ml)		> 240	> 240	Same
Mitomycin C (0.5 mg/ml)		> 240	> 240	Same
Mitoxantrone (2.0 mg/ml)		> 240	> 240	Same
Paclitaxel (6.0 mg/ml)		> 240	> 240	Same
* ThioTepa (10.0 mg/ml)		23.1	77.7	Similar
Vincristine Sulfate (1.0 mg/ml)		> 240	> 240	Same
Warning Statement		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	*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 67.6 minutes and Thiotepa: 77.7. Do not use with Carmustine and Thiotepa.	Similar
Fentanyl Resistant	ASTM D6978-05	> 240	> 240	Same

7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this subject glove is summarized as per below.

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

Dimension	ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions)	To measure the length, width and thickness of glove	**Length:** Each size satisfies ASTM requirement	Pass
			Width: Each size satisfies ASTM requirement	Pass
Dimension	ASTM D3767 (Standard Practice for Rubber - Measurement of Dimensions)	To measure the length, width and thickness of glove	**Thickness:** Each size satisfies ASTM requirement	Pass
Watertight	ASTM D5151 (Standard Test Method for Detection of Holes in Medical Gloves)	To measure glove integrity	Freedom from holes AQL 1.5	Pass
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 below 2.0 mg per glove	Pass
Biocompatibility	Primary Skin Irritation – ISO 10993-10 (E)	To assess the potential of glove to produce dermal irritation	Under the conditions of the study, not an irritant	Pass
Biocompatibility	Dermal Sensitization- ISO 10993-10 (E)	To assess the potential of glove to cause dermal sensitization	Under the conditions of the study, not a sensitizer	Pass
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11 (E)	To determine the acute systemic toxicity potential of glove	Under the conditions of the study, no acute systemic toxicity	Pass
Biocompatibility	Material Mediated Pyrogenicity, ISO 10993-11 (E)	To determine any pyrogenic response induced by the glove material	Under the conditions of the study, non-pyrogenic	Pass
	LAL Gel Clot Bacterial Endotoxin ANSI/AAMI ST72	To determine the endotoxin level on final finished gloves	≤20 EU/device	Pass

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 device, Polyisoprene Surgical Glove (Unified Double Layer), Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl, is as safe, effective, and performs as well as or better than the legally marketed predicate device K222058.