August 22, 2022

WRP Asia Pacific SDN. BHD.
% Michael Scaglione
U.S. Agent
SG Global, LLC
3700 Massillon Road, Suite 340
Uniontown, Ohio 44685

Re: K211601
Trade/Device Name: Natural Rubber Latex Examination Glove, Non-Sterile, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY
Dated: July 18, 2022
Received: July 19, 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)*
K211601

Device Name
Natural Rubber Latex Examination Glove, Non-Sterile, Powder Free

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY K211601

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
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Date of Summary Prepared: 12th August 2022

2.0 Identification of the subject device:

Trade Name	:	Natural Rubber Latex Examination Glove, Non-Sterile, Powder Free
Common Name	:	Patient Examination Gloves
Classification Name	:	Patient Examination Gloves
Device Classification	:	I
Regulation Number	:	21 CFR 880.6250
Product Code	:	LYY

3.0 Predicate Device:

	PREDICATE DEVICE
Manufacturer	Hi-Care Thai Gloves Co. Ltd.
Device Name	Palm Care Latex Examination Powder Free Glove
510 (k) Number	K202377
Regulatory Class	I
Product Code	LYY

4.0 Description of The Device:

The Device meets all requirements of ASTM standard D3578 and FDA 21 CFR 880.6250.

The powder free latex examination glove is manufactured from natural rubber 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 ambidextrous, i.e. can be worn on right hand or left hand. The physical properties of glove i.e. tensile strength meet ASTM standard D3578. Device is intended for single use and non-sterile.

The powder free latex examination glove, non-sterile is supplied in the following sizes: XS, S, M, L and XL. This glove is natural in color (no color is added) and powder free.

5.0 Indication for use:

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

6.0 Technological Characteristics Comparisons of the Device:

510(k) SUMMARY

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
510(k) Number	-	K202377	K211601	Different
Manufacturer(s)	-	Hi-Care Thai Gloves Co. Ltd.	WRP Asia Pacific	Different
Material	ASTM D3578	Natural rubber latex	Natural rubber latex	Similar
Color	-	Natural	Natural	Similar
Texture	-	Finger textured	Finger textured	Similar
Physical Properties <u>Before Aging</u> Tensile Strength: Ultimate Elongation: Stress at 500% Elongation: <u>After Aging</u> Tensile Strength: Ultimate Elongation: Stress at 500% Elongation:	ASTM D3578	Meets 18Mpa min 650% min 5.5Mpa max 14Mpa min 500% min -	Meets 18MPa min 650% min 5.5Mpa max 14MPa min 500% min -	 Similar Similar
Thickness: - Finger - Palm	ASTM D3578	Meets 0.08mm min 0.08mm min	Meets 0.11mm min 0.09mm min	Different but within the ASTM standard
Powder Free	ASTM D6124	Less than 2mg per glove	Less than 2mg per glove	Similar

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission 2012 Title 16, Chapter II, Part 1500.3 & 1500.41	Passes Not a primary skin irritant under the conditions of the study.	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 2012 Title 16, Chapter II, Part 1500.3 & 1500.41	Passes Not a contact sensitizer under the conditions of the study.	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
	Determination of In Vitro Cytotoxicity Effect over L929 Cell Lines by Direct Contact Method, ISO 10993-5: 2009 (E)	Passes Non-cytotoxic under the conditions of the study.	Qualitative reactivity grading of cytotoxicity of the test item treatment was not greater than 2. Hence, the test item is considered as 'Non-cytotoxic" to L929 mouse fibroblast cells.	Similar

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not systemic toxic under the conditions of the study.	It is concluded that the product did not induce any systemic toxicity.	Similar
Watertight (1000ml)	ASTM D5151	Inspection Level 1, AQL 1.5	Inspection Level 1, AQL 1.5	Similar
Intended use / Indications for 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.	Similar
Size	Medical Glove Guidance Manual – Labeling	Extra small Small Medium Large	Extra small Small Medium Large Extra Large	Similar with additional size, XL for current device
Single use	Medical Glove Guidance Manual – Labeling	Single use	Single use	Similar
Sterility status	Medical Glove Guidance Manual – Labeling	Non-sterile	Non-sterile	Similar
Extractable Protein Content	ASTM D5712-99	50 µg/ dm^2 for all available sizes	<50 µg/ dm^2 for all available sizes	Similar
Shelf Life Claim	ASTM D7160	No claim of shelf life	3 years claim shelf life	Different

There are no significant differences between the subject and the predicate devices. The subject and predicate are identical in terms of intended use, materials, color, compliance with standards for physical properties, powder free and watertightness and sterility status. The sizes are similar with additional size, XL for current device.

They are slightly differed in thickness; whereby the current device is thicker than the predicate device. On another hand, qualitative reactivity grading of cytotoxicity of the current device treatment was not greater than 2. Hence, the test item is considered as 'Non-cytotoxic" to L929 mouse fibroblast cells.

7.0 Summary of Non-Clinical Testing

The performance test data of the non-clinical test for this Glove are summarized as per below.

