March 24, 2022

Rimba Glove SDN BHD
% Michael Woude
U. S agent
Emergo Global Representative LLC,
2500 Bee Cave Road Building 1, Suite 300
Austin, Texas 78746

Re: K212916
Trade/Device Name: Black Nitrile Powder Free Patient Examination Glove, Non Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 13, 2022
Received: February 22, 2022

Dear Michael Woude:

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 BiFeng Qian, Ph.D.
Acting 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)*
K212916

Device Name
BLACK NITRILE POWDER FREE PATIENT EXAMINATION GLOVE, NON STERILE

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 are designed for single use only and should be disposed after use.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - K212916

1.0 Sponsor:

Company Name : Rimba Glove Sdn Bhd
Company Address : Plot 37, Medan Tasek, Tasek Industrial Area, 31400 Ipoh, Perak, Malaysia.

2.0 Submitter:

Name : Zahari Bin Darus
Address : Rimba Glove Sdn Bhd
Plot 37, Medan Tasek, Tasek Industrial Area, 31400 Ipoh, Perak, Malaysia.
Phone No. : +605-5483688
Fax No. : +605-5481688

Date of Summary Prepared: 20th Aug 2021 **(Revised date: 23rd March 2022)**

3.0 Identification of the subject device:

Trade Name : Black Nitrile Powder Free Patient Examination Glove, Non-Sterile
Common Name : Patient Examination Gloves
Classification Name : Patient Examination Gloves
Device Classification : 1
Regulation Number : 21 CFR 880.6250
Product Code : LZA.

3.0 Predicate Device:

K190942
Disposable Powder Free Nitrile Examination Glove, Black Color
Company: Ever Growth (Vietnam) Co. Ltd.

4.0 Description of The Device:

The powder free nitrile examination glove is manufactured from Nitrile 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 and it is a single use device.

Design : Ambidextrous (i.e. fit either hand)

Colour : Black.

Intended use : Single Use and Non-Sterile

Finishing : Finger Textured.

Performance : See Section 7 – Summary of Non-Clinical Testing

Storage : The product is kept away from direct sunlight and fluorescent lighting and stored in an environment with temperature not exceeding 40 degree C.

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 are designed for single use only and should be disposed after use.

Information for "Powder Free" Claim:

The finished powder free gloves meet ASTM D6319 requirements and are tested in according to ASTM D6124 method for powder measurement (less than 2mg per glove).

Glove Size and dimension:
Measurement is done as per ASTM D6319. Length is measured from the tip of the middle finger to the outside edge of the cuff. Width is measured at a level between the base of the index finger and the base of the thumb.

Size	Palm Width (mm)	Length (mm)
X-Small	70±10	Minimum 240
Small	80±10	Minimum 240
Medium	95±10	Minimum 240
Large	110±10	Minimum 240
X-Large	120±10	Minimum 240

5.0 Technological Characteristics Comparison of the Device:

Provided below is the technological comparison of the subject device vs the predicate device as shown in Table 1.

510(k) SUMMARY - K212916

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLACK	BLACK	
510(k) Number	-	K190942	**K212916**	
Manufacturer(s)	-	Ever Growth Enterprise Corporation	Rimba Glove Sdn Bhd	
Material	ASTM D6319	Nitrile	Nitrile	Same
Color	-	Black	Black	Same
Class	-	Class 1	Class 1	Same
Product Code	-	LZA	LZA	Same
Regulation	-	21 CFR 880.6250	21 CFR 880.6250	Same
Physical Properties <u>Before Aging</u> Tensile Strength: Ultimate Elongation: <u>After Aging</u> Tensile Strength: Ultimate Elongation:	ASTM D6319	 14Mpa, min 500% min 14Mpa, min 400% min	 30.9Mpa 583% 34.2Mpa 538%	 Different but within the ASTM standard Different but within the ASTM standard
Physical Dimension: Thickness: - Finger - Palm - **Glove Length** **- Palm Width**	ASTM D6319	 0.05mm min 0.05mm min **≥230mm** **X Small :70 ± 10mm** **Small :80 ± 10mm** **Medium :95 ± 10mm** **Large :110 ± 10mm** **X Large :120 ± 10mm**	 0.10mm 0.07mm **≥240mm** **X Small :70 ± 10mm** **Small :80 ± 10mm** **Medium :95 ± 10mm** **Large :110 ± 10mm** **X Large :120 ± 10mm**	 Different but within the ASTM standard Same

