August 3, 2021

Careplus (M) SDN BHD
Lim Shyan
CEO/ Managing Director
Lot 120 & 121, Jalan Senawang 3, Senawang Industrial Estate
Seremban, Negeri Sembilan 70450
Malaysia

Re: K210724
Trade/Device Name: ENCORE Latex Acclaim, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (50 ug/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs, GAMMEX Latex Standard, Powder Free Latex Surgical Gloves with Protein Content Labeling Claim (50 ug/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: June 22, 2021
Received: June 28, 2021

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,

Clarence W. Murray III -S

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)*
K210724

Device Name
ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

Indications for Use *(Describe)*
Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy:

Test Chemotherapy Drug (Concentration)	Minimum Breakthrough Detection Time in minutes
Fluorouracil (50.0mg/ml)	>240
Etoposide (20.0mg/ml)	>240
Cyclophosphamide (20.0mg/ml)	>240
Carmustine (3.3mg/ml)	14.1
Thiotepa (10.0mg/ml)	16.9
Paclitaxel (6.0mg/ml)	>240
Doxorubicin Hydrochloride (2.0mg/ml)	>240
Methotrexate (25.0mg/ml)	>240
Vincristine Sulfate (1.0mg/ml)	>240

"WARNING: Do not use with Carmustine and Thiotepa"

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."

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)*
K210724

Device Name
GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

Indications for Use *(Describe)*
Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy:

Test Chemotherapy Drug (Concentration)	Minimum Breakthrough Detection Time in minutes
Fluorouracil (50.0mg/ml)	>240
Etoposide (20.0mg/ml)	>240
Cyclophosphamide (20.0mg/ml)	>240
Carmustine (3.3mg/ml)	14.1
Thiotepa (10.0mg/ml)	16.9
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Doxorubicin Hydrochloride (2.0mg/ml)	>240
Methotrexate (25.0mg/ml)	>240
Vincristine Sulfate (1.0mg/ml)	>240

"WARNING: Do not use with Carmustine and Thiotepa"

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)

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K210724

510(K) SUMMARY

1.0 Applicant: CAREPLUS (M) SDN BHD

Address: Lot 120 & 121 , Jalan Senawang 3,
Senawang Industrial Estate,
70450 Seremban,
Negeri Sembilan Darul Khusus,
Malaysia.

Phone No. 60-6-6772781 Fax No. 60-6-6772780

Contact Person Lim Kwee Shyan

2.0 Date of Summary 31st July, 2021

3.0 Device Information

Device Name: Surgeons Glove, Latex Powder Free with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

Glove Trade Name: ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

Common Name: Surgical Gloves
Product Code: KGO
Subsequent Product Code: LZC
Classification Name: Surgeon's Gloves
Patient Examination Gloves Specialty (21 CFR 880.6250, KGO)

4.0 Device Description

It is the powder-free variation of the class I sterile latex surgical gloves made on-line by surface treatment on the outside and polymer coating on inner surface.

5.0 Predicate Device

Predicate device: Encore Acclaim Sterile Powder Free Latex Surgical Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim <50 µg/dm2 per Glove of Extractable Protein, 510(k) number K103714, product code KGO.

6.0 Intended Use of Device

Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.

