August 30, 2022

JR Engineering & Medical Technologies (M) SDN.BHD.
% Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. STE 114
Aurora, Illinois 60504

Re: K221157
Trade/Device Name: JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY, LZC, OPJ
Dated: August 4, 2022
Received: August 4, 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); 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)*
K221157

Device Name

JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs

Indications for Use *(Describe)*

JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs.

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	Minimum Breakthrough Detection Time
Carmustine (BCNU) (3.3 mg/ml)	23.8 Minutes
Carboplatin (10 mg/ml)	>240 Minutes
Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	24.1 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) (3.3 mg/ml) 23.8 Minutes
Thiotepa (10 mg/ml) 24.1 Minutes

Warning: Do not use with Carmustine or Thiotepa.

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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510K SUMMARY
K221157

As required by 21CFR§807.92(c)

A. APPLICANT INFORMATION

510(K) Owner's Name	JR Engineering & Medical Technologies (M) SDN.BHD.
Address	Lot 8 &10, Jalan Zurah 3 & Lot 1&3, Jalan Zurah 3A/1, Pusat Perindustrian 2, 44200 Rasa, Hulu Selangor, Selangor Darul Ehsan, Malaysia.
Phone	+603-60572081
Fax	+603-60572181
E-mail	ganeshjrmt@gmail.com
Contact Person	Mr. Ganesan Subramaniam
Designation	Managing Director
Contact Number	+6012 224 6677
Contact Email	ganeshjrmt@gmail.com
Date Submitted	August 25, 2022

B. DEVICE IDENTIFICATION

Name of the device	JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs.
Product proprietary or trade name	**JR MEDIC**
Common or usual name	Exam Gloves
Classification name	Patient Examination Gloves, Specialty
Device Classification	Class-1
Product Code	LYY, LZC, OPJ
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Textured, Blue, Latex Powder Free Examination Gloves, Tested For Use With Chemotherapy Drugs With Protein Labeling Claim (50µg/dm² or Less of Water Soluble Protein)
510(K) Number	K121926
Regulatory Class	1
Product code	LZC

D. DESCRIPTION OF THE DEVICE:

The subject device in 510(K) notification K221157 is JR Medic Blue Latex Examination Powder Free Gloves tested for use with Chemotherapy drugs. The subject device is a patient examination glove made from Natural Rubber Latex, blue color, powder free and non-sterile (as per 21CFR 880.6250, class I).

The subject device meets all the current specifications listed under the ASTM Specification D3578-2019, Standard Specification for Rubber Examination Gloves for Medical Application. This device also complies with requirements for standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs as per ASTM D6978- 05(2019).

E. INDICATIONS FOR USE/INTENDED USE OF THE DEVICE:

JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs

The tested chemotherapy drugs and their breakthrough detection times are as follows:

Tested Chemotherapy Drug Name & Concentration	**Minimum Breakthrough Detection Time (Minutes)**
Carmustine (BCNU) (3.3 mg/ml)	23.8 Minutes
Carboplatin (10 mg/ml)	>240 Minutes
Cisplatin (1 mg/ml)	>240 Minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240 Minutes
Dacarbazine (10.0 mg/ml)	>240 Minutes
Doxorubicin HCl (2 mg/ml)	>240 Minutes
Etoposide (20 mg/ml)	>240 Minutes
Fluorouracil (50 mg/ml)	>240 Minutes
Ifosfamide (50 mg/ml)	>240 Minutes
Methotrexate (25 mg/ml)	>240 Minutes
Mitomycin C (0.5 mg/ml)	>240 Minutes
Mitoxantrone (2 mg/ml)	>240 Minutes
Paclitaxel (6 mg/ml)	>240 Minutes
Thiotepa (10 mg/ml)	24.1 Minutes
Vincristine Sulfate (1 mg/ml)	>240 Minutes
Please note that the following drugs have low permeation times: **Carmustine (BCNU) (3.3 mg/ml) 23.8 Minutes** **Thiotepa (10 mg/ml) 24.1 Minutes** ***Warning: Do not use with Carmustine (BCNU) & Thiotepa***	

