February 7, 2024

ECO Medi Glove Sdn. Bhd
Suresh Kumar
QA Manager
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya
Industrial Estate
Taiping, Perak Darul Ridzuan 34600
Malaysia

Re: K232764
Trade/Device Name: Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs 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: December 13, 2023
Received: December 18, 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,

Allan Guan -S

For 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232764

Device Name
Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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 Citrate in accordance with ASTM D6978-05, Standards Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug Concentration	Minimum Breakthrough detection time in Minutes
Carmustine (3.3mg/ml or 3000ppm)	15.4 minutes
Cyclophosphamide (20mg/ml or 20,000ppm)	>240 minutes
Cytarabine (100mg/ml)	>240 minutes
Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm)	>240 minutes
Etoposide (20mg/ml or 20,000ppm)	>240 minutes
Flourouracil (50mg/ml or 50,000)	>240 minutes
Methorexate (25mg/ml or 25,000ppm)	>240 minutes
Paclitaxel (6mg/ml or 6,000ppm)	>240 minutes
Thiotepa (10mg/ml or 10,000ppm)	56.2 minutes
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 15.4 minutes.
- Thiotepa (10ug/ml) – Minimum Breakthrough detection time 56.2 minutes.

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.

Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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SST NO. : A11-1808-21015730

K232764
510(K) Summary

Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

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 : 7th February 2024

3.0 Name of the Device

Trade Name / Proprietary Name: Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Device Name: Nitrile Patient Examination gloves.

Device Classification Name: Patient Examination gloves (21 CFR 880.6250).

Device Class: Class I.

Product Code: LZA, LZC, OPJ and QDO

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SST NO. : A11-1808-21015730

4.0 Identification of The Legally Marketed Device:

Predicate Device: K103249, Cornflower Blue Powder-Free Exam Gloves with Tested for Use with Chemotherapy Drug Labeling Claim

Reference Device: K220375, Intercept Free, Nitrile Two Toned White/Green, Powder- Free, Textured Fingertips, Non-sterile, Ambidextrous, Beaded Cuff, Medical Examination Gloves, Tested for Use with the Opioids Fentanyl Citrate, Heroin, and both Opioids in simulated Gastric Acid (Vomit)

5.0 Device Description

The subject device in this 510(k) Notification is a Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate. The subject device is a patient examination glove made from nitrile rubber compound, Cornflower 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 citrate.

6.0 Indications for Use

Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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 Citrate in accordance with ASTM D6978-05, Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Fentanyl Citrate Concentration	Minimum Breakthrough detection time in Minutes
Carmustine (3.3mg/ml or 3000ppm),	15.4 minutes
Cyclophosphamide (20mg/ml or 20,000ppm),	>240 minutes
Cytarabine (100mg/ml)	>240 minutes
Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm),	>240 minutes
Etoposide (20mg/ml or 20,000ppm),	>240 minutes
Flourouracil (50mg/ml or 50,000),	>240 minutes

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Methorexate (25mg/ml or 25,000ppm),	>240 minutes
Paclitaxel (6mg/ml or 6,000ppm),	>240 minutes
Thiotepa (10mg/ml or 10,000ppm),	56.2 minutes
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 15.4 minutes.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 56.2 minutes.

WARNING: Not for use with Carmustine and ThioTepa

7.0 Specification for Nitrile exam gloves (ASTM D6319-19):

7.1 Dimension and Thickness of Gloves

Dimension	Size XXS	Size XS	Size S	Size M	Size L	Size XL	Size XXL
Overall Length (mm)	N/A	220min	220min	230min	230min	230min	230min
Width (± 10mm)	N/A	70	80	95	110	120	130
Thickness at Palm (mm)	N/A	0.05min	0.05min	0.05min	0.05min	0.05min	0.05min
Thickness at Finger Tip (mm)	N/A	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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Comparison of Proposed and Predicate Device

Characteristics	Acceptance Criteria	Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (subject device)	Predicate Device Cornflower Blue Powder-Free Exam Gloves with Tested for Use with Chemotherapy Drug Labeling Claim K103249	Reference Device Intercept Free, Nitrile Two Toned White/Green, Powder-Free, Textured Fingertips, Non-sterile, Ambidextrous, Beaded Cuff, Medical Examination Gloves, Tested for Use with the Opioids Fentanyl Citrate, Heroin, and both Opioids in simulated Gastric Acid (Vomit) K220375	Assessment Similarities and Differences
Product Code		LZA, LZC, OPJ and QDO	LZA, LZC	LZA, LZC, QDO	Same
Intended 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.	A Nitrile powder free medical examination glove is a disposable device, worn on the hand or finger to prevent contamination between examiner and patient or victim. This specialty glove has also been tested for use with the Opioid drugs fentanyl citrate, Heroin, and both Opioid in simulated Gastric Acid.	Similar Except the reference device glove intended use statement was extended to address the opioid drug Heroin and gastric acid
Material use	Nitrile compound	Nitrile compound	Nitrile compound	Nitrile compound	Same
Color		Cornflower Blue	Cornflower Blue	White Outside/Lime Green inside	Same
Sterility	Non sterile	Non sterile	Non sterile	Non sterile	Same
Single use	Single use	Single use	Single use	Single use	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Surface	Finger Textured	Finger Textured	Finger Textured	Finger Textured	Same
Cuffing Beading	Rolled Beading	Rolled Beading	Rolled Beading	Rolled Beading	Same
Design	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous	Same