7.0 Technological Characteristics Comparison

Characteristics	**Subject Glove** (ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs ,K210724)	**Predicate Device** (Encore Acclaim Sterile Powder Free Latex Surgical Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim, K103714)	**Discussion**
Product Code	KGO LZC	KGO LZC	Same
Regulation Number	21CFR878.4460 21CFR880.6250	21CFR878.4460 21CFR880.6250	Same
Device Class	Class 1	Class 1	Same
Freedom from holes	Meets ASTM D3577 Meets ASTM D5151	Meets ASTM D3577 Meets ASTM D5151	Same
<u>Dimension</u> Length (size: 5.5), mm Length (size: 6.0), mm Length (size: 6.5), mm Length (size: 7.0), mm Length (size: 7.5), mm Length (size: 8.0), mm Length (size: 8.5), mm Length (size: 9.0), mm Thickness (cuff), mm Thickness (palm), mm Thickness (finger), mm Width (size: 5.5), mm Width (size: 6.0), mm Width (size: 6.5), mm Width (size: 7.0), mm Width (size: 7.5), mm Width (size: 8.0), mm Width (size: 8.5), mm Width (size: 9.0), mm	 Meet 245mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 0.10mm min Meet 0.10mm min Meet 0.10mm min Meet 70 ± 6 mm Meet 76 ± 6 mm Meet 83 ± 6 mm Meet 89 ± 6 mm Meet 95 ± 6 mm Meet 102 ± 6 mm Meet 108 ± 6 mm Meet 114 ± 6 mm	 Meet 245mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 0.10mm min Meet 0.10mm min Meet 0.10mm min Meet 70 ± 6 mm Meet 76 ± 6 mm Meet 83 ± 6 mm Meet 89 ± 6 mm Meet 95 ± 6 mm Meet 102 ± 6 mm Meet 108 ± 6 mm Meet 114 ± 6 mm	Same
Physical Properties (Before Ageing) i) Tensile Strength(Mpa) ii) Ultimate Elongation(%) iii) Stress at 500% Elongation (After Ageing) i) Tensile Strength(Mpa) ii) Ultimate Elongation(%)	Meets ASTM D3577 Meets ASTM D3577	Meets ASTM D3577 Meets ASTM D3577	Same Same
Powder Content	Meets ASTM D3577 Meets ASTM D6124	Meets ASTM D3577 Meets ASTM D6124	Same

Biocompatibility Test i) Primary Skin Irritation Test	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Same
ii) Dermal Sensitization Test	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	iii) In vitro Cytotoxicity test. Conclusions: Under the conditions of this study, the test material is Cytotoxic at dilutions of 1:2, 1:4, 1:8, 1:6 and Non-cytotoxic, grade 2 at 1:32 and 1:64 dilutions.	iii) No data available	Different
iv) Acute Systemic Toxicity	iv) Acute Systemic Toxicity study. Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	iv) No data available	Different
Protein Label Claim	Contains 50 µg/dm^2 or less per glove of total aqueous extractable protein of total water extractable protein per gram.	Contains 50 micrograms or less of total aqueous extractable protein of total water extractable protein per gram.	Same
Chemo Drugs Claim	Chemo Claim	Chemo Claim	Same
Color	Natural	Natural	Same
White Pigment	Titanium Dioxide	Titanium Dioxide	Same
Indications for use	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Same
Shelf-life	3 years	3 years	Same
Sterile Packaging	Packed 1 pair in a wallet. One wallet in a pouch.	Packed 1 pair in a wallet. One wallet in a pouch.	Same
Sterility	Sterile	Sterile	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same

