May 18, 2022

Pt. Maja Agung Latexindo
℅ Jeni Chuason
Official Correspondent
Shamrock Marketing Co., Inc.
5445 Daniels Street
Chino, California 91710

Re: K212408
Trade/Device Name: Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: April 20, 2022
Received: April 25, 2022

Dear Jeni Chuason:

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.
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)*
K212408

Device Name
Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate).

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate.

Chemotherapy Drug and Permeation
The following chemicals have been tested with these gloves:

Chemotherapy Drug and Concentration	Breakthrough Detection Time in Minutes
Carboplatin (Paraplatin), 10 mg/ml (10,000ppm)	> 240 min.
Carmustine (BCNU), 3.3 mg/ml (3,300ppm)	58.3 min (Not recommended for use)
Cisplatin, 1.0 mg/ml (1,000ppm)	> 240 min
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	> 240 min
Dacarbazine, 10.0mg/ml (10,000ppm)	> 240 min
Docetaxel, 10mg/ml (10,000ppm)	> 240 min
Doxorubicin HCI, 2.0mg/ml (2,000ppm)	> 240 min
Etoposide, 20.0mg/ml (20,000ppm)	> 240 min
Fluorouracil, 50.0mg/ml (50,000ppm)	> 240 min
Ifosfamide, 50 mg/ml (50,000 ppm)	> 240 min
Methotrexate, 25mg/ml (25,000 ppm)	> 240 min
Mitomycin C, 0.5 mg/ml (500 ppm)	> 240 min
Paclitaxel, 6.0 mg/ml (6,000 ppm)	> 240 min
ThioTepa, 10.0mg/ml (10,000ppm)	119 min (Not recommended for use)
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	> 240 min
Simulated Gastric Acid	> 240 min
Fentanyl Citrate Injection 100.0 mg/2ml	> 240 min

WARNING: Do not use with Carmustine (BCNU) 3.3 mg/ml and Thiotepa (10mg/ml).

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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PT. MAJA AGUNG LATEXINDO
Manufacturer of Latex Gloves

510(k) Summary
K212408

1) Submitter

Name of applicant: Sivaprakash.S
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Contact person in USA: Jeni Chuason
Phone No.: (909) 591-8855
Fax No: (909) 591-8878
Email: jenit@smcgloves.com

Summary preparation Date: July 19, 2021
Type of submission: Traditional

2) Device Information:
Device Name /
Trade Name: Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate)
Classification Name: Patient Exam Glove, Medical Gloves with Chemotherapy / Simulated Gastric Acid / Fentanyl Citrate Labeling Claims
Classification: Class I, Non-Sterile
Classification panel: General Hospital
Regulation Number: 21 CFR 880.6250
Common Name: Patient Examination Glove, Specialty
Product Code: LZA, LZC, OPJ, QDO

3) Identification of the Legally Marketed Devices That Equivalency is Claimed:
Primary Predicate:
Device name: EMG Blue Nitrile Examination Gloves Powder free with tested for use with Chemotherapy Drugs
Company: ECO Medi Glove Sdn. Bhd
510(k): K171339
Regulatory Class I
Product Code: LZA, LZC

4) Device Description:
The Powder Free Nitrile Examination Gloves, Blue Color, Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate are non-sterile, single use, disposable gloves intended for

medical purposes to be worn on the hands of examiners to prevent contamination between patient and examiner. The gloves are ambidextrous, i.e. can be worn on right hand or left hand.
The gloves are manufactured from nitrile synthetic rubber. Inner surface of gloves undergo 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 gloves are designed and manufactured in accordance with the ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application and are tested for use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate per ASTM D6978-05(2019).

Gloves Specification
4.1. Dimension and Thickness of the Gloves

Dimension	**Size**					
Overall Length (mm)	**XS**	**S**	**M**	**L**	**XL**	**XXL**
min.	220	220	230	230	230	230
Palm Width (mm) min.	70 ± 10	80 ± 10	95 ± 10	110 ± 10	120 ± 10	130 ± 10
Thickness (mm) min.						
Cuff	0.05	0.05	0.05	0.05	0.05	0.05
Palm	0.05	0.05	0.05	0.05	0.05	0.05
Fingertip	0.05	0.05	0.05	0.05	0.05	0.05

4.2. Physical Properties and Freedom of Pinholes

Measurement	Before Aging	After Aging at 70°C for 168 hours
Tensile Strength (mpa)	14 min.	14 min.
Ultimate Elongation (%)	500 min.	400 min.
Freedom from pinholes Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

