August 5, 2022

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

Re: K213993
Trade/Device Name: Chloroprene Examination Glove Powder Free (Blue, Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: Class I, reserved
Product Code: LZA,
Dated: June 24, 2022
Received: July 6, 2022

Dear Lim Kwee 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, 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)*
K213993

Device Name
Chloroprene Examination Gloves Powder Free (Blue, Green)

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.

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."

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Quality and Relationship You Can Trust

510(K) SUMMARY

510(K) No.	**K213993**
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	August 5, 2022

Device Information

Trade Name	: Chloroprene Examination Gloves Powder Free (Blue, Green)
Common Name	: Chloroprene Examination Gloves Powder Free
Classification Name	: Patient Examination Gloves
Device Class	: I
Product Code	: LZA
Regulation	: 21 CFR 880.6250

Predicate Device

510(K) number K171743, Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves.

Device Description

It is a powder-free chloroprene patient examination gloves made by on-line polymer-coating and mild on-line chlorination process. The process modifies the surface characteristics without the use of any dusting or donning powder. The gloves are non-sterile, disposable and for single use only.

Characteristics:

- Ambidextrous with beaded cuff
- Blended synthetic latex (Chloroprene and Nitrile Latex)
- Blue or green Coloured
- Five sizes: X-Small, Small, Medium, Large and X-Large.

Intended Use of Device / 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.

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Comparison of the technological characteristic between the predicate and subject devices

The Chloroprene Examination Gloves Powder Free (Blue), are summarized with the following technological characteristics compared to ASTM D6977 or equivalent standards.

Characteristic	**Standard**	**Specification**	**Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green), 510(k) Number K213993**	**Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743**	**Remark**
Product Code	-	-	LZA	LZA	Same
Intended Use	-	-	Intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Intended for medical purposes that is worn on the examiner's hand or finger 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 or finger 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 or finger to prevent contamination between patient and examiner	Same

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standard	Specification	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Construction	-	-	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Ambidextrous, Polyacrylic Polymer Inner Coating, Powder Free Nitrile	Similar
Color Description	-	-	Blue	Pink, Black	Different
Material	-	-	Mixture of Nitrile and Chloroprene	Polychloroprene	Different
Single Use	-	-	Yes	Yes	Same
Packaging	-	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Dimension					
Length (size: XSmall), mm	ASTM D6977-19	220 min	Meet 220mm min	Meet 220mm min	Similar
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					
(Before Aging)					
i) Tensile Strength (MPa)	ASTM D6977-19	Min. 14	Meet 14MPa min	Meet 14MPa min.	Similar
ii) Ultimate Elongation (%)		Min. 500	Meet 500% min	Meet 500% min	
(After Aging)					
i) Tensile Strength (MPa)		Min. 14	Meets 14MPa min	Meets 14MPa min	
ii) Ultimate Elongation (%)		Min. 400	Meet 400% min.	Meet 400% min.	

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Water Leak Test, 1000 ml Before Aging, AQL After Aging, AQL	 ASTM D6977-19 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
Powder Free Residue Powder Free Residue, mg/glove	 ASTM D6977-19 ASTM D6124-06	 Max. 2mg/glove	 Meet 2mg/glove max.	 Meet 2mg/glove max	 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 the study, not an irritant	 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 the study, not a sensitizer	Same

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Biocompatibility Test					
iii) In Vitro Cytotoxicity	ISO 10993-5	-	iii) In Vitro Cytotoxicity Test. Conclusion: Under the conditions of this study, the test material exhibited cytotoxicity response at 100% of extract concentration.	iii) No Information	Different
iv) Acute Systemic Toxicity	ISO 10993-11	-	iv) Acute Systemic Toxicity Conclusion: Under the 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.	iv) No Information	Different

The Chloroprene Examination Gloves Powder Free (Green), are summarized with the following technological characteristic compared to ASTM D6977 or equivalent standards.

