April 1, 2025

Careglove Global Sdn. Bhd.
Lim Shyan
Managing Director
Lot 17479, Lorong Senawang 3/2, Off Jalan Senawang 3,
Senawang Indsutrial Estate
Seremban, Negeri Sembilan 70450
Malaysia

Re: K250578
Trade/Device Name: Nitrile Examination Gloves Powder Free Tested for Use With Chemotherapy Drugs & Fentanyl Citrate (Blue & Black)
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: February 19, 2025
Received: February 27, 2025

Dear Lim Shyan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Assistant Director
DHT4C: Division of Infection
Control 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.

510(k) Number *(if known)*
250578

Device Name
NITRILE EXAMINATION GLOVES POWDER FREE TESTED FOR USE WITH CHEMOTHERAPY DRUGS & FENTANYL CITRATE (BLUE & BLACK)

Indications for Use *(Describe)*
A 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. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Table below shows the Summary Test Result for Resistance of Nitrile Powder Free Examination Glove (Blue & Black) to Permeation by Chemotherapy Drugs and Fentanyl Citrate.

Chemotherapy Drugs and Fentanyl Citrate	Concentration	Minimum Breakthrough Detection Time (minutes)	
		Blue	Black
*Carmustine (BCNU)	3.3 mg/ml	22.6	21.8
Cisplatin	1.0 mg/ml	>240 min	>240 min
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min	>240 min
Dacarbazine	10.0 mg/ml	>240 min	>240 min
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min
Etoposide	20.0 mg/ml	>240 min	>240 min
Fluorouracil	50.0 mg/ml	>240 min	>240 min
Ifosfamide	50.0 mg/ml	>240 min	>240 min
Mitoxantrone	2 mg/ml	>240 min	>240 min
Paclitaxel	6.0 mg/ml	>240 min	>240 min
*Thio Tepa	10.0 mg/ml	43.9	17.7
Vincristine Sulfate	1.0 mg/ml	>240 min	>240 min
Methotrexate	25.0 mg/ml	>240 min	>240 min
Mitomycin C.	0.5 mg/ml	>240 min	>240 min
Fentanyl Citrate	100mcg/2ml	>240 min	>240 min

*Please note that following drugs have extremely low permeation times:
1. Carmustine (BCNU)
2. Thio Tepa

Warning: Do not 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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510(K) SUMMARY

K250578

Applicant Name:	**CAREGLOVE GLOBAL SDN BHD**
Location:	Lot 17479, Lorong Senawang 3/2, Off Jalan Senawang 3, Senawang Indsutrial Estate Seremban, Negeri Sembilan 70450 Malaysia
Phone No:	(60)6 6782377 Fax No: (60) 6 6785377
Contact Person:	Murni Razali
Summary Preparation Date:	March 27,2025

Device Information

Trade Name:	NITRILE EXAMINATION GLOVES POWDER FREE TESTED FOR USE WITH CHEMOTHERAPY DRUGS & FENTANYL CITRATE (BLUE & BLACK)
Common Name:	POWDER FREE NITRILE EXAMINATION GLOVES
Classification Name:	Non-Powdered Patient Examination Gloves
Product Code:	LZA, LZC, QDO, OPJ
Regulation:	21 CFR 880.6250

Predicate Device

Nitrile Examination Gloves Powder Free Tested for Use with Chemotherapy Drugs & Fentanyl Citrate (Blue & Black), 510(K) number K230121 product code LZA, LZC, QDO, OPJ.

Device Description

Non-Sterile Nitrile Patient Examination Glove is made from synthetic rubber latex. It is single use and powder-free class I Nitrile Patient Examination Gloves which coated by on-line polymer with mild on-line chlorination process. These processes modify the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder. The available sizes are X-Small, Small, Medium, Large and X-Large. The Nitrile Examination Gloves Powder Free (Blue & Black) have been tested for Chemotherapy Drugs as below:
The subject devices are identical in design and formulation to the predicate gloves of K230121.

Chemotherapy Drugs and Fentanyl Citrate	Concentration	Minimum Breakthrough Detection Time (minutes)	
		Blue	Black
*Carmustine (BCNU)	3.3 mg/ml	22.6	21.8
Cisplatin	1.0 mg/ml	>240 min	>240 min
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min	>240 min
Dacarbazine	10.0 mg/ml	>240 min	>240 min
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min
Etoposide	20.0 mg/ml	>240 min	>240 min
Fluorouracil	50.0 mg/ml	>240 min	>240 min
Ifosfamide	50.0 mg/ml	>240 min	>240 min
Mitoxantrone	2 mg/ml	>240 min	>240 min
Paclitaxel	6.0 mg/ml	>240 min	>240 min
*Thio Tepa	10.0 mg/ml	43.9	17.7
Vincristine Sulfate	1.0 mg/ml	>240 min	>240 min
Methotrexate	25.0 mg/ml	>240 min	>240 min
Mitomycin C.	0.5 mg/ml	>240 min	>240 min
Fentanyl Citrate	100mcg/2ml	>240 min	>240 min
*Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) 2. Thio Tepa Warning: Do not use with Carmustine and Thiotepa			

Indications for Use

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

Table below shows the Summary Test Result for Resistance of Nitrile Powder Free Examination Glove (Blue & Black) to Permeation by Chemotherapy Drugs and Fentanyl Citrate.