5) Indications for Use:
Powder Free Nitrile Examination Glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.
These gloves were tested for use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Test Results follows:

Drugs Name	Concentration Tested	Breakthrough Detection Time (Minutes)
Carboplatin (Paraplatin)	10 mg/ml (10,000 ppm)	> 240 min

Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	58.3 min
Cisplatin	1.0 mg/ml (1,000 ppm)	> 240 min
Cyclophosphamide (Cytoxan)	20 mg/ml (20,000 ppm)	> 240 min
Dacarbazine	10 mg/ml (10,000 ppm)	> 240 min
Docetaxel	10 mg/ml (10,000 ppm)	> 240 min
Doxorubicin HCl	2.0 mg/ml (2,000 ppm)	> 240 min
Etoposide	20 mg/ml (20,000 ppm)	> 240 min
Fluorouracil	50 mg/ml (50,000 ppm)	> 240 min
Ifosfamide	50 mg/ml (50,000 ppm)	> 240 min
Methotrexate	25 mg/ml (25,000 ppm)	> 240 min
Mitomycin C	0.5 mg/ml (500 ppm)	> 240 min
Paclitaxel	6 mg/ml (6,000 ppm)	> 240 min
ThioTepa	10 mg/ml (10,000 ppm)	119 min
Vincristine Sulfate	1 mg/ml (1,000 ppm)	> 240 min
Simulated Gastric Acid Fluid		> 240 min
Fentanyl Citrate Injection	100mcg/2mL	>240 min

Please note that the following drugs that have low permeation time are:
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) 58.3 min.
ThioTepa, 10 mg/ml (10,000 ppm) 119.0 min
Caution: Testing showed an average of breakthrough time 58.3-67.3 for Carmustine and 119 for ThioTepa

6) Comparison of the Technological Characteristics of the Device:

Device Characteristic	Predicate Device	Proposed Device	Comparison Analysis
Manufacturer	Eco Medi Glove Sdn, Bhd	PT. MAJA AGUNG LATEXINDO	N/A
Product code	LZA, LZC	LZA, LZC, OPJ, QDO	N/A
Trade Name	EMG Blue Nitrile Patient Examination Gloves Powder Free Tested for Use with Chemotherapy Drugs	Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate)	N/A
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
510(K)	K171339	K212408	
Intended use	A powder free patient	A patient examination glove is a	Similar

	examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.	disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	
Rx or OTC	Over the counter	Over the counter	Same
Materials	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Sterility	Non-sterile	Non-sterile	Same
Single use	Single use	Single use	Same
Contact Duration	N/A	Limited ≤ 24 hours	Different
Dimensions	Meets ASTM D6319-10 Size: Medium Palm Width: 98 mm Length: 247 mm Finger Thickness: 0.08 mm Palm Thickness: 0.05 mm	Complies with: ASTM D6319-10 Size: XS, S, M, L, XL, XXL Palm Width: 95 ± 10 (size M) Length: min 230 mm Finger Thickness: 0.13 mm Palm Thickness: min 0.12 mm	Similar
Physical Properties	Tensile strength (Mpa): Before Aging: 25.45 Mpa After Accelerated aging: 26.33 Mpa Ultimate Elongation(%): Before Aging: 600% After Aging: 550% Meets ASTM D6319-10	Tensile strength (Mpa): Before Aging: min 14 Mpa After Accelerated aging: 14 Mpa Ultimate Elongation(%): Before Aging: min 500% After Aging: min 400% Meets ASTM D6319-10	Similar
Freedom from pinholes	AQL 2.5 Meets ASTM D5151-06	AQL 2.5 Meets ASTM D5151-06	Same
Residual Powder	Complies with ASTM D6124-06 Average (size M): 0.17 mg/glove	Complies with ASTM D6124-06 Average (size M): 0.35mg/glove	Similar
Biocompatibility: **ISO 10993-10:** **Skin Irritation Test** **Skin Sensitizer** **ISO 10993-11:** **Systemic Toxicity**	 Not a skin irritant Not a skin sensitizer Not available	 Not a skin irritant Not a skin sensitizer Not Toxic	 Same Different

