December 28, 2023

Eco Medi Glove Sdn. Bhd.
Suresh Kumar
Official Correspondent
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya
Industrial Estate
Taiping, Perak Darul Ridzuan 34600
Malaysia

Re: K233405
Trade/Device Name: Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl Test Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: October 2, 2023
Received: October 5, 2023

Dear Suresh Kumar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233405

Device Name

Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl Test Claim

Indications for Use *(Describe)*

Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim is a disposable device intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

In addition, these gloves were tested for use with Chemotherapy drugs and Fentanyl Test claim in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs and Fentanyl Test claim

Chemotherapy Drug and Fentanyl Test Claim Concentration Minimum Breakthrough detection time in Minutes, ug/cm2/minute

1) Carmustine (3.3mg/ml or 3000ppm),	24.0 minutes
2) Cyclophosphamide (20mg/ml or 20,000ppm),	>240 minutes
3) Cisplatin (1.0mg/ml or 1,000ppm),	>240 minutes
4) Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm),	>240 minutes
5) Etoposide (20mg/ml or 20,000ppm),	>240 minutes
6) Flourouracil (50mg/ml or 50,000),	>240 minutes
7) Methorexate (25mg/ml or 25,000ppm),	>240 minutes
8) Paclitaxel (6mg/ml or 6,000ppm),	>240 minutes
9) Thiotepa (10mg/ml or 10,000ppm),	56.9 minutes
10) Ifosfamide (50mg/ml)	>240 minutes
11) Mitoxantrone (2mg/ml) ,	>240 minutes
12) Vincristine Sulfate (1mg/ml) ,	>240 minutes
13) Carboplatin (10.0mg/ml),	>240 minutes
14) Dacarbazine (DTIC) (10.0mg/ml)	>240 minutes
15) Mitomicin C (0.5mg/ml)	>240 minutes
16) Fentanyl Citrate Injection 100mg/2ml	>240 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 24.0 ug/cm2/minute.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 56.9 ug/cm2/minute.

WARNING: Not for use with Carmustine and 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.

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SST NO. : A11-1808-21015730

510(K) Summary K233405

Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl Test Claim

1.0 Submitter:

Company Name	:	ECO Medi Glove Sdn. Bhd.
Company Address	:	Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping, Perak Darul Ridzuan, Malaysia.
Contact Person	:	Mr. Suresh Kumar
Telephone	:	+605-806 2316
Fax	:	+605-806 2315
Email	:	qa1@riverstone.com.my

2.0 Preparation Date : 25th December 2023

3.0 Name of the Device

Trade Name / Proprietary Name: Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl Test Claim

Device Name: Nitrile Patient Examination gloves.

Device Classification Name: Non-Powdered Patient Examination gloves (21 CFR 880.6250). Device Class: Class I.

Product Code: LZA, LZC, OPJ, and QDO

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4.0 Identification of The Legally Marketed Device:

Predicate Device: K171339, EMG Blue Nitrile Examination Glove Powder Free with Chemotherapy Drugs.

5.0 Device Description

The subject device in this 510(k) Notification is EMG Blue Powder Free Nitrile Examination Gloves with Chemotherapy Drugs and Fentanyl Test Claim. The subject device is a patient examination glove made from nitrile latex compound, blue color, powder-free, and non-sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-19, the Standard Specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs and fentanyl test claims.

The Blue Nitrile Medical Examination Gloves, Powder Free, is a disposable device intended for medical purposes that are worn on the examiner's hand or finger to prevent contamination between patient and examiner (product Code LZA) and are used with chemotherapy drugs (Product code LZC and OPJ) and fentanyl test (Product code QDO).

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6.0 Intended Use/Indications for Use

Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim 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. It is for over-the-counter use.

In addition, these gloves were tested for use with Chemotherapy drugs and Fentanyl Test claim in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs and Fentanyl Test claim.

