November 17, 2023

WRP Asia Pacific Sdn. Bhd.
Muhammad Ameer Arief Mohd Mujab
Regulatory Affairs Executive
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi
Sepang, Selangor 43900
Malaysia

Re: K232538
Trade/Device Name: Dual Color Nitrile Examination Gloves, Powder Free, Non-Sterile, Tested For Use With Chemotherapy Drugs And Fentanyl
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: August 1, 2023
Received: August 22, 2023

Dear Muhammad Ameer Arief Mohd Mujab:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 and Reconstructive 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)*
K232538

Device Name
DUAL COLOR NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 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)	44.5
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)	79.1
Vincristine Sulfate	(1.0 mg/ml)	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 44.5 minutes and Thiotepa: 79.1 minutes. Do not use with Carmustine and Thiotepa.

Opioid Drug	Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (50 mcg/ml)	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, K232538

1.0 Submitter:

Sponsor:	WRP Asia Pacific Sdn. Bhd.
Contact Name:	Muhammad Ameer Arief bin Mohd Mujab
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
Fax No.:	+60 3 8706 1485

Date of Summary Prepared: 17 November 2023

2.0 Identification of the subject device:

Trade Name	:	Dual Color Nitrile Examination Gloves, Powder Free, Non-Sterile, Tested For Use With Chemotherapy Drugs And Fentanyl
Common Name	:	Patient Examination Gloves
Classification Name	:	Patient Examination Gloves
Device Classification	:	I
Regulation Number	:	21 CFR 880.6250
Product Code	:	LZA, LZC, OPJ, QDO

3.0 Predicate Device:

PREDICATE DEVICE	
Manufacturer	WRP Asia Pacific Sdn. Bhd.
Device Name	Dermagrip Powder Free Blue Nitrile Patient Examination Gloves, Non-sterile, Tested For Use With Chemotherapy Drugs
Regulation Number	21 CFR 880.6250
510 (k) Number	K161422
Regulatory Class	I
Product Code	LZA, LZC

4.0 Reference Device:

REFERENCE DEVICE	
Manufacturer	Summit Glove, Inc
Device name	Intercept Free, Nitrile Two Toned White/Green, Textured Fingertips, Powder-Free, Non-sterile, Ambidextrous, Beaded Cuff, Medical Examination Gloves, Tested for Use with Opioids Fentanyl citrate, Heroin, and both Opioids in simulated Gastric Acid (Vomit)
Regulation Number	21 CFR 880.6250
510(k) Number	K220375
Regulatory Class	I
Product Code	LZA, QDO

5.0 Description of The Device:

Dual Color Nitrile Examination Gloves, Powder Free, Non-Sterile, Tested For Use With Chemotherapy Drugs And Fentanyl meets all requirements of ASTM standard D6319-19.

The powder free examination glove is manufactured from synthetic rubber nitrile. 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 ambidextrous, i.e. can be worn on right hand or left hand. The physical properties of glove i.e. tensile strength meet ASTM standard D6319. Device is intended for single use and non-sterile.

The powder free examination glove, non-sterile is supplied in the following sizes: S, M, L, XL and XXL. This glove is green (inner) and white (outer) in color and powder free.

6.0 Indication for use:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drug	**Concentration**	**Breakthrough Detection Time (Minutes)**
*Carmustine (BCNU)	3.3 mg/ml	44.5
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	79.1
Vincristine Sulfate	1.0 mg/ml	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 44.5 minutes and Thiotepa: 79.1 minutes. Do not use with Carmustine and Thiotepa.

