DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Careglove Global SDN BHD
Lim Kwee Shyan
Managing Director
Lot 17479, Lrg Senawang 3/2 Off Jln Senawang 3
Senawang In
Seremban, Negeri Sembilan, 70450 MY

Re: K161833
Trade/Device Name: Latex Examination Gloves Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 25, 2017
Received: April 28, 2017

Dear Lim Kwee Shyan:

This letter corrects our substantially equivalent letter of May 23, 2017.

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 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" (21CFR 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 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,

Lori A. Wiggins -S6

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)*
K161833

Device Name
LATEX EXAMINATION GLOVES POWDER FREE

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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Tel: 60-6-6782377, 60-6-6788377 Fax: 60-6-6785377
Email: info@careglove.com

K161833
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: 17th May, 2017

Device Information

Trade Name: LATEX EXAMINATION GLOVES POWDER FREE

Common Name: LATEX EXAMINATION GLOVES POWDER FREE

Classification Name: Patient Examination Gloves

Product Code: Latex – LYY

Regulation Number: 21 CFR 880.6250.

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.

Brief Description of Non-Clinical Test
Testing performed as per ASTM D3578-05, Standard Specification for Rubber Examination Gloves and 21 CFR 800.20. The subject device meet all the ASTM D3578-05 requirements. Primary skin irritation testing in the rabbit and Closed patch sensitization testing in the guinea pig were conducted in accordance with ISO 10993-10 indicate no irritation or sensitization.

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Non-clinical laboratory and animal based test indicate that the powder free latex examination glove meets all the performance and biocompatibility requirements.

Summary of Technological Characteristic

Table 1; Comparison of Proposed and Predicate Device

Parameter	ASTM Specifications	Standard References	Subject Device Measured Values, K161833		Predicate Device, K152593
			Value	Status	
Dimension					
Length (size:XSmall), mm	220 min.	ASTM D 3578-05	224mm-236mm	Meet Specification	Meet Specification
Length (size:Small), mm	220 min	ASTM D 3578-05	225mm – 240mm	Meet Specification	Meet Specification
Length (size: Medium), mm	230 min	ASTM D 3578-05	235mm – 246mm	Meet Specification	Meet Specification
Length (size: Large), mm	230 min	ASTM D 3578-05	235mm – 245mm	Meet Specification	Meet Specification
Length (size:XLarge), mm	N/A	ASTM D 3578-05	N/A	N/A	N/A
Thickness (palm), mm	0.08min.	ASTM D 3578-05	0.12mm-0.14mm	Meet Specification	Meet Specification
Thickness (finger), mm	0.08 min.	ASTM D 3578-05	0.15mm-0.17mm	Meet Specification	Meet Specification
Width (size: XSmall)	70 ± 10	ASTM D3578-05	73mm – 75mm	Meet Specification	Meet Specification
Width (size: Small), mm	80 ± 10	ASTM D3578-05	82mm-87mm	Meet Specification	Meet Specification
Width (size: Medium), mm	95 ± 10	ASTM D3578-05	94mm- 97mm	Meet Specification	Meet Specification
Width (size: Large), mm	111 ± 10	ASTM D3578-05	102mm-107mm	Meet Specification	Meet Specification
Width (Size: XLarge)	N/A	ASTM D3578-05	N/A	N/A	N/A

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Parameter	ASTM Specifications	Standard References	Subject Device Measured Values K161833		Predicate Device K152593
			Value	Status	
Physical Properties					
Tensile Strength, Before Aging, MPa	18 min.	ASTM D 3578-05	21.18MPa-26.17MPa	Meet Specification	Meet Specification
Stress at 500% Elongation	5.5 MPa max.	ASTM D 3578-05	3.0MPa-4.2MPa	Meet Specification	Meet Specification
Ultimate Elongation, Before Aging, %	650 min.	ASTM D 3578-05	750.20%-820.20%	Meet Specification	Meet Specification
Tensile Strength, After Aging, Mpa	14 min.	ASTM D 3578-05	18.28MPa-23.88MPa	Meet Specification	Meet Specification
Ultimate Elongation, After Aging, %	500 min.	ASTM D 3578-05	550.40%-700.50%	Meet Specification	Meet Specification
Water Leak Test, 1000 ml					
Before Aging, AQL	2.5	ASTM D 3578-05	1.5 and below	Meet Specification	1.5 and below
After Aging, AQL	2.5	ASTM D 3578-05	2.5 and below	Meet Specification	2.5 and below
Extractable Protein					
Water Extractable Protein, µg/dm^2	50 µg/dm^2	ASTM D 5712-10	50 µg/dm^2 and below	Meet Specification	50 µg/dm^2 and below
Residual Powder Content					
Residual Powder Content, mg/glove	2 mg/glove max.	ASTM D 3578-05	2 mg/glove and below	Meet Specification	2 mg/glove and below

Summary of Clinical Testing

Not applicable.

Conclusions.

The conclusions drawn from nonclinical tests demonstrate that the subject device is a safe, as effective, and performs as well as or better than the legally marketed predicate device, K152593.