	Chemotherapy Drug and Fentanyl Test Claim Concentration	Minimum Breakthrough detection time in Minutes, ug/cm^2/minute
1	Carboplatin (10mg/ml or 10,000ppm)	>240 minutes
2	Carmustine (3.3mg/ml or 3000ppm),	24.0 minutes
3	Cisplatin (1.0mg/ml or 1,000ppm),	>240 minutes
4	Cyclophosphamide (20mg/ml or 20,000ppm),	>240 minutes
5	Dacarbazine (DTIC) (10.0mg/ml)	>240 minutes
6	Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm),	>240 minutes
7	Etoposide (20mg/ml or 20,000ppm),	>240 minutes
8	Fluorouracil (50mg/ml or 50,000),	>240 minutes
9	Ifosfamide (50mg/ml)	>240 minutes
10	Methorexate (25mg/ml or 25,000ppm),	>240 minutes
11	Mitomycin (0.5mg/ml or 500ppm)	>240 minutes
12	Mitoxantrone (2mg/ml or 2,000ppm) ,	>240 minutes
13	Paclitaxel (6mg/ml or 6,000ppm),	>240 minutes
14	Thiotepa (10mg/ml or 10,000ppm),	56.9 minutes
15	Vincristine Sulfate (1mg/ml) ,	>240 minutes
16	Fentanyl Citrate Injection 100mg/2ml	>240 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 24.0 ug/cm^2/minute.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 56.9 ug/cm^2/minute.

WARNING: Not for use with Carmustine and ThioTepa

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7.0 Specification for the subject Nitrile gloves:

7.1 Dimension and Thickness of Gloves

Dimension	Size XXS	Size XS	Size S	Size M	Size L	Size XL	Size XXL	Size XXXL
Overall Length (mm)	230min	230min	230min	230min	230min	230min	230min	230min
Width (± 10mm)	65	75	85	95	105	115	125	135
Thickness at Palm (mm)	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min
Thickness at Finger Tip (mm)	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min

7.2 Gloves Physical Properties and Holes

Measurement	Before Ageing	After Aging at 70ºC for 168 hrs @ 100ºC for 22 hrs
Tensile Strength (MPa)	14min	14 Min
Ultimate Elongation (%)	500min	400min
Pin-hole Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

Gloves meet all the specifications listed in ASTM D 6319-19

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Technological Characteristics Comparison of the Proposed and Predicate Devices

Characteristics	Acceptance Criteria	Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim K233405	Predicate Device EMG Blue Nitrile Examination Glove Powder-Free with Chemotherapy Drugs K171339	Assessment Similarities and Differences
Product Code		LZA, LZC , OPJ, and QDO	LZA, LZC	Similar
Intended use/Indications for Use		A powder-free 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. The device is for over-the-counter use.	A powder-free 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. The device is for over-the-counter use.	same
Material use	Nitrile compound	Nitrile compound	Nitrile compound	Same
Color		Blue	Blue	Same
Sterility		Non sterile	Non sterile	Same
Surface	Finger Textured	Finger Textured	Finger Textured	Same
Cuffing Beading	Rolled Beading	Rolled Beading	Rolled Beading	Same
Design	Ambidextrous	Ambidextrous	Ambidextrous	Same
Dimensions	Overall Length (mm) Min 230mm Width (± 10mm) **Size XXS = 65mm** **Size XS = 75mm** **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** **Size XXL=125mm** **Size XXXL=135mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Overall Length (mm) Min 230mm Width (± 10mm) **Size XXS = 65mm** **Size XS = 75mm** **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** **Size XXL=125mm** **Size XXXL=135mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Overall Length (mm) Min 230 mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Similar additional sizes were added to the subject device

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Characteristics	Acceptance Criteria	Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim,	Predicate Device EMG Blue Nitrile Examination Glove Powder-Free with Chemotherapy Drugs K171339	Assessment Similarities and Differences
Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-19	Meets ASTM D6319-19	same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19	Meets ASTM D5151-19	same
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	same
Biocompatibility	ISO 10993-23: 2021 Biological evaluation of medical devices- Part 23: Test for irritation	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	same
	ISO 10993-10: 2021 Biological Evaluation on Medical Device – Part 10: Test for Skin Sensitization	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	same
	ISO 10993-11 Biological evaluation on medical device Part 11 – Test for systemic toxicity	Under the conditions of this study, not induce any acute systemic toxicity	Under the conditions of this study, not induce any acute systemic toxicity	Same