510(k) SUMMARY

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results		Status
			[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 18.0 MPa	Min 14.0 MPa	Extra small – 24.40 MPa	Extra small – 25.59 MPa	Pass
						Small – 24.56 MPa	Small – 22.37 MPa	
						Medium – 27.18 MPa	Medium – 27.16 MPa	
						Large – 26.51 MPa	Large – 25.95 MPa	
						Extra Large – 26.11 MPa	Extra Large – 26.67 MPa	
			Ultimate elongation	Min 650%	Min 500%	Extra small – 792 %	Extra small – 802 %	Pass
						Small – 808 %	Small – 723 %	
						Medium – 817 %	Medium – 809 %	
						Large – 811 %	Large – 829 %	
						Extra Large – 783 %	Extra Large –785 %	
			Stress at 500% Elongation	Max. 5.5 MPa	-	Extra small – 4.77 MPa	Extra small – 4.39 MPa	Pass
						Small – 5.11 MPa	Small – 4.85 MPa	
						Medium – 4.55 MPa	Medium – 4.61 MPa	
						Large – 4.85 MPa	Large – 3.17 MPa	
						Extra Large – 5.22 MPa	Extra Large – 5.09 MPa	

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Test Method	Standard	Purpose of Testing	Acceptance Criteria		Results			Status
Dimension	ASTM D3767 Standard Practice for Rubber - Measurement of Dimensions	To measure the length, width and thickness of glove	**Length**	Extra small – Min 240 mm	**Length**	Extra small – 243 mm		Pass
				Small – Min 240 mm		Small – 243 mm		
				Medium – Min 240 mm		Medium – 243 mm		
				Large – Min 240 mm		Large – 243 mm		
				Extra Large – Min 240 mm		Extra Large – 243 mm		
			Width	Extra small – Max 80 mm	**Width**	Extra small – 78 mm		Pass
				Small – Min 80 ± 10 mm		Small – 84 mm		
				Medium – Min 95 ± 10 mm		Medium – 95 mm		
				Large – Min 110 ± 10 mm		Large – 106 mm		
				Extra Large – Min 110mm		Extra Large – 116 mm		
			Thickness	Finger – Min 0.11 mm	**Thickness**	Finger	Extra small – 0.14	Pass
							Small – 0.14 mm	
							Medium – 0.15 mm	
							Large – 0.15 mm	
							Extra Large – 0.16 mm	
				Palm – Min 0.09 mm		Palm	Extra small – 0.12	
							Small – 0.12 mm	
							Medium – 0.12 mm	
							Large – 0.12 mm	
							Extra Large – 0.13 mm	

510(k) SUMMARY

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
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: XS Sample size: 200 pcs Inspection level: G1 AQL: 1.0, Acceptance No. 5, Found 0	The batch size for this sampling is 35,001 to 150,000. Hence, according to the single sampling plan GI, the sample to be drawn under code L is equivalent to 200 pieces with accept 5 and reject 6 to be accepted under AQL 1.0. During the test, 0 pieces were found with leaks. Hence it falls within the acceptance criteria.	Pass
			Size: S Sample size: 500 pcs Inspection level: G1 AQL: 1.0, Acceptance No. 10, Found 1	The batch size for this sampling is 500,001 to over. Hence, according to the single sampling plan GI, the sample to be drawn under code N equivalent to 500 pieces with accept 10 and reject 11 to be accepted under AQL 1.0. During the test, 1 piece was found with leaks. Hence it falls within the acceptance criteria.	Pass
			Size: M Sample size: 500 pcs Inspection level: G1 AQL: 1.0, Acceptance No. 10, Found 3	The batch size for this sampling is 500,001 to over. Hence, according to the single sampling plan GI, the sample to be drawn is under code N equivalent to 500 pieces with accept 10 and reject 11 to be accepted under AQL 1.0. During the test, 3 pieces were found with leaks. Hence it falls within the acceptance criteria.	Pass
			Size: L Sample size: 500 pcs Inspection level: G1 AQL: 1.0, Acceptance No. 10, Found 3	The batch size for this sampling is 500,001 to over. Hence, according to the single sampling plan GI, the sample to be drawn is under code M equivalent to 500 pieces with accept 10 and reject 11 to be accepted under AQL 1.0. During the test, 3 pieces were found with leaks. Hence it falls within the acceptance criteria.	Pass
			Size: XL Sample size: 200 pcs Inspection level: G1 AQL: 1.0, Acceptance No. 5, Found 3	The batch size for this sampling is 35,001 to 150,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code L equivalent to 200 pieces with accept 5 and reject 6 to be accepted under AQL 1.0. During the test, 3 pieces were found with leaks. Hence it falls within the acceptance criteria.	Pass

510(k) SUMMARY

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results (Sample size: 5 pcs)	Status
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	Extra small – 0.2 mg	Pass
				Small – 0.5 mg	
				Medium – 0.1 mg	
				Large – 0.1 mg	
				Extra Large – 0.2 mg	

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results (Sample size: 3 pcs)	Status
Extractable Protein Content	ASTM D5712-99 (Standard Test Method for Analysis of Protein in Natural Rubber)	To determine the extractable protein in gloves	200 µg/ dm^2 Max	Less than 50 µg/ dm^2	Pass

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.

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 Natural Rubber Latex Examination Glove, Non-Sterile, Powder Free is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K202377.