Characteristics	**Subject Glove** (GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs ,K210724)	**Predicate Device** (Encore Acclaim Sterile Powder Free Latex Surgical Gloves, Tested for use with Chemotherapy Drugs with a Protein Content Label Claim, K103714)	**Discussion**
Product Code	KGO LZC	KGO LZC	Same
Regulation Number	21CFR878.4460 21CFR880.6250	21CFR878.4460 21CFR880.6250	Same
Device Class	Class 1	Class 1	Same
Freedom from holes	Meets ASTM D3577 Meets ASTM D5151	Meets ASTM D3577 Meets ASTM D5151	Same
<u>Dimension</u> Length (size: 5.5), mm Length (size: 6.0), mm Length (size: 6.5), mm Length (size: 7.0), mm Length (size: 7.5), mm Length (size: 8.0), mm Length (size: 8.5), mm Length (size: 9.0), mm Thickness (cuff), mm Thickness (palm), mm Thickness (finger), mm Width (size: 5.5), mm Width (size: 6.0), mm Width (size: 6.5), mm Width (size: 7.0), mm Width (size: 7.5), mm Width (size: 8.0), mm Width (size: 8.5), mm Width (size: 9.0), mm	 Meet 245mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 0.10mm min Meet 0.10mm min Meet 0.10mm min Meet 70 ± 6 mm Meet 76 ± 6 mm Meet 83 ± 6 mm Meet 89 ± 6 mm Meet 95 ± 6 mm Meet 102 ± 6 mm Meet 108 ± 6 mm Meet 114 ± 6 mm	 Meet 245mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 265mm min Meet 0.10mm min Meet 0.10mm min Meet 0.10mm min Meet 70 ± 6 mm Meet 76 ± 6 mm Meet 83 ± 6 mm Meet 89 ± 6 mm Meet 95 ± 6 mm Meet 102 ± 6 mm Meet 108 ± 6 mm Meet 114 ± 6 mm	Same
Physical Properties (Before Ageing) i) Tensile Strength(Mpa) ii) Ultimate Elongation(%) iii) Stress at 500% Elongation (After Ageing) i) Tensile Strength(Mpa) ii) Ultimate Elongation(%)	Meets ASTM D3577 Meets ASTM D3577	Meets ASTM D3577 Meets ASTM D3577	Same Same
Powder Content	Meets ASTM D3577 Meets ASTM D6124	Meets ASTM D3577 Meets ASTM D6124	Same

Biocompatibility Test i) Primary Skin Irritation Test	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Passes i) Primary Skin Irritation Test. Conclusion: Under the conditions of this study, the test material did not cause and irritant response.	Same
ii) Dermal Sensitization Test	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	iii) In vitro Cytotoxicity test. Conclusions: Under the conditions of this study, the test material is Cytotoxic at dilutions of 1:2, 1:4, 1:8, 1:6 and Non-cytotoxic, grade 2 at 1:32 and 1:64 dilutions.	iii) No data available	Different
iv) Acute Systemic Toxicity	iv) Acute Systemic Toxicity study. Conclusion: Under the conditions of this study, the test material both inner and outer surface did not reveal systemic toxicity.	iv) No data available	Different
Protein Label Claim	Contains 50 µg/dm^2 or less per glove of total aqueous extractable protein of total water extractable protein per gram.	Contains 50 micrograms or less of total aqueous extractable protein of total water extractable protein per gram.	Same
Chemo Drugs Claim	Chemo Claim	Chemo Claim	Same
Color	Natural	Natural	Same
White Pigment	Titanium Dioxide	Titanium Dioxide	Same
Indications for use	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Powder Free Surgical gloves are sterile disposable devices intended to be worn by operating room personnel to protect a surgical wound from contamination.	Same
Shelf-life	3 years	3 years	Same
Sterile Packaging	Packed 1 pair in a wallet. One wallet in a pouch.	Packed 1 pair in a wallet. One wallet in a pouch.	Same
Sterility Status	Sterility	Sterile	Same
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Same

Chemotherapy Drug	**ASTM D6978-05**	**Subject Glove,** K210724 (ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm² per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs and GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm² per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs)
Test Chemotherapy Drug	**Concentration**	**Minimum Breakthrough Detection Time (min)**
Fluorouracil	50.0mg/ml	> 240
Etoposide	20.0mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0mg/ml	> 240
*Carmustine (BCNU)	3.3mg/ml	14.1
*Thiotepa	10.0mg/ml	16.9
Paclitaxel	6.0mg/ml	> 240
Doxorubicin Hydrochloride	2.0mg/ml	> 240
Methotrexate	25.0mg/ml	> 240
Vincristine Sulfate	1.0mg/ml	> 240
Warning Statement		*Warning: Do not use with Carmustine and ThioTepa"

8.0 Summary of Non-Clinical Testing

The non-clinical performance test data demonstrate that the subject devices met the acceptance criteria or the specification for the test methodology or standard shown below.

ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (<50 µg/dm² per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs

<table>
<tr><th>Standard/
Test Method</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>ASTM D 3577
ASTM D 5151</td><td>Freedom From Holes</td><td>Meet requirement inspection level G-I, AQL 1.5</td><td>Pass</td></tr>
<tr><td>ASTM D 3577</td><td>Dimension</td><td>
<table>
<tr><td>Size</td><td>5.5</td><td>6.0</td><td>6.5</td><td>7.0</td><td>7.5</td><td>8.0</td><td>8.5</td><td>9.0</td></tr>
<tr><td>Length, min. mm</td><td>245</td><td colspan="7">265</td></tr>
<tr><td>Thickness, min. mm</td><td colspan="8">0.10</td></tr>
<tr><td>Width, ± 6 mm</td><td>70</td><td>76</td><td>83</td><td>89</td><td>95</td><td>102</td><td>108</td><td>114</td></tr>
</table>
</td><td>Pass</td></tr>
<tr><td>ASTM D 3577,
Type I</td><td>Physical Properties</td><td>
<table>
<tr><td colspan="3">Before Aging</td><td colspan="2">After Accelerated Aging</td></tr>
<tr><td>Tensile Strength</td><td>Ultimate Elongation</td><td>Stress at 500% Elongation</td><td>Tensile Strength</td><td>Ultimate Elongation</td></tr>
<tr><td>24 MPa min</td><td>750% min</td><td>5.5 MPa max</td><td>18 MPa min</td><td>560% min</td></tr>
</table>
</td><td>Pass</td></tr>
<tr><td>ASTM D 3577
ASTM D 6124</td><td>Powder Content</td><td>Not more than 2mg per glove</td><td>Pass</td></tr>
<tr><td>ASTM D 3577
ASTM D 5712</td><td>Protein Content</td><td>This glove contains 50 µg/dm² or less per glove of total aqueous extractable protein of total water extractable protein per gram</td><td>Pass</td></tr>
<tr><td>ISO10993-10</td><td>Biocompatibility
Primary Skin Irritation Test
Dermal Sensitization Test</td><td>Not a skin irritant under the conditions of test.

Not a skin sensitizer under the conditions of test</td><td>Pass</td></tr>
<tr><td>ISO 10993-11</td><td>Biocompatibility
Acute Systemic Toxicity</td><td>Did not reveal systemic toxicity under the conditions of test.</td><td>Pass</td></tr>
</table>

GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and
Tested for use with Chemotherapy drugs

<table>
<tr><th>Standard/
Test Method</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>ASTM D 3577
ASTM D 5151</td><td>Freedom From Holes</td><td>Meet requirement inspection level G-I, AQL 1.5</td><td>Pass</td></tr>
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ASTM D 6124</td><td>Powder Content</td><td>Not more than 2mg per glove</td><td>Pass</td></tr>
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ASTM D 5712</td><td>Protein Content</td><td>This glove contains 50 µg/dm^2 or less per glove of total aqueous extractable protein of total water extractable protein per gram</td><td>Pass</td></tr>
<tr><td>ISO10993-10</td><td>Biocompatibility
Primary Skin Irritation Test
Dermal Sensitization Test</td><td>
Not a skin irritant under the conditions of test.

Not a skin sensitizer under the conditions of test</td><td>Pass</td></tr>
<tr><td>ISO 10993-11</td><td>Biocompatibility
Acute Systemic Toxicity</td><td>Did not reveal systemic toxicity under the conditions of test.</td><td>Pass</td></tr>
</table>

9.0 Summary of Clinical Testing

Clinical testing is not applicable to this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(K) K210724, the ENCORE® Latex Acclaim, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs and GAMMEX® Latex Standard, Powder free Latex Surgical Gloves with Protein Content Labeling Claim (< 50 µg/dm^2 per glove of total aqueous extractable protein) and Tested for use with Chemotherapy drugs, proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K103714.