October 21, 2022

JR Engineering & Medical Technologies (M) SDN.BHD.
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE114
Aurora, Illinois 60504

Re: K222349
Trade/Device Name: JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 1, 2022
Received: August 3, 2022

Dear Manoj Zacharias:

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)*
K222349

Device Name
JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple)

Indications for Use *(Describe)*

Nitrile Examination Gloves Powder Free is a disposable device intended for medical purpose that is worn on the examiner's hand 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
As required by: 21CFR§807.92(c)

K222349

A. APPLICANT INFORMATION

510(k Owner's Name	JR Engineering & Medical Technologies (M) Sdn. Bhd.
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Official 510k Correspondent	Manoj Zacharias, Consultant Official Contact for JR Engineering & Medical Technologies (M) Sdn. Bhd
Official 510k Correspondent Firm	Liberty Management Group Ltd 75 Executive Dr. STE114, Aurora, IL 60504 USA (630) 270-2921 [voice] (815) 986-2632 [fax] manoj@libertymanagement.us
Date Summary Prepared	19 OCTOBER 2022

B. DEVICE IDENTIFICATION

Name of the device	JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple)
Product proprietary or trade name	JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple)
Common or usual name	Exam Gloves
Classification name	Polymer Patient Examination Glove
Device Classification	Class-1
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Blue Nitrile Examination Gloves Powder Free
Manufacturer	JR Engineering & Medical Technologies (M) SDN.BHD.
510(k) Number	K192333
Regulatory Class	1
Product code	LZA

D. DESCRIPTION OF THEDEVICE:

JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple) are Class I patient examination gloves bearing the product code Nitrile - LZA (21CFR880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are available in Orange & Purple color and are powder free and are provided non-sterile. These gloves have a shelf life for 3 years.

E. INTENDED USE OF THE DEVICE:

JR MEDIC Nitrile Examination Gloves Powder Free is a disposable device intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Characteristics	Standards	Device Performance		Comparison Analysis
		Predicate K192333	**Subject** K222349	
Name of device	-	Blue Nitrile Examination Gloves Powder-free	JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple)	Similar
Manufacturer(s)	-	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	JR Engineering & Medical Technologies (M) SDN.BHD. Malaysia.	Same
Intended use	-	JR MEDIC Blue Nitrile Examination Gloves Powder-free is disposable devices intended for medical purpose that are won on the examiner's hand to prevent contamination between patient and examiner.	Nitrile Examination Gloves Powder free is a disposable device intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Color	-	Blue	Orange, Purple	Different
Texture	-	Finger Texture	Finger texture	Same
Size	ASTM D6319-2019	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
Shelf Life	Medical Glove Guidance Manual Labeling	3 Years	3 Years	Same

Characteristics	**Standards**	**Device Performance**		**Comparison Analysis**
		Predicate K192333	**Subject** K222349	
Color	-	Blue	Orange, Purple	Different
Dimensions	ASTM D6319-2019	Length min 220mm (XS, S) min 230 mm (M, L, XL) Width 70 +/-10 mm (XS) 80 +/-10 mm (S) 95+/-10 mm (M) 110+/-10 mm (L) 120+/-10 mm (XL)	Length min 220mm (XS, S) min 230 mm (M, L, XL) Width 70 +/-10 mm (XS) 80 +/-10 mm (S) 95+/-10 mm (M) 110+/-10 mm (L) 120+/-10 mm (XL)	Same
Physical Properties	ASTM D6319-2019	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	Same
Thickness	ASTM D6319-2019	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
Powder Residue	ASTM D6319-2019	≤2 mg/glove	≤2 mg/glove	Same
Watertight (1000 ml)	ASTM D5151-2019	Passes AQL-1.5	Passes AQL-2.5	Similar
Material	ASTM D6319-2019	Nitrile	Nitrile	Same
Biocompatibility	Primary Skin Irritation-ISO 10993 - 10:2010 (E)	Under the condition of study not an irritant	Under the condition of study not an irritant	Same
	Dermal Sensitization- ISO 10993-10:2010 - (E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5:2009 (E)	Under the conditions of the study, cytotoxic	Under the conditions of the study, cytotoxic	Same
	Acute Systemic Toxicity Test ISO 10993-11:2017(E)	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Same

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods. Both devices meet the ASTM standard D6319-2019.

