September 24, 2022

Hartalega NGC SDN BHD
Nurul Kong
Deputy General Manager - Quality Assurance
NO. 1 Persiaran Tanjung
Kawasan Perindustrian Tanjung
Sepang, Selangor Darul Ehsan 43900
Malaysia

Re: K221718
Trade/Device Name: Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs (Natural)
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: August 15, 2022
Received: August 23, 2022

Dear Nurul Kong:

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)*
K221718

Device Name
Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs is intended to be worn by operating room personnel to protect surgical wound from contamination. It is also tested for use against Chemotherapy Drugs.

The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	12.3
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	17.4
Vincristine Sulfate (1.0 mg/ml)	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 12.3 minutes and 17.4 minutes respectively.
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.

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510(k) SUMMARY (K221718)

FOR

POLYISOPRENE POWDER FREE SURGICAL GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS

(The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92)

APPLICANT INFORMATION

Date Prepared	:	April 27, 2022
Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor, Malaysia
Establishment Registration Number	:	3011200663

CORRESPONDENT AND/OR PREPARER INFORMATION

Contact Name	:	Nurul Aisyah Kong
Contact Title	:	Deputy General Manager – Quality Assurance
Phone Number	:	(603) 3280 3888
Fax Number	:	(603) 3271 0135
Contact Email	:	wkkong@hartalega.com.my

DEVICE IDENTIFICATION

Common Name of the Device	:	Surgeon's Glove
Trade Name (Proprietary Name)	:	Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs
Device Class	:	1
Product Code	:	KGO, LZC
Regulation Number	:	21 CFR 878.4460
Reason for 510(k) Submission	:	New device

PREDICATE DEVICE INFORMATION

510(k) Number	Tradename	Product Code
K190018	Gammex Non-Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs	KGO

DESCRIPTION OF THE DEVICE:

Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs is a disposable single-use, sterile, natural-colored and powder-free surgical glove made from synthetic polyisoprene latex.

INDICATIONS FOR USE:

Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs is intended to be worn by operating room personnel to protect surgical wound from contamination. It is also tested for use against Chemotherapy Drugs.

The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	12.3
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	17.4
Vincristine Sulfate (1.0 mg/ml)	> 240

Please note that Carmustine and Thiotepa have extremely low permeation times of 12.3 minutes and 17.4 minutes respectively.

Warning: Do not use with Carmustine and Thiotepa

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K190018)</th><th>Discussion</th></tr>
<tr><td>Trade Name</td><td>Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs</td><td>Gammex Non-Latex Polyisoprene White Surgical Gloves Tested for Use with Chemotherapy Drugs</td><td>Different</td></tr>
<tr><td>Applicant</td><td>Hartalega NGC Sdn. Bhd.</td><td>Ansell Healthcare Products LLC</td><td>Different</td></tr>
<tr><td>Product Code</td><td>KGO, LZC</td><td>KGO</td><td>Similar</td></tr>
<tr><td>Classification</td><td>1</td><td>1</td><td>Similar</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 878.4460</td><td>21 CFR 878.4460</td><td>Similar</td></tr>
<tr><td>Regulation Name</td><td>Surgeon's Glove</td><td>Surgeon's Glove</td><td>Similar</td></tr>
<tr><td>Indications for Use</td><td>Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs is intended to be worn by operating room personnel to protect surgical wound from contamination. It is also tested for use against Chemotherapy Drugs.
The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.</td><td>Gammex Non Latex PI White Surgical Gloves Tested for Use with Chemotherapy Drugs are 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 D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.</td><td>Similar</td></tr>
<tr><td>Test Chemotherapy Drugs</td><td>
<table>
<tr><th>Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>12.3</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Cyclophosphamide (20.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Doxorubicin Hydrochloride (2.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Methotrexate (25.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Mitomycin C (0.5 mg/ml)</td><td>> 240</td></tr>
<tr><td>Paclitaxel (6.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Thiotepa (10.0 mg/ml)</td><td>17.4</td></tr>
</table>
</td><td>
<table>
<tr><th>Chemotherapy Drug and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>10.2</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Cyclophosphamide (20.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Doxorubicin Hydrochloride (2.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Methotrexate (25.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Mitomycin C (0.5 mg/ml)</td><td>> 240</td></tr>
<tr><td>Paclitaxel (6.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Thiotepa (10.0 mg/ml)</td><td>11.5</td></tr>
</table>
</td><td>Performance level for Carmustine and Thiotepa between subject device and predicate device is comparable.