Tested Chemotherapy Drugs and breakthrough detection time in minutes	Carboplatin (Paraplatin) 10mg/ml (10,000 ppm) >240 min	Carboplatin (Paraplatin) 10mg/ml (10,000 ppm) >240 min	Same
	Carmustine (BCNU) 3.3 mg/ml (3300 ppm) 24 mins	Carmustine (BCNU) 3.3 mg/ml (3300 ppm) 58.3 mins	Similar
	Cisplatin 1mg/ml (1000 ppm) >240 min	Cisplatin 1mg/ml (1000 ppm) >240 min	Same
	Cyclophosphamide (Cytoxan) 20mg/ml (20000 ppm) >240 min	Cyclophosphamide (Cytoxan) 20mg/ml (20000 ppm) >240 min	Same
	Dacarbazine 10mg/ml (10000 ppm) >240 min	Dacarbazine 10mg/ml (10000 ppm) >240 min	Same
		Docetaxel 10mg/ml (10000 ppm) >240 min	Different
	Doxorubicin HCl 2mg/ml (2000 ppm) >240 min	Doxorubicin HCl 2mg/ml (2000 ppm) >240 min	Same
	Etoposide 20mg/ml (2000 ppm) >240 min	Etoposide 20mg/ml (2000 ppm) >240 min	Same
	Fluorouracil 50mg/ml (50000 ppm) >240 min	Fluorouracil 50mg/ml (50000 ppm) >240 min	Same
	Ifosfamide 50mg/ml (50000 ppm) >240 min	Ifosfamide 50mg/ml (50000 ppm) >240 min	Same
	Methotrexate 25mg/ml (25000 ppm) >240 min	Methotrexate 25mg/ml (25000 ppm) >240 min	Same
	Mitomycin C 0.5mg/ml (500 ppm) >240 min	Mitomycin C 0.5mg/ml (500 ppm) >240 min	Same
	Mitoxantrone 2mg/ml >240 min		Different
	Paclitaxel 6mg/ml (6000 ppm) >240 min	Paclitaxel 6mg/ml (6000 ppm) >240 min	Same
	ThioTepa 10mg/ml (10000 ppm) 56.9 mins	ThioTepa 10mg/ml (10000 ppm) 119 mins	Similar
	Vincristine Sulfate 1mg/ml (1000 ppm) >240 min	Vincristine Sulfate 1mg/ml (1000 ppm) >240 min	Same
Simulated Gastric Acid		Simulated Gastric Acid Fluid >240 min	Different
Fentanyl Testing		Fentanyl Citrate Injection 100mcg/2mL >240 min	Different

Summary of the technological characteristics of the proposed device in comparison to the predicate device.

Based on the comparison of technological characteristics between proposed device and the predicate device, the devices were found to be similar in terms of indications for use, dimension, physical properties, freedom from pinholes, and residual powder and met with ASTM D5151-06 and D6319-19 standard. Both proposed and predicate devices also were tested for use with chemotherapy drugs per ASTM D6978-05 standard, but the proposed device also added fentanyl and simulated gastric acid testing that made the difference. Lastly, both performed biocompatibility testing and found with the similar result to be non-irritant, non-sensitizer, nor toxic.

7) **Substantial Equivalent Based on Assessment of Non-Clinical Performance Data.**
Summary of Non-Clinical Testing

a. Biocompatibility Testing

Table below summarize the biocompatibility testing result:

Name of test / citation	Purpose	Acceptance Criteria	Results
ISO 10993-10: Biological Evaluation of Medical Devices, Part 10	Irritation Testing	Pass/Fail	Pass Not a primary skin irritant
ISO 10993-10: Biological Evaluation of Medical Devices, Part 10	Sensitization Testing	Pass/Fail	Pass Not a primary skin sensitizer
ISO 10993-5: Biological Evaluation of Medical Devices, Part 5	In Vitro Cytotoxicity Testing	Pass/Fail	Failed Exhibit cytotoxicity reactivity
ISO 10993-11: Biological Evaluation of Medical Devices, Part 11	Systemic Toxicity Testing	Pass/Fail	Pass Not toxic

b. Performance Test Data – Summary of Non-Clinical Testing

The test results demonstrated that the proposed device met the performance criteria as specified utilizing the following test method, standards, and specification:

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06, Standard Tested Method for Residual Powder on medical Gloves