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Dimensions	Overall Length (mm) XS, S: Min 220mm M, L, XL, XXL: Min 230mm Width (±10mm) **Sizes :** **Extra Extra Small (XXS) = 65mm** **Extra Small (XS) = 70mm** **Small (S) = 80mm** **Medium (M) = 95mm** **Large (L) = 110mm** **Extra Large (XL) = 120mm** **Double Extra Large (XXL) = 130mm**	Overall Length (mm) Min 230mm Width (± 10mm) **Sizes :** **Extra Extra Small (XXS) = 65mm** **Extra Small (XS)= 70mm** **Small (S) = 80mm** **Medium = 95mm** **Large (L) = 110mm** **Extra Large (XL) = 120mm** **Double Extra Large (XXL) = 130mm**	Meets sizes specified in ASTM D6319.	Meets sizes specified in ASTM D6319.	Different: Subject device sizes meet ASTM D6319-19 with addition of XXS.
	Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm			

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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	Meets ASTM D6319-19	Same
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19	Meets ASTM D5151-19	Meets ASTM D5151-19	Same
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06(2022)	Meets ASTM D6124-06(2022)	Meets ASTM D6124-06(2022)	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.	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.	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	Not induce any acute systemic toxicity	Not induce any acute systemic toxicity	Not induce any acute systemic toxicity	Same

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Resistance against Chemotherapy Drugs and Fentanyl Citrate	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-05(2019)	1) Carmustine (BCNU) 3.3mg/ml 15.4 minutes 2) Cyclophosphamide (Cytoxan) (20mg/ml) >240 minutes 3) Cytarabine HCI (100mg/ml) >240 minutes 4) Doxorubicin HCI (2.0mg/ml) >240 minutes 5) Etoposide (20.0mg/ml >240 minutes 6) Fluorouracil (50.0mg/ml) >240 minutes 7) Methotrexate (25mg/ml) >240 minutes 8) Paclitaxel (6.0mg/ml) >240 minutes 9) ThioTepa (10.0mg/ml) 56.2 minutes Tested with: Fentanyl Citrate (Injection), 100mg/2ml: no breakthrough time at 240 minutes 240 minutes Warning: Not for use with Carmustine or Thio Tepa	1) Carmustine (BCNU) 3.3mg/ml 7.28 minutes 2) Cisplatin 1.0mg/mL, >240 minutes 3) Cyclophosphamide (Cytoxan) (20mg/ml) >240 minutes 4) Doxorubicin HCI (2.0mg/ml) >240 minutes 5) Etoposide (20.0mg/ml >240 minutes 6) 5-Fluorouracil (50.0mg/ml) >240 minutes 7) Methotrexate (25mg/ml) >240 minutes 8) Paclitaxel (6.0mg/ml) >240 minutes 9) ThioTepa (10.0mg/ml) 2.67 minutes Warning : Not for use with Carmustine or Thio Tepa	Tested with: Fentanyl citrate (Injectable): 100mg/2mil: No breakthrough time at 240 minutes Heroin saturated in injectable Fentanyl No breakthrough time at 240 minutes And both opioid drugs Fentanyl and Heroin mixed with simulated gastric acid: represents opioid-contaminated vomit from overdose victims. No breakthrough time at 240 minutes	Similar: Subject Device was tested with the same chemicals as the predicate except with the addition of fentanyl citrate (reference device).

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8.0 Summary of Non-Clinical Testing

Characteristics	Test Standard	Acceptance Criteria	Test Result
Freedom from Pin holes	ASTM D5151 -19 (Re-approved 2011)	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-19
Dimensions	ASTM D6319 -19	Length XS, X: Min 220mm M, L, XL, XXL: Min 230mm	Meets ASTM D6319-19
	ASTM D6319 -19	Width **Size XXS = 65mm±10 (Internal Requirement)** **Size XS = 70mm±10** **Size S = 80mm±10** **Size M = 95mm±10** **Size L = 110mm±10** **Size XL = 120mm±10** **Size XXL =130mm±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(2022)	≤ 2.0 mg/pc	Meets ASTM D6124-06 (2022)
Irritation	ISO 10993-23:2021	Not an irritant	Pass
Sensitization	ISO 10993-10:2021	Not a sensitizer	Pass
Acute Systemic Toxicity	ISO 10993-11:2017	Not induce acute systemic toxicity	Pass

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8.0 Summary of Clinical Testing

N/A.

9.0 Conclusion

The Conclusions drawn from the non-clinical tests demonstrate that the subject device, Cornflower Blue Powder Free Nitrile Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K103249.