Additional Chemotherapy drugs were tested on the predicate device.</td></tr>
</table>

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K190018)</th><th>Discussion</th></tr>
<tr><td></td><td>
<table>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
</table>
Please note that Carmustine and Thiotepa have extremely low permeation times of 12.3 minutes and 17.4 minutes respectively.
Warning: Do not use with Carmustine and Thiotepa</td><td>
<table>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Blenoxane (15 mg/ml)</td><td>> 240</td></tr>
<tr><td>Busulfan (6 mg/ml)</td><td>> 240</td></tr>
<tr><td>Cytarabine (100 mg/ml)</td><td>> 240</td></tr>
<tr><td>Daunorubicin (5 mg/ml)</td><td>> 240</td></tr>
<tr><td>Docetaxel (10.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Fludarabine (25 mg/ml)</td><td>> 240</td></tr>
<tr><td>Gemcitabine (38 mg/ml)</td><td>> 240</td></tr>
<tr><td>Idarubicin (1 mg/ml)</td><td>> 240</td></tr>
<tr><td>Ifosfamide (50.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Irinotecan (20.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Mechlorethamine HCI (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Melphalan (5 mg/ml)</td><td>> 240</td></tr>
<tr><td>Mitoxantrone (2.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Oxaliplatin (2.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Paraplatin (10 mg/ml)</td><td>> 240</td></tr>
<tr><td>Ellence (2 mg/ml)</td><td>> 240</td></tr>
<tr><td>Rituximab (10 mg/ml)</td><td>> 240</td></tr>
</table>
Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 10.2 minutes and Thiotepa:11.5 minutes.
Warning: Do not use with Carmustine and Thiotepa</td><td></td></tr>
<tr><td>**Type of use**</td><td>Over the counter use</td><td>Over the counter use</td><td>Similar</td></tr>
<tr><td>**Materials**</td><td>Polyisoprene</td><td>Polyisoprene</td><td>Similar</td></tr>
<tr><td>**Color**</td><td>Natural</td><td>White</td><td>Different</td></tr>
<tr><td>**Design**</td><td>• Single Use
• Sterile
• Powder-Free
• Hand Specific</td><td>• Single Use
• Sterile
• Powder-Free
• Hand Specific</td><td>Similar</td></tr>
</table>

Characteristics and Parameters	Subject Device	Predicate Device (K190018)	Discussion
	• Beaded Cuff	• Beaded Cuff	
Sterility	Sterile	Sterile	Similar
Sterilization	Radiation 10^{-6} SAL	Radiation 10^{-6} SAL	Similar
Freedom from holes	Meets ASTM D3577-19 requirements of AQL 1.5	Meets ASTM D3577-19 requirements of AQL 1.5	Similar
Length	Length (mm): ≥ 265 mm	Length (mm): ≥ 265 mm	Similar. Meets ASTM D3577-19
Dimensions	5.5: 70 ± 6 (mm) 6.0: 76 ± 6 (mm) 6.5: 83 ± 6 (mm) 7.0: 89 ± 6 (mm) 7.5: 95 ± 6 (mm) 8.0: 102 ± 6 (mm) 8.5: 108 ± 6 (mm) 9.0: 114 ± 6 (mm)	5.5: 70 ± 6 (mm) 6.0: 76 ± 6 (mm) 6.5: 83 ± 6 (mm) 7.0: 89 ± 6 (mm) 7.5: 95 ± 6 (mm) 8.0: 102 ± 6 (mm) 8.5: 108 ± 6 (mm) 9.0: 114 ± 6 (mm)	Similar. Meets ASTM D3577-19
Thickness	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Similar. Meets ASTM D3577-19
Physical Properties	Tensile Strength Before Aging: ≥ 17 MPa Tensile Strength After Aging: ≥ 12 MPa Ultimate Elongation Before Aging: ≥ 650 % Ultimate Elongation After Aging: ≥ 490 %	Tensile Strength Before Aging: ≥ 17 MPa Tensile Strength After Aging: ≥ 12 MPa Ultimate Elongation Before Aging: ≥ 650 % Ultimate Elongation After Aging: ≥ 490 %	Similar. Meets ASTM D3577-19
Powder residual	Residual Powder: ≤ 2 mg per glove	Residual Powder: ≤ 2 mg per glove	Similar. Meets ASTM D3577-19
In Vitro Cytotoxicity ISO 10993-5	Under the conditions of the study, the device was found to be cytotoxic	Under the conditions of the study, the device was found to be cytotoxic	Similar
Primary Skin Irritation ISO 10993-10	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device not an irritant	Similar
Dermal Sensitization ISO 10993-10	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device not a sensitizer	Similar
Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, there was no evidence of systemic toxicity	Under the conditions of the study, there was no evidence of systemic toxicity	Similar
Pyrogenicity Test USP <151>	Under the conditions of the study, the test article was non-pyrogenic	N/A	Additional Pyrogenicity Test was tested on the subject device

