January 9, 2022

Careglove Global SDN. BHD.
Siti Ahmad
Official Correspondent
Careglove Global SDN BHD
Lot 17479, Lorong Senawang 2/3, Off Jalan Senawang 3,
Senewang Industrial Estate
Seremban, Negeri Sembilan Darul Khusus 70450
Malaysia

Re: K211666
Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue Chemotest
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: November 25, 2021
Received: December 6, 2021

Dear Siti Ahmad:

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,

For Clarence W. Murray III, PhD
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)*

K211666

Device Name
POWDER FREE NITRILE EXAMINATION GLOVES, BLUE, CHEMOTEST

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 as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Chemotherapy Drugs Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drugs Concentration Breakthrough Detection Time in 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
*Thio Tepa 10.0 mg/ml >43.9
Vincristine Sulfate 1.0 mg/ml >240 min

*WARNING: Not recommended for use with Carmustlne and Thlotepa. Please note that following drugs have extremely low permeation times:
Carmustine (BCNU): 22.6 minutes and Thiotepa: 43.9 munites

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
K211666

Applicant: **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: 5th January, 2021

Device Information

Trade Name:POWDER FREE NITRILE EXAMINATION GLOVES, BLUE, CHEMOTEST
Common Name:POWDER FREE NITRILE EXAMINATION GLOVES
Classification Name: Patient Examination Gloves
Product Code: LZA, LZC
Regulation: 21 CFR 880.6250

Predicate Device Identification

510(k) Number: K162858,
Device Name: Careplus Powder Free Nitrile Examination Glove, Blue, Chemotest

Device Description

It is the powder-free variation of the class I latex patient examination gloves made by on-line polymer-coating and mild on-line chlorination process. The process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder.

Intended Use of Device
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.

Comparison of technological characteristics between the predicate and subject devices.

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

Characteristic	**Standard**	**Specification**	**Subject Device Powder Free Nitrile Examination Gloves, Blue, Chemotest) K211666**	**Predicate Device (Careplus Powder Free Nitrile Examination Glove, Blue, Chemotest) K162858**	**Remarks**
Product Code	-	-	LZA, LZC	LZA, LZC	Same
Intended Use	-	-	Intended for medical purposes that is worn on the examiner's hand to prevent contamination	Intended for medical purposes that is worn on the examiner's hand to prevent	Same

			between patient and examiner	contamination between patient and examiner	
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	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	Same
Construction	-	-	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Same
Color Description	-	-	Blue	Blue	Similar
Material	-	-	Nitrile	Nitrile	Same
Single Use	-	-	Yes	Yes	Same
Packaging	-	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same
Chemo Drugs Claim	-	-	Chemo Claim	Chemo Claim	Same

Summary of non-clinical performance test result

Characteristic	**Standard**	**Specification**	**Subject Device Powder Free Nitrile Examination Gloves, Blue, Chemotest) K211666**	**Predicate Device (Careplus Powder Free Nitrile Examination Glove, Blue, Chemotest) K162858**	**Remarks**
Dimension	ASTM D6319-19				Same
Length (size: XSmall), mm		220 min	Meet 220mm min	Meet 220mm min	
Length (size: Small), mm		220 min	Meet 220mm min	Meet 220mm min	
Length (size: Medium), mm		230 min	Meet 230mm min	Meet 230mm min	
Length (size: Large), mm		230 min	Meet 230mm min	Meet 230mm min	
Length (size: XLarge), mm		230 min	Meet 230mm min	Meet 230mm min	
Thickness (palm), mm		0.05 min	Meet 0.05mm min	Meet 0.05mm min	
Thickness (finger), mm		0.05 min	Meet 0.05mm min	Meet 0.05mm min	
Width (size: XSmall), mm		70 ± 10	Meet 70 ± 10 mm	Meet 70 ± 10 mm	
Width (size: Small), mm		80 ± 10	Meet 80 ± 10 mm	Meet 80 ± 10 mm	
Width (size: Medium), mm		95 ± 10	Meet 95 ± 10 mm	Meet 95 ± 10 mm	
Width (size: Large), mm		110 ± 10	Meet 110 ± 10 mm	Meet 110 ± 10 mm	
Width (size: XLarge), mm		120 ± 10	Meet 120 ± 10 mm	Meet 120 ± 10 mm	
Physical Properties	ASTM D6319-19				Similar
(Before Ageing)					
i) Tensile Strength (MPa)		Min. 14	Meet 14MPa min.	Meet 14MPa min.	
ii) Ultimate Elongation (%)		Min. 500	Meet 500% min	Meet 500% min	

(After Aging) i) Tensile Strength (MPa) ii) Ultimate Elongation (%)		Min. 14 Min. 400	Meets 14MPa min Meet 400% min.	Meets 14MPa min Meet 400% min.	
<u>Water Leak Test, 1000 ml</u> Before Aging, AQL After Aging, AQL	ASTM D6319-19 ASTM D5151-19	G- I, AQL 2.5 (FDA GII, AQL 2.5)	Meet AQL 1.5 Meet AQL 2.5	Meet AQL 1.5 Meet AQL 2.5	Similar
<u>Powder Free Residue</u> Powder Free Residue, mg/glove	ASTM D6319-19 ASTM D6124-06	Max. 2mg/glove	Meet 2mg/glove max.	Meet 2mg/glove max	Similar
<u>Biocompatibility Test</u> i) Primary Skin Irritation Test	ISO 10993-10	No Animal Irritation	i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study the test material did not cause an irritant response	i)Primary Skin Irritation Test. Conclusion: Under the conditions of this study the test material did not cause an irritant response.	Same
ii)Skin Sensitization Test	ISO 10993-10	No Animal Irritation	ii)Dermal Sensitization Test. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	ii)Dermal Sensitization Test. 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	-	iii) In Vitro Cytotoxicity 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.	iii) No data available	Different
Iv) Acute Systemic Toxicity	ISO 10993-11	-	iv) Acute Systemic Toxicity. 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.	No data available	Different
Chemotherapy Drug Permeation Claim	ASTM D6978-05	-	Carmustine (BCNU) (3.3 mg/ml) – 22.6, Cisplatin (1.0 mg/ml) - >240 min Cyclophosphamide (Cytoxan) (20.0 mg/ml)	Carmustine (BCNU) (3.3 mg/ml) – 10.2 min Cisplatin (1.0 mg/ml) - >240 min, Cyclophosphamide	Similar

			- >240 min Dacarbazine (10 mg/ml) - >240 min Doxorubicin HCL (2.0 mg/ml) - >240 min Etoposide (20 mg/ml) - >240 min Flurouracil (50 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	(Cytoxan) (20mg/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 Flurouracil (50.0 mg/ml) - >240 min Ifosfamide (50 mg/ml) - >240 min, Mitoxantrone (2.0 mg/ml) - >240 min Paclitaxel (6.0 mg/ml) - >240 min ThioTepa (10.0 mg/ml) - >40.5 min Vincristine Sulfate (1.0 mg/ml) - >240 min	

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

<table>
<tr><th>Test</th><th>Standard</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-I, 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>
</table>

Summary of Clinical Testing

Not applicable

Conclusions:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K211666, the Powder Free Nitrile Examination Glove Blue Chemotest is a safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K162858.