December 30, 2019

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

Re: K190241
Trade/Device Name: Sterile Latex Surgical Glove, Powder Free
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO
Dated: November 8, 2019
Received: November 12, 2019

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190241

Device Name
STERILE LATEX SURGICAL GLOVES, POWDER FREE

Indications for Use *(Describe)*
A sterile latex surgical glove, powder free is a disposable device intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.

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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K190241

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: 23rd December, 2019

Device Information

Trade Name: STERILE LATEX SURGICAL GLOVES, POWDER FREE

Common Name: STERILE LATEX SURGICAL GLOVES, POWDER FREE

Classification Name: Surgeon's Gloves

Product Code: KGO

Regulation: 21 CFR 878.4460

Device Class: I

Predicate device
Device Name: STERILE POWDER FREE LATEX SURGEON GLOVES WITH PROTEIN LABELING CLAIM (50 MICROGRAM OR LESS)

Company name: SUPERMAX GLOVE MANUFACTURING SDN BHD

510(K) Number: K014230

Device Description
The subject device is a powder-free variation of the class I latex surgical gloves made by on-line polymer-coating process. This process modifies the surface characteristics and causes it to remain tack-free without the use of any dusting or donning powder.

Indication for Use
A sterile latex surgical glove, powder free is a disposable device intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.

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Summary of the Technological Characteristics of the Device

Table 1: Comparison of the Technological Characteristics of the Subject and Predicate Device.

Characteristic	Standard	Specification	Subject Device Sterile Latex Surgical Powder Free K190241	Legally Marketed Predicate Device K014230	Remark
Product Code	-	-	KGO	KGO	Same
Indication for Use Statement	-	-	A sterile latex surgical glove, powder free is a disposable device intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.	A sterile latex surgical glove, powder free is a disposable device intended for medical purposes that is worn by operating room personnel to protect a surgical wound from contamination.	Same
Design	-	-	Powder Free, Sterile, Hand Specific, Beaded Cuff	Powder Free, Sterile, Hand Specific, Beaded Cuff	Same
Construction	-	-	Hand Specific, Polymer Coated or Chlorinated, Latex Surgical Gloves, Powder Free	Hand Specific, Polymer Coated or Chlorinated, Latex Surgical Gloves, Powder Free with Protein Claim (50 Microgram or less Per Gram of Gloves)	Similar
Color Information	-	-	Natural	Natural	Same
Material	-	-	Natural Rubber	Natural Rubber	Same
Single Use	-	-	Yes	Yes	Same
Sterility	ISO 11737-2	-	Sterile	Sterile	Same
Sterilization Method	-	-	Gamma Irradiation	Gamma Irradiation	Same
Packaging	-	-	Packed in Pouches	Packed in Pouches	Same

Summary of Non-Clinical Testing

Testing performed as per ASTM D3577-15, Standard Specification for Rubber Surgical Gloves, and 21 CFR 878.4460. The subject device meets all the ASTM D3577-15 requirements. The table below summarizes the non-clinical tests performed and the standards used in this submission.

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Table 2: Summary of the Non-Clinical Testing for the Subject Device and Comparison to the Predicate Device.

Characteristic	**Standard**	**Specification**	**Subject Device Sterile Latex Surgical Powder Free K190241**	**Legally Marketed Predicate Device K014230**	**Remark**
Dimension	ASTM D3577-15				
Length (size: 5.5), mm		245 min	Meet 245mm min	Meet 245mm min	Same
Length (size: 6.0), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 6.5), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 7.0), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 7.5), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 8.0), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 8.5), mm		265 min	Meet 265mm min	Meet 265mm min	
Length (size: 9.0), mm		265 min	Meet 265mm min	Meet 265mm min	
Thickness (cuff), mm		0.10 min	Meet 0.10mm min	Meet 0.10mm min	Same
Thickness (palm), mm		0.10 min	Meet 0.10mm min	Meet 0.10mm min	
Thickness (finger), mm		0.10 min	Meet 0.10mm min	Meet 0.10mm min	
Width (size: 5.5), mm		70 ± 6	Meet 70 ± 6 mm	Meet 70 ± 6 mm	Same
Width (size: 6.0), mm		76 ± 6	Meet 76 ± 6 mm	Meet 76 ± 6 mm	
Width (size: 6.5), mm		83 ± 6	Meet 83 ± 6 mm	Meet 83 ± 6 mm	
Width (size: 7.0), mm		89 ± 6	Meet 89 ± 6 mm	Meet 89 ± 6 mm	
Width (size: 7.5), mm		95 ± 6	Meet 95 ± 6 mm	Meet 95 ± 6 mm	
Width (size: 8.0), mm		102 ± 6	Meet 102 ± 6 mm	Meet 102 ± 6 mm	
Width (size: 8.5), mm		108 ± 6	Meet 108 ± 6 mm	Meet 108 ± 6 mm	
Width (size: 9.0), mm		114 ± 6	Meet 114 ± 6 mm	Meet 114 ± 6 mm	
Water Leak Test, 1000 ml	ASTM D3577-15 ASTM D5151-06				Same
Before Aging, AQL		G- I, AQL 1.5 (FDA GII, AQL 1.5)	Meet AQL 1.5	Meet AQL 1.5	
After Aging, AQL			Meet AQL 1.5	Meet AQL 1.5	
Physical Properties	ASTM D3577-15				
(Before Ageing)					
i) TensileStrength (MPa)		Min. 24	Meet 24MPa min.	Meet 24MPa min.	Similar
ii) Ultimate Elongation (%)		Min. 750	Meet 750% min	Meet 750% min	
ii) Stress at 500% Elongation (MPa)		Max. 5.5	Meet 5.5 MPa max	Meet 5.5 MPa max	
(After Aging)					
i) Tensile Strength (MPa)		Min. 18	Meets 18MPa min	Meets 18MPa min	
ii) Ultimate Elongation (%)		Min. 560	Meet 560% min.	Meet 560% min.	

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Characteristic	**Standard**	**Specification**	**Subject Device Sterile Latex Surgical Powder Free K190241**	**Legally Marketed Predicate Device K014230**	**Remark**
Residual Powder Content Residual Powder Content, mg/glove	ASTM D3577-15 ASTM D6124-06	Max. 2mg/glove	Meet 2mg/glove max.	Meet 2mg/glove max	Similar
Extractable Protein Content Water Extractable Protein Content, µg/dm^2	ASTM D5712-10	50 µg/dm^2 and below	Meet Specification	50 µg/dm^2 and below	Similar
Biocompatibility Test i) Primary Skin Irritation Test	ISO 10993-10	No Animal Irritation	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study the test material did not cause an irritant response	Passes 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 Sensitization	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) Cytotoxicity Test	ISO 10995-5	Non-cytotoxicity	moderate-cytotoxicity at 6 cm^2/mL extraction	Data not available from manufacture	Different
iv) Acute Toxicity Oral	ISO 10993-11	No toxic	No adverse biological reaction	Data not available from manufacture	Different
v) Pyrogenic Test	USP 40, General Chapter <151>	Non pyrogenic	Non pyrogenic	Data not available from manufacture	Different

Non-clinical laboratory and animal-based tests indicate that the sterile latex surgical glove, powder free meets all the performance and biocompatibility requirements for the referenced standards.

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Summary of Clinical Testing

Not applicable.

Conclusions: The conclusions drawn from nonclinical tests demonstrate that the subject device (K190241) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K014230.