May 15, 2023

Careglove Global SDN. BHD.
Lim Kwee Shyan
Managing Director
Lot 17479, Lrg Senawang 3/2, Off Jln Senawang 3
Senawang Ind. Estate
Seremban, Negeri Sembilan 70450
Malaysia

Re: K230121
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: April 10, 2023
Received: April 13, 2023

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 (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 -S

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)*
K230121

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

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 per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time (Minutes)
*Carmustine (BCNU)	3.3 mg/ml	22.6
Cisplatin	1.0 mg/ml	>240 min
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min
Dacarbazine	10.0 mg/ml	>240 min
Doxorubicin HCl	2.0 mg/ml	>240 min
Etoposide	20.0 mg/ml	>240 min
Fluorouracil	50.0 mg/ml	>240 min
Ifosfamide	50.0 mg/ml	>240 min
Mitoxantrone	2 mg/ml	>240 min
Paclitaxel	6.0 mg/ml	>240 min
*Thiotepa	10.0 mg/ml	43.9
Vincristine Sulfate	1.0 mg/ml	>240 min
Fentanyl Citrate Injection	100mcg/2ml	>240 min

*Please note that following drugs have extremely low permeation times:
Carmustine (BCNU) 3.3mg/ml 22.6 minutes
Thiotepa 10.0mg/ml 43.9 minutes

Warning: Do not use these gloves 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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)*
K230121

Device Name
NITRILE EXAMINATION GLOVES POWDER FREE TESTED FOR USE WITH CHEMOTHERAPY DRUGS & FENTANYL CITRATE (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 per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time (Minutes)
*Carmustine (BCNU)	3.3 mg/ml	21.8
Cisplatin	1.0 mg/ml	>240 min
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min
Dacarbazine	10.0 mg/ml	>240 min
Doxorubicin HCl	2.0 mg/ml	>240 min
Etoposide	20.0 mg/ml	>240 min
Fluorouracil	50.0 mg/ml	>240 min
Ifosfamide	50.0 mg/ml	>240 min
Mitoxantrone	2 mg/ml	>240 min
Paclitaxel	6.0 mg/ml	>240 min
*Thiotepa	10.0 mg/ml	17.7
Vincristine Sulfate	1.0 mg/ml	>240 min
Fentanyl Citrate Injection	100mcg/2ml	>240 min

*Please note that following drugs have extremely low permeation times:
Carmustine (BCNU) 3.3mg/ml 21.8 minutes
Thiotepa 10.0mg/ml 17.7 minutes

Warning: Do not use these gloves 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) SUMMARY

K230121

Applicant Name	**CAREGLOVE GLOBAL SDN BHD**		
Location	Lot 17479, Lorong Senawang 2/3 Off Jalan Senawang 3, Senawang Industrial Estate, 70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.		
Phone No:	(60) 6 6782377	Fax No:	(60) 6 6785377
Contact Person:	Lim Kwee Shyan		

Summary Preparation Date: 15th May 2023

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:	21CFR:880.6250

Predicate Device

Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, 510(K) number K213408 product code LZA, LZC, QDO.

Device Description

Non-Sterile Nitrile Patient Examination Glove is made from synthetic rubber latex. It is single use and powder-free variation of the class I Nitrile Patient Examination Gloves which is 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 and Fentanyl Citrate as below:

Chemotherapy Drugs	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
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.

Chemotherapy Drugs	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
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**	**Subject Device K230121**	**Predicate Device K213408**	**Remarks**
Product Code	-	LZA, LZC, QDO, OPJ	LZA, LZC, QDO	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	Different
Material	-	Nitrile	Nitrile	Similar
Single Use	-	Yes	Yes	Same
Packaging	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same
Chemo Drugs Claim	-	Chemo Drugs & Fentanyl Citrate claim	Chemo Drugs & Fentanyl Citrate claim	Same
Sterility	-	Non-Sterile	Non-Sterile	Same
Dimension 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	 Minimum 240mm 0.06 – 0.09mm 0.07 – 0.10mm 70 - 75 mm 80 - 86 mm 93 - 97 mm 102 - 106 mm 114 - 116 mm	 Similar Similar Similar

Characteristic	Standard	Subject Device K230121	Predicate Device K213408	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.	Similar Similar
Water Leak Test, 1000 ml Before Aging, AQL	ASTM D6319-19 ASTM D5151-19	Passes at AQL 1.5	Passes at AQL 1.5	Similar
Powder Free Residue Powder Free Residue, mg/glove	ASTM D6319-19 ASTM D6124-06	Meet 2mg/glove max.	Meet 2mg/glove max	Similar
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 (Not a primary skin irritant) There was no erythema or oedema noted on test site after (1±0.1), (24±2), (48±2) and (72±2) hours. The primary Irritation Index (PII) was "0". Also, no mortality after 72 hours. The gloves are considered negligible.	Similar
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 (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0, 24 hours and 48 hours) in animals treated with the test material and negative control. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect.	Similar
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.	Exhibit severe cytotoxicity reactivity at 100%, 50%, and 25% extract concentration. No cytotoxicity reactivity at 12.5%, 6.25% and 3.125% extract concentrations.	Similar
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	Passes (no adverse biological reaction) No mortality was observed (72±2) hours.	Similar

Characteristic	Standard	Subject Device K230121	Predicate Device K213408	Remarks
		rats during the period of the study.		

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

i) Primary Skin Irritation
ii) Skin Sensitization
iii) In Vitro Cytotoxicity

iv) Acute Systemic Toxicity</td><td>

ISO 10993-10
ISO 10993-10
ISO 10993-5:2009

ISO 10993-11</td><td>

Not a primary skin irritant
Not a contact sensitizer
No adverse biological reaction

No adverse biological reaction</td><td>

Pass
Pass
Moderate cytotoxicity reactivity at 6.0 cm^2/mL and no reactivity at 3.0 cm^2/mL extract concentrations

Pass</td></tr>
<tr><td>Chemotherapy Drug</td><td>Concentration</td><td>Minimum Breakthrough Detection Time (minutes)</td><td>Remark</td></tr>
</table>

		Proposed Device		Predicate Device	
		Blue	Black	Blue	
*Carmustine (BCNU)	3.3 mg/ml	22.6	21.8	22.5	Different
Cisplatin	1.0 mg/ml	>240 min	>240 min	>240 min	Same
Cyclophosphamide (Cytoxan)	20.0 mg/ml	>240 min	>240 min	>240 min	Same
Dacarbazine	10.0 mg/ml	>240 min	>240 min	>240 min	Same
Doxorubicin HCL	2.0 mg/ml	>240 min	>240 min	>240 min	Same
Etoposide	20.0 mg/ml	>240 min	>240 min	>240 min	Same
Fluorouracil	50.0 mg/ml	>240 min	>240 min	>240 min	Same
Ifosfamide	50.0 mg/ml	>240 min	>240 min	>240 min	Same
Mitoxantrone	2 mg/ml	>240 min	>240 min	>240 min	Same
Paclitaxel	6.0 mg/ml	>240 min	>240 min	>240 min	Same
*Thio Tepa	10.0 mg/ml	43.9	17.7	36.1	Different
Vincristine Sulfate	1.0 mg/ml	>240 min	>240 min	>240 min	Same
Fentanyl Citrate	100mcg/2ml	>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)	Similar

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, K213408, Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Blue) Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.