March 4, 2022

WRP Asia Pacific SDN BHD
% Saravanan Ramasamy
HEAD of QARA
Wrp Usa Inc
3700 Massillon Road, Suite 340
Uniontown, Ohio 44685

Re: K210330
Trade/Device Name: Dermagrip Powder Free Black Nitrile Examination Gloves, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistant
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 8, 2022
Received: February 14, 2022

Dear Saravanan Ramasamy:

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,

Clarence W. Murray, III, PhD
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)*
K210330

Device Name
DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVE, NON STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE

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 per ASTM D6978-05 (Re-approved 2013) Standard Practice for assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	21.2
Cisplatin	> 240
Cyclophosphamide (Cytoxan)	> 240
Dacarbazine	> 240
Doxorubicin Hydrochloride	> 240
Etoposide	> 240
Fluorouracil	> 240
Ifosfamide	> 240
Methotraxate	> 240
Mitomycin C	> 240
Mitoxantrone	> 240
Paclitaxel	> 240
*Thiotepa	34.6
Vincristine Sulfate	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 21.1 minutes and Thiotepa: 34.6. Do not use with Carmustine and Thiotepa.

Fentanyl Resistance	Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection	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 for K210330

1.0 Submitter:

Name: Saravanan Ramasamy
Address: WRP Asia Pacific Sdn Bhd
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43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Phone No.: +60 3 8706 1486
Fax No.: +60 3 8706 1485

Date of Summary Prepared: 3 March 2022

2.0 Identification of the subject device:

Trade Name : Dermagrip Powder Free Black Nitrile Patient Examination Glove, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance
Common Name : Patient Examination Gloves
Classification Name : Patient Examination Gloves
Device Classification : 1
Regulation Number : 21 CFR 880.6250
Product Code : LZA, QDO

3.0 Predicate Device:

K183287
Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.
Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.
Company: Kossan International Sdn. Bhd.

4.0 Description of The Device:

Powder Free Black Nitrile Patient Examination Gloves, Non-Sterile, Tested for Fentanyl Resistance meet all requirements of ASTM D6319, ASTM D6978, and FDA 21 CFR 880.6250.

The powder free nitrile examination glove is manufactured from nitrile, a synthetic rubber. 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.

5.0 Indication for use:

Dermagrip Powder Free Black Nitrile Patient Examination Glove, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance is a disposable device made of synthetic rubber latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device has also been tested for use with fentanyl citrate.

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 for the glove.		
Chemotherapy Drug	**Concentration**	**Breakthrough Detection Time in Minutes**
*Carmustine (BCNU)	3.3mg/ml	21.2
Cisplatin	1.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
Dacarbazine	10.0mg/ml	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240
Etoposide (Toposar)	20.0mg/ml	> 240
Fluorouracil	50.0mg/ml	> 240
Ifosfamide	50.0mg/ml	> 240
Mitoxantrone	2.0mg/ml	> 240
Paclitaxel (Taxol)	6.0mg/ml	> 240
*Thiotepa	10.0mg/ml	34.6
Vincristine Sulfate	1.0mg/ml	> 240
Methotrexate	25.0mg/ml	> 240
Mitomycin C	0.5mg/ml	> 240

*WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 21.1 minutes and Thiotepa: 34.6. 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

6.0 Summary of the Technological Characteristics of the Device:

Dermagrip Powder Free Black Nitrile Patient Examination Glove, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Resistance are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards as shown in Table 1.

510(k) SUMMARY for K210330

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLUE	DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE	
510(k) Number	-	K183287	K210330	
Manufacturer(s)	-	Kossan International Sdn. Bhd.	WRP Asia Pacific	Same
Material	ASTM D6319	Nitrile	Nitrile	Same
Color	-	Blue	Black	Same
Texture	-	Fingertips textured	Hand textured (Fully textured surface from fingertips to end of palm)	Different
Physical Properties Before Aging Tensile Strength: Ultimate Elongation: After Aging Tensile Strength: Ultimate Elongation:	ASTM D6319	Meets 28Mpa min 500% min 30Mpa min 480% min	Meets 14MPa min 500% min 14MPa min 400% min	 Different but within the ASTM standard Different but within the ASTM standard
Thickness : - Finger - Palm - Cuff	ASTM D6319	 0.10mm 0.06mm 0.04mm	 0.05mm min 0.05mm min 0.05mm min	 Different but within the ASTM standard
Powder Free	ASTM D6124	Less than 2mg per glove	Less than 2mg per glove	Same