Powder Free	ASTM D6124	< 2mg per glove	0.20 mg/glove	Different but within the ASTM standard

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLACK	BLACK	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500	Passes	The test material did not cause an irritant response. The Primary Irritant Response Category is deemed 'Negligible'	Similar
	Dermal Sensitization- ISO 10993-10: 2010 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Passes	The test material did not produce a skin sensitization effect in the guinea pigs.	Similar
	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	Passes	The test material demonstrated a cytotoxic effect under the condition of this study. Grade 2 for 6.25% & 12.5% Grade 4 for 25%, 50% & 100% Additional test i.e. Acute Systemic Toxicity was tested.	Different – but additional test of Acute Systemic Toxicity is conducted.

510(k) SUMMARY - K212916

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	SUBJECT DEVICE	
		BLACK	BLACK	
Biocompatibility	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Not Applicable	The test item did not induce any systemic toxicity in Swiss albino mice.	Different.
Watertight (1000ml)	ASTM D5151:2019	In accordance with ASTM D6319-10 and ASTM D5151-06 (reapproved 2011), G-1, AQL 2.5	Gloves passed AQL 1.5	Different, but within the ASTM standard.
Intended use / Indications for use	-	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hands 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	X Small Small Medium Large X Large	Extra Small Small Medium Large Extra Large	Same
Single use	Medical Glove Guidance Manual – Labeling	Yes	Single Use	Same
Sterility Status	Medical Glove Guidance Manual – Labeling	Non-Sterile	Non-Sterile	Same

There are no significant differences between the two products and they are the same or similar in terms of intended use, materials design, physical properties, thickness and biocompatibility test.

6.0 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 - K212916

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 14.0 MPa	Min 14.0 MPa	30.9Mpa	34.2Mpa	Pass
			Ultimate elongation	Min 500%	Min 400%	583%	538%	Pass

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.	Sample size: 315 pcs Inspection level: G1 AQL: 1.5, Acceptance No. 10	The batch size for this sampling is 150,001 to 500,000. Hence, according to the single 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, 0 piece was found with leaks. Hence it falls within the acceptance criteria.	Pass

510(k) SUMMARY - K212916

Test Method	Standard	Purpose of Testing	Glove Size	Acceptance Criteria		Results		Status
Dimension	ASTM D3767 Standard Practice for Rubber—Measurement of Dimensions	To measure the length, width and thickness of glove	X-Small	Length	Min 240 mm	Length	251 mm	Pass
				Width	70 ± 10 mm	Width	78.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass
			Small	Length	Min 240 mm	Length	250 mm	Pass
				Width	80 ± 10 mm	Width	88.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass
			Medium	Length	Min 240 mm	Length	251 mm	Pass
				Width	95 ± 10 mm	Width	98.0 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass
			Large	Length	Min 240 mm	Length	250 mm	Pass
				Width	110 ± 10 mm	Width	108 mm	Pass

				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass
			X-Large	Length	Min 240 mm	Length	249 mm	Pass
				Width	120 ± 10 mm	Width	118 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass

Test Method	Standard	Purpose of Testing	Acceptance Criteria	Results	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.	Less than 2 mg per glove	Sample size : 5 pcs Requirement : <2mg/glove Result :0.20mg/glove	Pass

510(k) SUMMARY - K212916

Biocompatibility Testing Information				
Standard	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500	Dermal Sensitization- ISO 10993-10: 2010 (E) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	Acute Systemic Toxicity, ISO 10993-11:2017 (E)
Results	The test material did not cause an irritant response. The Primary Irritant Response Category is deemed 'Negligible'	The test material did not produce a skin sensitization effect in the guinea pigs.	The test material demonstrated a cytotoxic effect under the condition of this study. Grade 2 for 6.25% & 12.5% Grade 4 for 25%, 50% & 100% Additional test i.e. Acute Systemic Toxicity was tested.	The test item did not induce any systemic toxicity in Swiss albino mice.

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 Black Nitrile Powder Free Patient Examination Glove, Non-Sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K190942.