Opioid Drug	**Concentration**	**Breakthrough Detection Time in Minutes**
Fentanyl Citrate Injection	50mcg/mL	No breakthrough up to 240 minutes

7.0 Comparison of Technological Characteristics Between the Subject Device and Predicate Device:

510(k) SUMMARY, K232538

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			
		PREDICATE	REFERENCE	CURRENT	COMPARISON ANALYSIS
510(k) Number	-	K161422	K220375	K232538	-
Manufacturer(s)	-	WRP Asia Pacific	Summit Glove, Inc	WRP Asia Pacific	Same
Material	ASTM D6319	Nitrile	Nitrile	Nitrile	Same
Color	-	Blue	Outer: White Inner: Green	Outer: White Inner: Green	Same with reference device
Texture	-	Finger Textured	Finger textured	Finger textured	Same
Physical Properties <u>Before Aging</u> Tensile Strength: Ultimate Elongation: <u>After Aging</u> Tensile Strength: Ultimate Elongation:	ASTM D6319	Meets 14Mpa min 500% min 14Mpa min 400% min	Meets 30 ± 0.03 Mpa 600% min 32 ± 0.03 Mpa 550%	Meets 14MPa min 500% min 14Mpa min 400% min	 Same Same
Thickness: - Finger - Palm	ASTM D6319	Meets 0.07 – 0.10mm 0.07 – 0.09mm	Meets 0.21 ± 0.03 mm 0.16 ± 0.03 mm	Meets 0.20 ± 0.03 mm 0.16 ± 0.03 mm	Different but within the ASTM standard
Powder Free	ASTM D6124	Less than 2mg per glove	Less than 2mg per glove	Less than 2mg per glove	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E)	Passes Not a primary skin irritant under the conditions of the study	Passes Not a primary skin irritant under the conditions of the study	Passes Not a primary skin irritant under the conditions of the study	Same
	Dermal Sensitization- ISO 10993-10: 2010 (E)	Passes Not a contact sensitizer under the conditions of the study.	Passes Not a contact sensitizer under the conditions of the study.	Passes Not a contact sensitizer under the conditions of the study.	Same
	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Passes It is concluded that the product did not induce any systemic toxicity.	Passes It is concluded that the product did not induce any systemic toxicity.	Passes It is concluded that the product did not induce any systemic toxicity.	Same
Watertight (1000ml)	ASTM D5151	Inspection Level 1, AQL 1.5	Inspection Level 1, AQL 0.65	Inspection Level 1, AQL 1.5	Similar

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON ANALYSIS
		PREDICATE	REFERENCE	CURRENT	
Intended use	-	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large Extra Large	Small Medium Large Extra Large Double Extra Large Triple Extra Large	Small Medium Large Extra Large Double Extra Large	Similar
Single use	Medical Glove Guidance Manual – Labeling	Single use	Single use	Single use	Same
Sterility status	Medical Glove Guidance Manual – Labeling	Non-sterile	Non-sterile	Non-sterile	Same
Shelf life	ASTM D7160	-	5 years	3 years	Different
Chemotherapy Drug Permeation Test	**ASTM D6978-05**	**Minimum Breakthrough Detection Time (Minutes)**			
* Carmustine (BCNU) (3.3 mg/ml)		15.0	N/A	44.5	Similar

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			
		PREDICATE	REFERENCE	CURRENT	COMPARISON ANALYSIS
Cisplatin (1.0 mg/ml)		> 240	N/A	> 240	Same
Cyclophosphamide (Cytoxan) (20.0 mg/ml)		> 240	N/A	> 240	Same
Dacarbazine (10.0 mg/ml)		> 240	N/A	> 240	Same
Doxorubicin Hydrochloride (2.0 mg/ml)		> 240	N/A	> 240	Same
Etoposide (20.0 mg/ml)		> 240	N/A	> 240	Same
Fluorouracil (50.0 mg/ml)		> 240	N/A	> 240	Same
Ifosfamide (50.0 mg/ml)		> 240	N/A	> 240	Same
Methotrexate (25.0 mg/ml)		> 240	N/A	> 240	Same
Mitomycin C (0.5 mg/ml)		> 240	N/A	> 240	Same
Mitoxantrone (2.0 mg/ml)		> 240	N/A	> 240	Same
Paclitaxel (6.0 mg/ml)		> 240	N/A	> 240	Same
* ThioTepa (10.0 mg/ml)		2.0	N/A	79.1	Similar
Vincristine Sulfate (1.0 mg/ml)		> 240	N/A	> 240	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			
		PREDICATE	**REFERENCE**	**CURRENT**	**COMPARISON ANALYSIS**
Warning Statement		WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 15.0 minutes and Thiotepa: 2.0	N/A	WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 44.5 minutes and Thiotepa: 79.1 minutes. Do not use with Carmustine and Thiotepa.	Similar
Fentanyl Citrate		N/A	> 240	> 240	Same with reference device
Fentanyl + Heroin		N/A	> 240	N/A	Different
Fentanyl + Heroin in simulated Gastric Acid Mix		N/A	> 240	N/A	Different