Physical Dimensions

Purpose	Test Method		Test Result	Acceptance
Dimension	**ASTM D6319-19**			**Criteria (Y/N)**
Length	**Size**	**(mm)**	**(mm)**	
	X-Small	220 min	240 - 245	Y
	Small	220 min	240 - 245	Y
	Medium	230	240 - 245	Y
	Large	230	240 - 243	Y
	Extra-Large	230	240 - 243	Y
	XX-Large	230	240 - 242	Y
Width	**Size**	**(mm)**	**(mm)**	
	X-Small	70 ± 10	77 - 79	Y
	Small	80 ± 10	84 -86	Y
	Medium	95 ± 10	95 - 97	Y
	Large	110 ± 10	104 - 106	Y
	Extra-Large	120 ± 10	111 - 115	Y
	XX-Large	130 ± 10	120 - 123	Y
Palm Thickness	**Size**	**(mm)**	**(mm)**	
	X-Small	0.05 min	0.12	Y
	Small	0.05 min	0.12	Y
	Medium	0.05 min	0.12	Y
	Large	0.05 min	0.12	Y
	Extra-Large	0.05 min	0.12	Y
	XX-Large	0.05 min	0.12	Y
Finger Thickness	**Size**	**(mm)**	**(mm)**	
	X-Small	0.08 min	0.13	Y
	Small	0.08 min	0.13	Y
	Medium	0.05 min	0.13	Y
	Large	0.05 min	0.13	Y
	Extra-Large	0.05 min	0.13	Y
	XX-Large	0.05 min	0.13	Y

Physical Properties

Purpose	Test Method		Test Result		Acceptance Criteria (Y/N)
Physical Properties	**ASTM D6319-19 Standard**				
	Before Aging	After Aging at 70°C, 166 ± 2 hrs	Before Aging	After Aging at 70°C, 166 ± 2 hrs	
Tensile Strength	14 MPa min	14 MPa min	17.55 – 20.90 MPa	15.00 – 19.95 MPa	Y
Ultimate Elongation	500% min	400% min	750 – 830%	625 – 770%	Y

Freedom from Holes

Purpose	Test Method	Test Result	Acceptance Criteria (Y/N)
Freedom from Holes	**ASTM D5151-06 Standard, G-1, AQL 2.5**	XS/XXL – 0/160 S/M/XL – 1/250 L – 2/250 Passed Standard Acceptance	**Y**

Powder Content

Purpose	Test Method	Test Result	Acceptance Criteria (Y/N)
Residual Powder Content	**ASTM D6124-06, ≤ 2.0 mg/glove**	X-Small: 0.34 mg/glove (Average)	Y
		Small: 0.35 mg/glove (Average)	Y
		Medium: 0.35 mg/glove (Average)	Y
		Large: 0.37 mg/glove (Average)	Y
		X-Large: 0.35mg/glove (Average)	Y
		XX-Large: 0.33 mg/glove (Average)	Y

c. Permeation Testing

Permeation testing were conducted to support the labeling claim: Tested for use with chemotherapy drugs per ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
Table below is the summary of minimum breakthrough time.

Warning: Not recommended use with drugs that have low permeation time: Carmustine (58.3 average breakthrough time) and Thiotepa (119 average breakthrough time).

Purpose Test Chemotherapy Drugs	Test Method	Average Breakthrough Time	Acceptance Criteria (Y/N)
Carboplatin (Paraplatin), 10 mg/ml (10,000 ppm)	**ASTM D6978-05**	> 240 min	Y
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)		58.3 min	N
Cisplatin, 1.0 mg/ml (1,000 ppm)		> 240 min	Y
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)		> 240 min	Y
Dacarbazine, 10.0 mg/ml (10,000 ppm)		> 240 min	Y
Docetaxel, 10 mg/ml (10,000 ppm)		> 240 min	Y
Doxorubicin HCI, 2.0 mg/ml (2,000 ppm)		> 240 min	Y
Etoposide, 20.0 mg/ml (20,000 ppm)		> 240 min	Y

Fluorouracil, 50.0 mg/ml (50,000 ppm)		> 240 min	Y
Ifosfamide, 50 mg/ml (50,000 ppm)		> 240 min	Y
Methotrexate, 25 mg/ml (25,000 ppm)		> 240 min	Y
Mitomycin C, 0.5 mg/ml (500 ppm)		> 240 min	Y
Paclitaxel, 6.0 mg/ml (6,000 ppm)		> 240 min	Y
ThioTepa, 10.0 mg/ml (10,000 ppm)		119 min	N
Vincristine Sulfate, 1 mg/ml (1,000 ppm)		> 240 min	Y
Simulated Gastric Acid Fluid		>240 min	Y
Fentanyl Citrate Injection 100mcg/2mL		>240 min	Y

8) Summary of Clinical Testing

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

9) **Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.