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

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		PREDICATE	PROPOSED DEVICE	
510(K) Number	-	**K121926**	**K221157**	
Name of device		Textured, Blue, Latex Powder Free Examination Gloves, Tested For Use With Chemotherapy Drugs With Protein Labeling Claim (50µg/dm² or Less of Water Soluble Protein)	JR Medic Blue Latex Examination Powder Free Gloves Tested for Use with Chemotherapy Drugs	Similar
Product Code	-	LZC	LYY, LZC	Same
Intended use / Indications for Use		The 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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical	JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs are disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Additionally, the gloves were tested for use with chemotherapy drugs in accordance with	Similar

		Gloves to	ASTM D6978-05 (2019) Standard Practice for	

CHARACTERSTICS	STANDARDS	DEVICE PERFORMANCE		Comparison
		PREDICATE K121926	PROPOSED DEVICE K221157	
		Permeation of Chemotherapy Drugs	Assessment of Medical Glove to Permeation by Chemotherapy Drugs.	
Regulation Number	-	21 CFR 880.6250	21 CFR 880.6250	Same
Material	-	Natural Latex	Natural Latex	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger texture	Same
Size	ASTM D3578-2019	Small, Medium, Large, Extra Large	Small, Medium, Large, Extra Large	Same
Single Use	Medical Glove Guidance Manual - Labeling	Single Use	Single Use	Same
Sterile/nonsterile	-	Nonsterile	Nonsterile	Same
Dimensions	ASTM D3578-2019	Length: Small-Min 220 mm & Medium, Large & Extra-large-Min 230 mm Width Min 95+/-10 mm(Medium Size)	Length > 230 mm Width Min 95+/-10 mm(for medium size)	Similar
Physical Properties	ASTM D3578-2019	**Before Ageing** Tensile Strength min 18 Mpa Ultimate Elongation Min 650% **After Ageing** Tensile Strength min 14 Mpa Ultimate Elongation Min 500%	**Before Ageing** Tensile Strength > 18 Mpa Ultimate Elongation >650% **After Ageing** Tensile Strength >14 Mpa Ultimate Elongation > 500%	Similar
Thickness	ASTM D3578-2019	Palm min 0.08 mm	Palm > 0.08 mm Finger > 0.08 mm	Similar

		Finger min 0.08 mm		
Powder Free Residue	ASTM D3578-2019	≤2 mg/glove	≤2 mg/glove	Same
Watertight (1000 ml)	ASTM D3578-2019	Passes AQL-2.5	Passes AQL-1.5	Similar
Label and Labeling	FDA Label requirements	Meets FDA's requirements	Meets FDA's requirements	Same

CHARACTERSTICS	**STANDARDS**	**DEVICE PERFORMANCE**		Comparison
		PREDICATE K121926	**PROPOSED DEVICE K221157**	
Bio-compatibility	Primary Skin Irritation-ISO 10993-10:2010 (E)	Gloves are non-irritating	Under the condition of study not an irritant	Similar
	Dermal Sensitization-ISO 10993-10:2010(E)	Gloves do not display any potential for sensitization	Under the conditions of the study not a sensitizer	Similar
	In vitro cytotoxicity ISO10993-5 :2009(E)	No Data Available	Under the conditions of the study, cytotoxic	----
	Acute systemic toxicity		Under the conditions of the study no systemic toxicity	
	Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	No Data Available	Under the conditions of the study non pyrogenic	----
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978				
Carmustine (BCNU) (3.3 mg/ml)		15.4 Minutes	23.8 Minutes	Different
Carboplatin (10 mg/ml)		Not Tested	>240 Minutes	Different
Cisplatin (1 mg/ml)		>240 Minutes	>240 Minutes	Same
Cyclophosphamide (Cytoxan) (20 mg/ml)		>240 Minutes	>240 Minutes	Same
Dacarbazine (10.0 mg/ml)		>240 Minutes	>240 Minutes	Same
Doxorubicin HCl (2 mg/ml)		>240 Minutes	>240 Minutes	Same

