



December 1, 2021

Hong Seng Gloves Sdn Bhd
Michael Van Der Woude
U S Agent
Emergo Global Representative LLC,
2500 Bee Cave Road Building 1, Suite 300
Austin, Texas 78746

Re: K212804

Trade/Device Name: Powder free nitrile examination glove- blue, non-sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 12, 2021
Received: September 2, 2021

Dear Michael Van Der 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 Clarence W. Murray III, 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

Indications for Use

510(k) Number (if known)

K212804

Device Name

POWDER FREE NITRILE EXAMINATION GLOVE - BLUE, 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.

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

K212804

1.0 Submitter:

Name: Ho Chia Yao
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Lot 97, Jalan 10, Kawasan Perusahaan Bakar Arang, 08000,
Sungai Petani, Kedah, Malaysia
Phone No.: +604-4211555
Fax No.: +604-4211555

Date of Summary Prepared: 20th July 2021 (**REVISED DATE: 30th NOVEMBER 2021**)

2.0 Identification of the subject device:

Trade Name : Powder Free Nitrile Examination Glove - Blue, 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:

K192333

Blue Nitrile Examination Gloves Powder Free
Company: JR Engineering & Medical Technologies (M) SDN. BHD.

4.0 Description of The Device:

Powder Free Nitrile Examination Glove - Blue, Non-Sterile meet all requirements of ASTM standard D6319 and FDA 21 CFR 880.6250.

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.

5.0 Intended Use/Indication for use:

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

6.0 Comparison of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Glove - Blue, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards as shown in Table 1.

Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
510(k) Number	-	K192333	K212804	
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN. BHD.	Hong Seng Gloves Sdn Bhd	Same
Intended use/Indications for Use	-	JR MEDIC Blue Nitrile Examination Gloves Powder Free is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	A patient examination glove is a disposable device made of nitrile rubber intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Material	ASTM D6319	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger texture	Finger Texture	Same
Physical Properties	ASTM D6319			
<u>Before Aging</u> Tensile Strength: Ultimate Elongation:		25.6Mpa 868%	28.6Mpa 579%	Different but within the ASTM standard
<u>After Aging</u> Tensile Strength: Ultimate Elongation:		22.0Mpa 828%	33.1Mpa 535%	Different but within the ASTM standard
Thickness: - Finger - Palm	ASTM D6319	0.22mm 0.20mm	0.10mm 0.07mm	Different but within the ASTM standard

Powder Free	ASTM D6124	0.21 mg/glove	0.26 mg/glove	Different but within the ASTM standard
Watertight (1000ml)	ASTM D5151:2019	Gloves passes AQL 1.5	Gloves passed AQL 1.5	Same
Size	Medical Glove Guidance Manual – Labeling	Extra Small Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large	Same
Single use	Medical Glove Guidance Manual – Labeling	Single Use	Single Use	Same
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E)	Under the condition of study not an irritant	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)	Under the conditions of the study not a sensitizer	The test material did not produce a skin sensitization effect in the guinea pigs.	Similar
	Cytotoxicity - MEM Elution, ISO 10993-5: 2009 (E)	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern.	The test material demonstrated a cytotoxic effect under the condition of this study. Additional test i.e. Acute Systemic Toxicity was tested.	Similar
	Acute Systemic Toxicity, ISO 10993-11:2017 (E)	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	The test item did not induce any systemic toxicity in Swiss albino mice.	Similar

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.

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.

Test Method	Standard	Purpose of Testing	Acceptance Criteria			Results		Status
				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	28.6Mpa	33.1Mpa	Pass
			Ultimate elongation	Min 500%	Min 400%	579%	535%	Pass
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			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. 500 pcs were tested, 1 piece was found with leaks. Hence it falls within the acceptance criteria.		Pass
			Less than 2 mg per glove			Sample size : 5 pcs Requirement : <2mg/glove Result :0.26mg/glove		Pass

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	249 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	249 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	249 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	249 mm	Pass
				Width	110 ± 10 mm	Width	107 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

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 Powder Free Nitrile Examination Glove - Blue, Non-Sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate devices K192333.