DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 26, 2017

Careglove Global Sdn Bhd
Lim Shyan
Managing Director
Lot 17479, Lrg Senawang 3/2, Off Jln Senawang 3, Senawang In
Seremban, 70450 My

Re: K172015
Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue (colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 3, 2017
Received: July 3, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172015

Device Name

POWDER FREE NITRILE EXAMINATION GLOVES, BLUE (COLORED)

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.

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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CAREGLOVE GLOBAL SDN BHD
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K172015

510(K) SUMMARY

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: 31st August, 2017

Device Information

Trade Name:	POWDER FREE NITRILE EXAMINATION GLOVES, BLUE (COLORED)
Common Name:	POWDER FREE NITRILE EXAMINATION GLOVES
Classification Name:	Patient Examination Gloves
Regulatory Class:	I
Product Code:	LZA
Regulation:	21 CFR 880.6250

Predicate Device

Device Name:	CAREPLUS POWDER FREE NITRILE EXAMINATION GLOVES, BLUE (COLORED)
Product Code:	LZA
Classification Name:	Patient Examination Gloves
510K Number:	K142862
Regulatory Class:	I

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.

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.

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Summary of the Technological Characteristic

The Powder Free Nitrile Examination Gloves – Blue are summarized with the following technological characteristic compare to ASTM D6310 or equivalent standards.

Characteristic	**Subject Device**	**Predicate Device**	**Comparison Analysis**
Product Name	Powder Free Nitrile Examination Gloves, Blue (Colored)	Careplus Powder Free Nitrile Examination Glove, Blue (Colored)	Different
510(k) Reference	K172015	K142862	N/A
Product Code	LZA	LZA	Same
Regulatory Class	I	I	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	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	Same
Material	Nitrile	Nitrile	Same
Single Use	Yes	Yes	Same
Packaging	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same

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Dimension Length (size: XSmall), mm Length (size: Small), mm Length (size: Medium), mm Length (size: Large), mm Length (size: XLarge), mm Thickness (palm), mm Thickness (finger), mm Width (size: XSmall), mm Width (size: Small), mm Width (size: Medium), mm Width (size: Large), mm Width (size: XLarge), mm	 Meet 220mm min Meet 220mm min Meet 230mm min Meet 230mm min Meet 230mm min Meet 0.05mm min Meet 0.05mm min Meet 70 ± 10 mm Meet 80 ± 10 mm Meet 95 ± 10 mm Meet 110 ± 10 mm Meet 120 ± 10 mm	 Meet 230mm min Meet 220mm min Meet 230mm min Meet 230mm min Meet 230mm min Meet 0.05mm min Meet 0.05mm min Meet 70 ± 10 mm Meet 80 ± 10 mm Meet 95 ± 10 mm Meet 111 ± 10 mm Meet 120 ± 10 mm	Same
Physical Properties (Before Ageing) i) Tensile Strength (MPa) ii) Ultimate Elongation (%) (After Aging) i) Tensile Strength (MPa) ii) Ultimate Elongation (%)	 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
Water Leak Test, 1000 ml Before Aging, AQL After Aging, AQL	 Meet AQL 1.5 Meet AQL 2.5	 Meet AQL 1.5 Meet AQL 2.5	Same
Residual Powder Content Residual Powder Content, mg/glove	 Meet 2mg/glove max.	 Meet 2mg/glove max	Same

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Biocompatibility Test i) Primary Skin Irritation Test ii)Skin Sensitization Test	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study the test material did not cause an irritant response ii)Dermal Sensitization Test. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	Passes i)Primary Skin Irritation Test. Conclusion: Under the conditions of this study the test material did not cause an irritant response. ii)Dermal Sensitization Test. Conclusion: Under the conditions of this study, the test material did not produce a skin sensitization effect	Same

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Summary of Clinical Testing

Not applicable

Substantial Equivalence Conclusions.

The subject device is a safe, as effective, and performs as well as or better than the legally marketed predicate device, K142862 (Careplus Powder Free Nitrile Examination Gloves, Blue (Colored)).