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Characteristics	Acceptance Criteria	Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim,	Predicate Device EMG Blue Nitrile Examination Glove Powder-Free with Chemotherapy Drugs K171339	Assessment Similarities and Differences
Resistance against Chemotherapy Drugs	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASM D6978-05	1) Carboplatin (10mg/ml or 10,000ppm) >240 minutes 2) Carmustine (3.3mg/ml or 3000ppm), 24.0 minutes 3) Cisplatin (1.0mg/ml or 1,000ppm), >240 minutes 4) Cyclophosphamide (20mg/ml or 20,000ppm), >240 minutes 5) Dacarbazine (DTIC) (10.0mg/ml) >240 minutes 6) Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), >240 minutes 7) Etoposide (20mg/ml or 20,000ppm), >240 minutes 8) Fluorouracil (50mg/ml or 50,000), >240 minutes 9) Ifosfamide (50mg/ml) >240 minutes 10) Methorexate (25mg/ml or 25,000ppm), >240 minutes 11) Mitomicin (0.5mg/ml or 500ppm) >240 minutes 12) Mitoxantrone (2mg/ml or 2,000ppm) , >240 minutes 13) Paclitaxel (6mg/ml or 6,000ppm), >240 minutes 14) Thiotepa (10mg/ml or 10,000ppm), 56.9 minutes 15) Vincristine Sulfate (1mg/ml) , >240 minutes 16) Fentanyl Citrate Injection 100mg/2ml >240 minutes Warning : Not for use with Carmustine or Thio Tepa	1) Carmustine (BCNU) 3.3mg/ml 24.0 minutes 2) Cisplatin 1.0mg/mL, >240 minutes 3) Cyclophosphamide (Cytoxan) (20mg/ml) >240 minutes 4) Dacarbazine (10mg/ml) >240 minutes 5) Doxorubicin HCI (2.0mg/ml) >240 minutes 6) Etoposide (20.0mg/ml >240 minutes 7) Fluorouracil (50.0mg/ml) >240 minutes 8) Methotrexate (25mg/ml) >240 minutes 9) Paclitaxel (6.0mg/ml) >240 minutes 10) ThioTepa (10.0mg/ml) 56.9 minutes 11) Vincristine Sulfate 1.0mg/ml, >240 minutes 12) Ifosfamide (50mg/ml) 13) Mitoxantrone (2mg/ml or 2,000ppm) , 14) Carboplatin (10mg/ml or 10,000ppm) 15) Vincristine Sulfate (1mg/ml) , Warning : Not for use with Carmustine or Thio Tepa	Similar. Additional Fentanyl test is conducted for Device sample

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8.0 Summary of Non-Clinical Performance test data

Characteristics	Test Standard	Acceptance Criteria	Test Result	Remark
Freedom from Pin holes	ASTM D5151 -19 (Re-approved 2011)	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19	Per Lot Size 500,000pcs
Dimensions	ASTM D6319 -19	Length Min 230mm	Meets ASTM D6319-19	Lot Size 500,000pcs
	ASTM D6319 -19	Width **Size XXS = 65mm±10** **Size XS = 75mm±10** **Size S = 85mm±10** **Size M = 95mm±10** **Size L = 105mm±10** **Size XL = 115mm±10** **SizeXXL =125mm±10** **Size XXXL = 135mm±10**	ISO 2859-1 / S2/AQL 4.0	
	ASTM D6319 -19	Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	ISO 2859-1 / S2/AQL 4.0	
Physical properties	ASTM D6319 -19 ASTM D412-16(2021)	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min	Meets ASTM D6319-19	
	ASTM D6319 -19 and ASTM D412-06(2021)	**After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min		
Powder-free residue	ASTM D6124-06	≤ 2.0 mg/pc	Meets ASTM D6124-06 (2022)	Once every PO
Biocompatibility	ISO 10993-23: 2021 Biological evaluation of medical devices- Part 23: Test for irritation	The Device shall be non-irritant.	Under the conditions of this study, the test article was a non-irritant	As per Device with same color
	ISO 10993-10: 2021 Biological Evaluation on Medical Device – Part 10: Test for Skin Sensitization	The device shall be non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	As per Device with same color
	ISO 10993-11 Biological evaluation on medical device Part 11 – Test for systemic toxicity	The device shall not induce any acute systemic toxicity	Under the conditions of this study, not induce any acute systemic toxicity	As per Device with same color

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Summary of Clinical Testing: Not applicable.

9.0 Conclusion

The Conclusion drawn from the non-Clinical test demonstrates that the subject device in 510(K) Submission, Blue Powder Free Nitrile Examination Glove with Chemotherapy Drugs and Fentanyl test claim is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K171339.