January 17, 2020

Wrp Asia Pacific Sdn Bhd
Hasnah Hamid
Quality Assurance Manager
Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi
Sepang, 43900 My

Re: K192635
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Orange)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 24, 2019
Received: October 28, 2019

Dear Hasnah Hamid:

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,

For Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192635

Device Name
Powder Free Nitrile Patient Examination Glove, Non-Sterile (Orange)

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.

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
K192635

1.0 Submitter:

Name:	Hasnah Abdul Hamid
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Phone No.:	+60 3 8706 1486
Fax No.:	+60 3 8706 1485

Date of Summary Prepared: **10th January 2020**

2.0 Identification of the subject device:

Trade Name:	Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Orange)
Common Name:	Patient Examination Gloves
Classification Name:	Patient Examination Gloves
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA

3.0 Predicate Device:

K133168
Dermagrip Powder Free Blue Nitrile Examination Gloves
WRP Asia Pacific Sdn Bhd

4.0 Description of The Device:

Powder Free Nitrile Patient Examination Glove, Non-Sterile (Orange) meet all the requirements of ASTM standard D6319-10 and FDA 21 CFR 880.6250.

The powder free nitrile examination glove is manufactured from synthetic rubber latex. Inner surface of gloves undergo 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:

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.

510(k) SUMMARY
K192635

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves, Non-Sterile (Orange) are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRRENT	
		BLUE	ORANGE	
510(k) Number		K133168	K192635	Not Available
Manufacturer(s)	-	WRP Asia Pacific Sdn Bhd	WRP Asia Pacific Sdn Bhd	Same
Material	ASTM D6319-10	Nitrile	Nitrile	Same
Color	-	Blue	Orange	Different
Texture	-	Finger textured (Textured only at the finger part)	Hand textured (Fully textured surface from fingertips to end of palm)	Different
Physical Properties <u>Before Aging</u> Tensile Strength : Ultimate Elongation : <u>After Aging</u> Tensile Strength : Ultimate Elongation :	ASTM D6319-10	 14MPa min 500% min 14MPa min 400% min	 14MPa min 500% min 14MPa min 400% min	 Same Same
Thickness - Finger - Palm - Cuff	ASTM D6319-10	0.07–0.10mm 0.07–0.09mm 0.06–0.08mm	0.21–0.23mm 0.19–0.22mm 0.10–0.12mm	Different
Powder Free	ASTM D6124-06	≤ 2 mg/glove	≤ 2 mg/glove	Same

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRRENT	
		BLUE	ORANGE	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2002(E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500	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"	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
Biocompatibility	Dermal Sensitization- ISO 10993-10:2002 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 24 hours and 48 hours) in animals treated with the test material and negative control.	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
Biocompatibility	Cytotoxicity – MEM Elution, ISO 10993-5:2009 (E)	Not available.	Exhibit severe cytotoxicity reactivity at 100%, 66%, and 44% extract concentration. Moderate cytotoxicity reactivity at 30%, mild cytotoxicity reactivity at 20% and slight cytotoxicity reactivity at 15% extract concentrations. **Cytotoxicity concern was addressed by acute systematic toxicity testing.**	Different

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	ORANGE	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not Available	It is concluded that the extracts (polar and non - polar) of the product did not show any systemic toxicity.	Different
Watertight (1000ml)	ASTM D5151-06	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 or finger 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	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Similar
Single Use	Medical Glove Guidance Manual – Labeling	Single use	Single use	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 and thickness. The current device is orange in color and thicker than predicate device.

7.0 Summary of Non-Clinical Testing

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

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results		Status
			[redacted]	Before aging	After aging	Before aging	After aging	
Physical Properties	ASTM D412-16 (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	24.5 MPa (Average)	26.4 MPa (Average)	Pass
			Ultimate elongation	Min 500%	Min 400%	547%	449%	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria		Results		Status
Dimension	ASTM D3767 - 03(2014) Standard Practice for Rubber—Measurement of Dimensions	To measure the length, width and thickness of glove	Length	Min 240 mm	Length	Min 242 mm	Pass
			Width	Min 95 ± 10 mm	Width	95 mm	Pass
			Thickness	Finger – 0.05 mm Palm – 0.05 mm	Thickness	Finger – 0.22 mm Palm – 0.21 mm	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Watertight	ASTM D5151 - 06 (Standard Test Method for Detection of Holes in Medical Gloves)	To detect holes that leak water and thereby compromise the usefulness of	Sample size: 315 pcs Inspection level: G1 AQL: 1.5, Acceptance No. 10, Found 2	The batch size for this sampling is 150,001 to 500,000. Hence, according to the single	Pass

		the glove.		sampling plan GI, the sample to be drawn is under code M equivalent to 315 pieces with accept 10 and reject 11 to be accepted under AQL 1.5. During the test, 2 pieces were found with leaks. Hence it falls within the acceptance criteria.	

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Residual Powder	ASTM D6124-06 (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	Sample size : 5 pcs Requirement : <2mg/glove Result : 1.9 mg/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 test demonstrate that the subject Powder Free Nitrile Patient Examination Glove, Non-Sterile (Orange) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K133168.