May 7, 2021

Onetexx SDN BHD
% Michael Woude
U.S. Agent
Emergo Global Representation
2500 Bee Cave Road, Building 1 Suite 300
Austin, Texas 78746

Re: K210366
Trade/Device Name: Blue 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 3, 2021
Received: February 8, 2021

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 Ryan Ortega, Ph. D
Acting Assistant Director
DHT4A: Division of General 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)*
K210366

Device Name
BLUE 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.

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

510(k) No: K210366

1.0 Submitter:

Name:	Freddy Low
Address:	Onetexx Sdn Bhd No: 73-86, Jalan Logam 5, Perindustrian Kamunting 3, Kamunting Raya Industrial Estate, 34600 Kamunting, Perak Darul Ridzuan, Malaysia
Phone No.:	+60 5 8070 666
Fax No.:	+60 5 8070 666

Date of Summary Prepared: 3rd February 2021

2.0 Identification of the subject device:

Trade Name	: Blue 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:

K192333
Blue Nitrile Examination Gloves Powder Free
Company: JR Engineering & Medical Technologies (M) SDN. BHD.

4.0 Description of The Device:

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

The powder free nitrile examination glove is manufactured from synthetic 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.

5.0 Indication for use:

A patient examination glove 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.

6.0 Summary of the Technological Characteristics of the Device:

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

510(k) SUMMARY

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Table 1

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
510(k) Number	-	K192333		
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN. BHD.	Onetexx Sdn Bhd	Same
Material	ASTM D6319	Nitrile	Nitrile	Same
Color	-	Blue	Blue	Same
Texture	-	Finger texture	Finger Texture	Same
Physical Properties <u>Before Aging</u> Tensile Strength: Ultimate Elongation: <u>After Aging</u> Tensile Strength: Ultimate Elongation:	ASTM D6319	 25.6Mpa 868% 22.0Mpa 828%	 32.35Mpa 568% 36.10Mpa 551%	 Different but within the ASTM standard 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	0.24 mg/glove	Different but within the ASTM standard

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CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010 (E) & Consumer Product Safety Commission Title 16. Chapter II, Part 1500	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) & Consumer Product Safety Commission, Title 16, Chapter II, Part 1500.3 (c) (4)	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

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CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE		COMPARISON ANALYSIS
		PREDICATE	CURRENT	
		BLUE	BLUE	
Biocompatibility	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.	Similar
Watertight (1000ml)	ASTM D5151:2019	Gloves passes AQL 1.5	Gloves passed AQL 1.5	Same
Intended 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 synthetic rubber latex 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	Same
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 and biocompatibility test, however the performance data for proposed product is different on the physical properties (higher on Tensile Strength but lower on the elongation compared to predicate device) and glove thickness (lower than the predicate device) but well within the ASTM D 6139 standard.

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.

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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	32.35Mpa	36.10Mpa	Pass
			Ultimate elongation	Min 500%	Min 400%	568%	551%	Pass

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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	250 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	87.0 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	248 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	250 mm	Pass
				Width	120 ± 10 mm	Width	117 mm	Pass
				Thickness	Finger – min 0.05mm Palm – min 0.05mm	Thickness	0.10 mm 0.07 mm	Pass

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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: 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. During the test, 1 piece was found with leaks. Hence it falls within the acceptance criteria.	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 :0.24mg/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 Blue 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 K192333.