Characteristic	**Standard**	**Specification**	**Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993**	**Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743**	**Remark**
Product Code	-	-	LZA	LZA	Same
Intended Use	-	-	Intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Intended for medical purposes that is worn on the examiner's hand or finger 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 or finger 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 or finger to prevent contamination between patient and examiner	Same

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standard	Specification	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Construction	-	-	Ambidextrous, Polymer Coated or Chlorinated, Powder Free Nitrile	Ambidextrous, Polyacrylic Polymer Inner Coating, Powder Free Nitrile	Similar
Color Description	-	-	Green	Pink, Black	Different
Material	-	-	Mixture of Nitrile and Chloroprene	Polychloroprene	Different
Single Use	-	-	Yes	Yes	Same
Packaging	-	-	Packed in Dispenser Boxes	Packed in Dispenser Boxes	Same

CAREGLOVE GLOBAL SDN BHD (Co. No : 933760-W)
Lot 17479, Lorong Senawang 3/2
Off Jalan Senawang 3, Senawang Industrial Estate
70450 Seremban, Negeri Sembilan Darul Khusus, Malaysia.
Tel: 60-6-678 2377 Fax: 60-6-678 5377 Email: info@careglove.com Website : www.careplus.com

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Dimension					
Length (size: XSmall), mm	ASTM D6977-19	220 min	Meet 220mm min	Meet 220mm min	Similar
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					
(Before Ageing)					
i) Tensile Strength (MPa)	ASTM D6977-19	Min. 14	Meet 14MPa min	Meet 14MPa min.	Similar
ii) Ultimate Elongation (%)		Min. 500	Meet 500% min	Meet 500% min	
(After Aging)					
i) Tensile Strength (MPa)		Min. 14	Meets 14MPa min	Meets 14MPa min	
ii) Ultimate Elongation (%)		Min. 400	Meet 400% min.	Meet 400% min.	

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Water Leak Test, 1000 ml Before Aging, AQL After Aging, AQL	 ASTM D6977-19 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
Powder Free Residue Powder Free Residue, mg/glove	 ASTM D6977-19 ASTM D6124-06	 Max. 2mg/glove	 Meet 2mg/glove max.	 Meet 2mg/glove max	 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 the study, not an irritant	 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 the study, not a sensitizer	Same

Characteristic	Standards	Related Defects	Subject Device Chloroprene Examination Gloves Powder Free (Blue, Green) 510(k) Number K213993	Predicate Device Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) Number K171743	Remark
Biocompatibility Test					
iii) In Vitro Cytotoxicity	ISO 10993-5	-	iii) In Vitro Cytotoxicity Test. Conclusion: Under the conditions of this study, the test material exhibited cytotoxicity response at 100% of extract concentration.	iii) No Information	Different
iv) Acute Systemic Toxicity	ISO 10993-11	-	iv) Acute Systemic Toxicity Conclusion: Under the 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.	iv) No Information	Different

Summary of Non-Clinical Testing

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 D6977-19
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 D6977-19</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 D6977-19</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 D6977-19
ASTM D6124-06</td><td>Not more than 2 mg per glove</td><td>Pass</td></tr>
<tr><td>Biocompatibility</td><td></td><td></td><td></td></tr>
<tr><td>i) Primary Skin Irritation Test</td><td>ISO 10993-5</td><td>No Animal Irritation</td><td>Pass</td></tr>
<tr><td>ii) Skin Sensitization Test</td><td>ISO 10993-10</td><td>No Animal Irritation</td><td>Pass</td></tr>
<tr><td>iii) In Vitro Cytotoxicity</td><td>ISO 10993-5</td><td>No cytotoxicity reactivity at 100.0% extract concentrations under the conditions of this test</td><td>The test material exhibited cytotoxicity response at 100% of extract concentration</td></tr>
<tr><td>iv) Acute Systemic Toxicity</td><td>ISO 10993-11</td><td>No adverse biological reaction</td><td>Pass</td></tr>
</table>

Summary of Clinical Testing

Not applicable

Conclusions:

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Chloroprene Examination Gloves Powder Free (Blue, Green), is as safe, as effective, and performs as well as or better than the legally marketed device, Powder Free Pink Polychloroprene Copolymer Examination Gloves, Powder Free Black Polychloroprene Copolymer Examination Gloves, 510(k) number K171743.