Chemotherapy Drugs and Fentanyl Citrate	Concentration	Minimum Breakthrough Detection Time (minutes)	
		Blue	Black
*Carmustine (BCNU)	3.3 mg/ml	22.6	21.8
Cisplatin	1.0 mg/ml	>240 min	>240 min
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Dacarbazine	10.0 mg/ml	>240 min	>240 min
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min
Etoposide	20.0 mg/ml	>240 min	>240 min
Fluorouracil	50.0 mg/ml	>240 min	>240 min
Ifosfamide	50.0 mg/ml	>240 min	>240 min
Mitoxantrone	2 mg/ml	>240 min	>240 min
Paclitaxel	6.0 mg/ml	>240 min	>240 min
*Thio Tepa	10.0 mg/ml	43.9	17.7
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Fentanyl Citrate	100mcg/2ml	>240 min	>240 min
*Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) 2. Thio Tepa Warning: Do not use with Carmustine and Thiotepa			

Summary of The Technological Characteristic

The Nitrile Examination Gloves Powder Free – Blue & Black, are summarized with the following technological characteristic compared to ASTM D6319 or equivalent standards.

Characteristic	Standard	Predicate Device K230121	Subject Device K250578	Remarks
Product Code	-	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Intended Use	-	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Same
Design	-	Powder Free, Non-Sterile, Ambidextrous, Beaded Cuff	Powder Free, Non-Sterile, Ambidextrous, Beaded Cuff	Same
Indications for Use	-	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Same
Construction	-	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Same
Color Description	-	Blue & Black	Blue & Black	Same
Material	-	Nitrile	Nitrile	Same
Single Use	-	Yes	Yes	Same
Packaging	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same
Chemo Drugs Claim	-	12 Chemotherapy Drugs & Fentanyl Citrate claim	14 Chemotherapy Drugs & Fentanyl Citrate claim	Different
Sterility	-	Non-Sterile	Non-Sterile	Same
<u>Dimension</u> Length XS, S M, L, XL Thickness (palm), Thickness (finger), Width	ASTM D6319-19	 Meet 220mm min Meet 230mm min Meet 0.05mm min Meet 0.05mm min XS: Meet 70 ± 10 mm S: Meet 80 ± 10 mm M: Meet 95 ± 10 mm L: Meet 110 ± 10 mm XL: Meet 120 ± 10 mm	 Meet 220mm min Meet 230mm min Meet 0.05mm min Meet 0.05mm min XS: Meet 70 ± 10 mm S: Meet 80 ± 10 mm M: Meet 95 ± 10 mm L: Meet 110 ± 10 mm XL: Meet 120 ± 10 mm	 Same Same Same

Characteristic	Standard	Predicate Device K230121	Subject Device K250578	Remarks
Physical Properties (Before Ageing) i) Tensile Strength (MPa) ii) Ultimate Elongation (%) (After Aging) i) Tensile Strength (MPa) ii) Ultimate Elongation (%)	ASTM D6319-19	Meet 14MPa min. Meet 500% min Meets 14MPa min Meet 400% min.	Meet 14MPa min. Meet 500% min Meets 14MPa min Meet 400% min.	Same Same
Water Leak Test, 1000 ml Before Aging, AQL	ASTM D6319-19 ASTM D5151-19	Passes at AQL 1.5	Passes at AQL 1.5	Same
Powder Free Residue Powder Free Residue, mg/glove	ASTM D6319-19 ASTM D6124-06	Meet 2mg/glove max.	Meet 2mg/glove max	Same
Biocompatibility Test i) Primary Skin Irritation Test	ISO 10993-10	Passes Conclusion: Under the conditions of this study the test material did not cause an irritant response	Passes Conclusion: Under the conditions of this study the test material did not cause an irritant response	Same
ii) Skin Sensitization Test	ISO 10993-10	Passes Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	Passes Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	Same
iii) In Vitro Cytotoxicity Test	ISO 10993-5:2009	Conclusion: Under condition of this study, test material exhibited moderate cytotoxicity reactivity at 6.0 cm^2/mL extract concentrations and no cytotoxicity reactivity at the 3.0 cm^2/mL extract concentrations of the test.	Conclusion: Under condition of this study, test material exhibited moderate cytotoxicity reactivity at 6.0 cm^2/mL extract concentrations and no cytotoxicity reactivity at the 3.0 cm^2/mL extract concentrations of the test.	Same
Iv) Acute Systemic Toxicity	ISO 10993-11	Conclusion: Under condition. of this study, the test material showed no adverse biological reaction after administration of the sample's extract on the rats during the period of the study.	Conclusion: Under condition. of this study, the test material showed no adverse biological reaction after administration of the sample's extract on the rats during the period of the study.	Same