Etoposide (20 mg/ml)	>240 Minutes	>240 Minutes	Same
Fluorouracil (50 mg/ml)	>240 Minutes	>240 Minutes	Same
Ifosfamide (50 mg/ml)	Not Tested	>240 Minutes	Different
Methotrexate (25 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitomycin C (0.5 mg/ml)	>240 Minutes	>240 Minutes	Same
Mitoxantrone (2 mg/ml)	Not Tested	>240 Minutes	Different
Paclitaxel (6 mg/ml)	>240 Minutes	>240 Minutes	Same
Thiotepa (10 mg/ml)	1.6 Minutes	24.1 Minutes	Different
Vincristine Sulfate (1 mg/ml)	>240 Minutes	>240 Minutes	Same

G. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Test Method	Purpose	Acceptance Criteria	Result
ASTM D3578-2019 Standard Specification for Rubber Examination Gloves	To determine the length of the gloves	Min 230 mm for all sizes	Small 304 mm Medium 304 mm Large 305 mm X-Large 305 mm
ASTM D3578-2019 Standard Specification for Rubber Examination Gloves	To determine the width of the gloves	Small 80+/-10mm Medium 95+/-10 mm Large 111+/-10 mm X-Large 115+/-10 mm	Small 84 mm Medium 94 mm Large 105 mm X-Large 114 mm

Test Method	Purpose	Acceptance Criteria	Result		
ASTM D3578-2019 Standard Specification for Rubber Examination Gloves	To determine the thickness of the gloves	Palm 0.08 mm min Finger 0.08 mm min for all sizes	**Size** Small Medium Large X-Large	**Palm** 0.31mm 0.31mm 0.31mm 0.31mm	**Finger** 0.38mm 0.38mm 0.38mm 0.38mm
ASTM D3578-2019 Standard Specification for Rubber Examination Gloves	To Determine the physical properties-Tensile strength	**Before Ageing** Tensile Strength 18Mpa Min for all sizes **After Ageing** Tensile Strength 14Mpa Min for all sizes	**Size** Small Medium Large X-Large	**Before ageing** 33.16 Mpa 32.93 Mpa 32.43 Mpa 32.36 Mpa	**After ageing** 30.78 Mpa 30.73 Mpa 30.23 Mpa 30.16 Mpa
	To Determine the physical properties-Ultimate Elongation	**Before Ageing** Ultimate Elongation 650% Min for all sizes **After Ageing** Ultimate Elongation 500% Min for all sizes	**Size** Small Medium Large X-Large	**Before ageing** 1320% 1288% 1376% 1200%	**After ageing** 1066% 1105% 1225% 1041%
	To Determine the physical properties-stress at 500% Elongation	**Before Ageing** 5.5 Mpa Max for all sizes	**Size** Small Medium Large X-Large	**Before ageing** 5.1 Mpa 5.2 Mpa 5.2 Mpa 5.2 Mpa	**NA**
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 1.5		
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** Small Medium Large X-Large	**Residual Powder Content** 0.21 mg/glove 0.22 mg/glove 0.22 mg/glove 0.22 mg/glove	
ASTM D 5712-95 (Re approved 2010) Standard Test Method for the Analysis of Protein in Natural Rubber	To determine the extractable protein in the gloves.	200 µg/ dm² Max for all sizes	**Size** Small Medium Large X-Large	**Extractable Protein content** 43.12 µg/ dm² 41.16 µg/ dm² 42.06 µg/ dm² 46.24 µg/ dm²	

H. BIO-COMPATIBILITY 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.
Acute systemic toxicity	To determine the acute systemic toxicity potential of the test item in Swiss albino mice		Under the conditions of the study, no systemic toxicity
Material Mediated Pyrogenicity ISO 10993-11:2017(E) / USP 41<151>	To determine the pyrogenic potential of the test item extract following intravenous injection in New Zealand white Rabbits.	Under the conditions of the study non pyrogenic	Under the conditions of the study non pyrogenic

I. CLINICAL TESTING SUMMARY

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

J. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission JR Medic Blue Latex Examination Powder Free Gloves Tested for use with Chemotherapy drugs is as safe, as effective, and performs as well as or better than the legally marketed predicate device *Textured, Blue, Latex Powder Free Examination Gloves, Tested For Use With Chemotherapy Drugs With Protein Labeling Claim (50µg/dm² or Less of Water-Soluble Protein) K121926.*