510(k) SUMMARY for K210330

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLUE	DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500	Non Irritating	Passes (Not a primary skin irritant) There was no erythema or oedema noted on test site after (24±2), (48±2) and (72±2) hours. The primary Irritation Index (PII) was "0"	Similar
	Dermal Sensitization- ISO 10993-10: 2010 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Non Sensitization	Passes (Not a contact sensitizer). There was no positive allergic reaction observed during the challenge phase (at 0, 24 hours and 48 hours) in animals treated with the test material and negative control.	Similar
	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	Non Cytotoxic	Acute systemic toxicity testing performed to demonstrate safety.	Different

510(k) SUMMARY for K210330

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLUE	DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not Available	It is concluded that the product did not induce any systemic toxicity.	Different
Watertight (1000ml)	ASTM D5151:2019	Inspection Level 1, AQL 1.5	Inspection Level 1, AQL 1.5	Same
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 or finger to prevent contamination between patient and examiner.	Same
Size	Medical Glove Guidance Manual – Labeling	X Small Small Medium Large Extra Large	X Small Small Medium Large Extra Large	Same
Single use	Medical Glove Guidance Manual – Labeling	Single use	Single use	Same

510(k) SUMMARY for K210330

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLUE	DERMAGRIP POWDER FREE BLACK NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE, TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL RESISTANCE	
Chemotherapy Drugs Permeation Test	ASTM D6978	**Minimum Breakthrough Detection Time in Minutes**	**Minimum Breakthrough Detection Time in Minutes**	
Carmustine (BCNU) (3.3mg/ml)		10.1	21.1	Different
Cisplatin (1.0mg/ml)		>240	>240	Same
Cyclophosphamide (Cytoxan) (20.0mg/ml)		>240	>240	Same
Cytarabine (100.0mg/ml)		>240	Not Available	Different
Dacarbazine (10.0mg/ml)		>240	>240	Same
Doxorubicin Hydrochloride (2.0mg/ml)		>240	>240	Same
Etoposide (Toposar) (20.0mg/ml)		>240	>240	Same
Fluorouracil (50.0mg/ml)		>240	>240	Same
Ifosfamide (50.0mg/ml)		>240	>240	Same
Methotrexate (25.0mg/ml)		>240	>240	Same
Mitoxantrone (2.0mg/ml)		>240	>240	Same
Mitomycin C (0.5mg/ml)		>240	>240	Same
Paclitaxel (Taxol) (6.0mg/ml)		>240	>240	Same
*Thiotepa (10.0mg/ml)		30.2	34.6	Different
Vincristine Sulfate (1.0mg/ml)		>240	>240	Same
Warning Statement		Please note that Carmustine (BCNU) has extremely low permeation times of 10.1 minutes	WARNING: Please note the following drugs have extremely low permeation times: Carmustine (BCNU): 21.1 minutes and Thiotepa: 34.6. Do not use with Carmustine and Thiotepa.	Different
Fentanyl Resistant (100mcg/2ml)	ASTM D6978	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	Same

There are no significant differences between the two products and are identical in terms of intended use, materials design, manufacturing methods except for color, physical properties and thickness.

7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this powder free nitrile examination glove is summarized as per below.

510(k) SUMMARY for K210330

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 (all sizes)	Min 240 mm	Pass
			Width	XS: ≤ 80 mm S: 80 ± 10 M: 95 ± 10 L: 110 ± 10 XL: ≥ 110	Pass Pass Pass Pass Pass
			Thickness (all sizes)	Finger: Min 0.05 mm Palm: Min 0.05 mm Cuff: Min 0.05 mm	Pass

510(k) SUMMARY for K210330

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: 500 pcs Inspection level: G1 AQL: 1.5, Acceptance No. 10, Found 2	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.	Less than 2 mg per glove	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 (Dermagrip Powder Free Black Nitrile Patient Examination Glove, Non-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 devices K183287.