G. NON-CLINICAL TESTING SUMMARY OF JR MEDIC NITRILE EXAMINATION GLOVES POWDER FREE

PERFORMANCE DATA – ORANGE COLOR

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 220mm (XS, S) Min 230 mm (M, L, XL)	X-Small:- 236 mm Small:- 236 mm Medium:- 238 mm Large:- 238 mm X-Large:- 240 mm		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	X-Small:- 70+/-10 mm Small:- 80+/-10 mm Medium:- 95+/-10mm Large:- 110+/-10 mm X-Large:- 120+/-10 mm	X-Small- 74 mm Small:- 84 mm Medium:- 94 mm Large:- 104 mm X-Large:- 114 mm		
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	**Size** X-Small Small Medium Large X-Large	**Palm** 0.18mm 0.18mm 0.18mm 0.18mm 0.18mm	**Finger** 0.20mm 0.20mm 0.20mm 0.20mm 0.20mm
ASTM D6319-2019 Standard Specification for Examination Gloves for Medical Application	To determine the physical properties - Tensile strength	**Before Aging** Tensile Strength 14Mpa Min for all sizes **After Aging** Tensile Strength 14Mpa Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before Aging** 22.77 Mpa 22.80 Mpa 24.46 Mpa 24.51 Mpa 24.59 Mpa	**After Aging** 20.50 Mpa 20.69 Mpa 21.28 Mpa 21.34 Mpa 21.36 Mpa
	To determine the physical properties - Ultimate Elongation	**Before Aging** Ultimate Elongation 500% Min for all sizes **Before Aging** Ultimate Elongation 400% Min for all sizes	**Size** X-Small Small Medium Large X-Large	**Before Aging** 885% 886% 888% 891% 892%	**After Aging** 760% 764% 767% 769% 772%

PERFORMANCE DATA – PURPLE COLOR

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 220mm (XS, S) Min 230 mm (M, L, XL)	X-Small:- 245 mm Small:- 245 mm Medium:- 246 mm Large:- 248 mm X-Large:- 248 mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	X-Small:- 70+/-10 mm Small:- 80+/-10 mm Medium:- 95+/-10mm Large:- 110+/-10 mm X-Large:- 120+/-10 mm	X-Small:- 76 mm Small:- 85 mm Medium:- 95 mm Large:- 104 mm X-Large:- 115 mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Palm 0.05 mm min Finger 0.05 mm min for all sizes	**Size** / **Palm** / **Finger** X-Small 0.18mm 0.21mm Small 0.18mm 0.21mm Medium 0.18mm 0.21mm Large 0.18mm 0.21mm X-Large 0.18mm 0.21mm
ASTM D6319-2019 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the physical properties- Tensile strength	**Before Aging** Tensile Strength 14Mpa Min for all sizes **After Aging** Tensile Strength 14Mpa Min for all sizes	**Size** / **Before Aging** / **After Ageing** X-Small 22.78 Mpa 20.48 Mpa Small 22.82 Mpa 20.67 Mpa Medium 24.47 Mpa 21.30 Mpa Large 24.52 Mpa 21.35 Mpa X-Large 24.58 Mpa 21.36 Mpa
	To determine the Physical properties- Ultimate Elongation	**Before Aging** Ultimate Elongation 500% Min for all sizes **After Aging** Ultimate Elongation 400% Min for all sizes	**Size** / **Before Aging** / **After Aging** X-Small 884% 759% Small 885% 763% Medium 887% 766% Large 892% 768% X-Large 893% 772%
ASTM D5151-2019 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 Mg/Glove Max	**Size** / **Residual Powder Content** X-Small 0.16 mg/glove Small 0.16 mg/glove Medium 0.16 mg/glove Large 0.16 mg/glove X-Large 0.16 mg/glove

BIOCOMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done for irritation.	To determine the potential of the material under test to produce dermal irritation in Rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO 10993-10 Biological Evaluation of Medical Devices Test for Irritation and Skin Sensitization. Test done Skin sensitization.	To determine the skin sensitization potential of the material both in terms of induction and elicitation in Guinea Pig.	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer
ISO 10993-5:2009 Biological evaluation of medical devices - part 5, tests for in vitro cytotoxicity.	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method.	Under the conditions of study non cytotoxic	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern.
ISO 10993-11:2017 Biological evaluation of medical devices - part 11, tests for systemic toxicity.	To determine the acute systemic toxicity potential of the test item extracts (both inside and outer surfaces) in Swiss Albino mice.	Under the conditions of study the device extracts do not pose a systemic toxicity concern	Under the conditions of study the device extracts do not pose a systemic toxicity concern

H. Clinical Testing Summary

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

I. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(K) submission, JR MEDIC Nitrile Examination Gloves Powder Free (Orange, Purple) is as safe, as effective, and performs as well as or better than the legally marketed predicate device K192333.