Test Results for Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (ASTM D6978-05):

Chemotherapy Drug and Fentanyl Citrate	Concentration	Minimum Breakthrough Detection Time (minutes)				Remark
		Proposed Device		Predicate Device		
		Blue	Black	Blue	Black	
*Carmustine (BCNU)	3.3 mg/ml	22.6	21.8	22.6	21.8	Same
Cisplatin	1.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Dacarbazine	10.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Etoposide	20.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Fluorouracil	50.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Ifosfamide	50.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Mitoxantrone	2 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Paclitaxel	6.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
*Thio Tepa	10.0 mg/ml	43.9	17.7	43.9	17.7	Same
Vincristine Sulfate	1.0 mg/ml	>240 min	>240 min	>240 min	>240 min	Same
Methotrexate	25.0 mg/ml	>240 min	>240 min	Not Tested	Not Tested	Different
Mitomycin C.	0.5 mg/ml	>240 min	>240 min	Not Tested	Not Tested	Different
Fentanyl Citrate	100mcg/2ml	>240 min	>240 min	>240 min	>240 min	Same
Warning		Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) (3.3 mg/ml) 2. Thio Tepa (10 mg/ml)		Please note that following drugs have extremely low permeation times: 1. Carmustine (BCNU) (3.3 mg/ml) 2. Thio Tepa (10 mg/ml)		Same

Summary of Non-Clinical Testing

Following is a table showing the actual measured parameters of the gloves (e.g length, thickness, physical properties, etc.) as compared to ASTM, EN and ISO. All data meets the standard reference requirement.

<table>
<tr><th>Test</th><th>Method</th><th>Acceptance Criteria</th><th>Result</th></tr>
<tr><td>Freedom From Holes</td><td>ASTM D6319-19
ASTM D5151-19</td><td>Meet requirement inspection level G-1, AQL 2.5</td><td>Pass</td></tr>
<tr><td>Dimension</td><td>ASTM D6319-19</td><td>
<table>
<tr><td>Size</td><td>XSmall</td><td>Small</td><td>Medium</td><td>Large</td><td>XLarge</td></tr>
<tr><td>Length, min. mm</td><td colspan="2">220</td><td colspan="3">230</td></tr>
<tr><td>Thickness, min. mm</td><td colspan="5">0.05</td></tr>
<tr><td>Width, ± 10 mm</td><td>70</td><td>80</td><td>95</td><td>110</td><td>120</td></tr>
</table>
</td><td>Pass</td></tr>
<tr><td>Physical properties</td><td>ASTM D6319-19</td><td>
<table>
<tr><td colspan="2">Before Aging</td><td colspan="2">After Accelerated Aging</td></tr>
<tr><td>Tensile Strength</td><td>Ultimate Elongation</td><td>Tensile Strength</td><td>Ultimate Elongation</td></tr>
<tr><td>14 MPa min.</td><td>500% min.</td><td>14 MPa min.</td><td>400 % min.</td></tr>
</table>
</td><td>Pass</td></tr>
<tr><td>Residual Powder Content</td><td>ASTM D6319-19
ASTM D6124-06</td><td>Not more than 2 mg per glove</td><td>Pass</td></tr>
<tr><td>Biocompatibility</td><td></td><td></td><td></td></tr>
<tr><td>i) Primary Skin Irritation</td><td>ISO 10993-10</td><td>Not a primary skin irritant</td><td>Pass</td></tr>
<tr><td>ii) Skin Sensitization</td><td>ISO 10993-10</td><td>Not a contact sensitizer</td><td>Pass</td></tr>
<tr><td>iii) In Vitro Cytotoxicity</td><td>ISO 10993-5:2009</td><td>No adverse biological reaction</td><td>Moderate cytotoxicity reactivity at 6.0 cm^2/mL and no reactivity at 3.0 cm^2/mL extract concentrations</td></tr>
<tr><td>iv) Acute Systemic</td><td>ISO 10993-11</td><td>No adverse biological reaction</td><td>Pass</td></tr>
</table>

Summary of Clinical Testing

Not applicable.

CONCLUSIONS

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K230121, Nitrile Examination Gloves Powder Free Tested for Use with Chemotherapy Drugs & Fentanyl Citrate (Blue & Black).