There are no significant differences between the devices. Both devices have been tested for use with Chemotherapy Drugs in accordance with ASTM D6978-05.

They are slightly different in thickness; whereby the current device is thicker than the predicate device. Predicate device comes in blue color whereas the subject device comes in a combination of fluoresced green (inner part) and white (outer part) color. Other differences noted, subject device was tested for Fentanyl Citrate which accords to ASTM D6978-05.

8.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this Glove are 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 14.0 MPa	Min 14.0 MPa	Pass	Pass
			Ultimate elongation	Min 500%	Min 400%	Pass	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	Length	Small – Min 220 mm	Pass
				Medium – Min 230 mm	
				Large – Min 230 mm	
				Extra Large – Min 230 mm	
				Double Extra Large – Min 230	
			Width	Small – 80 ± 10 mm	Pass
				Medium – 95 ± 10 mm	
				Large – 110 ± 10 mm	
				Extra Large – 120 ± 10 mm	
				Double Extra Large – 130 ± 10 mm	

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 0.05mm	Pass
				Palm – min 0.05mm	

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	Size: Small Sample size: 200 pcs Inspection level: GI AQL: 1.5, Acceptance No. 7, Found 0	Pass
			Size: Medium Sample size: 315 pcs Inspection level: GI AQL: 1.5, Acceptance No. 10, Found 0	Pass
			Size: Large Sample size: 315 pcs Inspection level: GI AQL: 1.5, Acceptance No. 10, Found 0	Pass
			Size: Extra Large Sample size: 315 pcs Inspection level: GI AQL: 1.5, Acceptance No. 10, Found 0	Pass
			Size: Double Extra Large Sample size: 200 pcs Inspection level: GI AQL: 1.5, Acceptance No. 7, Found 0	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)	To assess the potential of glove to produce dermal irritation	Under the conditions of the study, not an irritant	Pass
	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
	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

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	
Chemotherapy Drug and Fentanyl Citrate Permeation	ASTM D6978-05 (Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs)	To assess the resistance of medical glove materials to permeation by chemotherapy drugs and fentanyl citrate	Minimum breakthrough time >240min	Carmustine 3.3 mg/ml Cisplatin 1 mg/ml Cyclophosphamide 20 mg/ml Dacarbazine 10 mg/ml Doxorubicin HCI 2 mg/ml Etoposide 20 mg/ml Fluorouracil 50 mg/ml Ifosfamide 50 mg/ml Methotrexate 25 mg/ml Mitoxantrone HCI 2 mg/ml Paclitaxel 6 mg/ml Thiotepa 10 mg/ml Vincristine Sulfate 1 mg/ml Fentanyl Citrate 50 mcg/ml	44.5 min >240 min >240 min >240 min >240 min >240 min >240 min >240 min >240 min >240 min >240 min 79.1 min >240 min >240 min

The shelf-life study claim of this Glove describes the effect of accelerated aging on visual appearance, hole defect and physical properties for establishing a 3 years shelf life based on ASTM D7160.

9.0 Summary of Clinical Testing:

No clinical study is included in this submission.

10.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject Dual Color Nitrile Examination Gloves, Powder Free, Non-Sterile, Tested For Use With Chemotherapy Drugs And Fentanyl is as safe, as effective, and performs as well as or better than the legally marketed predicate device K161422.