SUMMARY OF NON-CLINICAL TESTING:

Non-clinical testing was performed to verify that the subject device meets the acceptance criteria of the performance test and all design specifications. The test results demonstrated that the subject device complies with the following standards as shown below.

- **ASTM D3577-19** Standard Specification for Rubber Surgical Gloves
- **ASTM D5151-19** Standard Test Method for Detection of Holes in Medical Gloves
- **ASTM D6124-06** (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- **ASTM D6978-05** (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- **ASTM F1929 -15** Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- **ISO 11137-1:2006** Sterilization of health care products - Radiation - Part 1: Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- **ISO 11137-2:2013** Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- **ISO 10993-5** In Vitro Cytotoxicity
- **ISO 10993-10** Primary Skin Irritation
- **ISO 10993-10** Dermal Sensitization
- **ISO 10993-11** Acute Systemic Toxicity
- **USP <151>** Pyrogen Test (USP Rabbit Test)
- **USP <85>** Bacterial Endotoxins Test

Physical Characteristics

<table>
<tr><th>Test Methodology/ Standards</th><th>Acceptance Criteria of the Standards</th><th>Result Summary</th></tr>
<tr>
<td>Dimensions

ASTM D3577-19 Standard Specification for Rubber Surgical Gloves</td>
<td>
<table>
<tr><th>Size</th><th>Length (mm)</th><th>Width (mm)</th></tr>
<tr><td>5.5</td><td>Min 245</td><td>70 ± 6</td></tr>
<tr><td>6.0</td><td>Min 265</td><td>76 ± 6</td></tr>
<tr><td>6.5</td><td>Min 265</td><td>83 ± 6</td></tr>
<tr><td>7.0</td><td>Min 265</td><td>89 ± 6</td></tr>
<tr><td>7.5</td><td>Min 265</td><td>95 ± 6</td></tr>
<tr><td>8.0</td><td>Min 265</td><td>102 ± 6</td></tr>
<tr><td>8.5</td><td>Min 265</td><td>108 ± 6</td></tr>
<tr><td>9.0</td><td>Min 265</td><td>114 ± 6</td></tr>
</table>
</td>
<td>Meets ASTM D3577-19 requirements for length, and width. Similar to predicate device.
<table>
<tr><th>Size</th><th>Average Length (mm)</th><th>Average Width (mm)</th></tr>
<tr><td>5.5</td><td>285</td><td>74</td></tr>
<tr><td>6.0</td><td>283</td><td>80</td></tr>
<tr><td>6.5</td><td>290</td><td>84</td></tr>
<tr><td>7.0</td><td>290</td><td>91</td></tr>
<tr><td>7.5</td><td>292</td><td>98</td></tr>
<tr><td>8.0</td><td>300</td><td>103</td></tr>
<tr><td>8.5</td><td>297</td><td>109</td></tr>
<tr><td>9.0</td><td>291</td><td>116</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>Dimensions

ASTM D3577-19
Standard Specification for Rubber Surgical Gloves</td>
<td>Thickness (mm)
<table><tr><td>Palm</td><td>Minimum 0.10</td></tr><tr><td>Finger</td><td>Minimum 0.10</td></tr><tr><td>Cuff</td><td>Minimum 0.10</td></tr></table></td>
<td>Meets ASTM D3577-19 requirements for thickness. Similar to predicate device
<table><tr><th>Size</th><th>Average Palm Thickness (mm) Min</th><th>Average Finger Thickness (mm)</th><th>Average Cuff Thickness (mm)</th></tr><tr><td>5.5</td><td>0.21</td><td>0.23</td><td>0.15</td></tr><tr><td>6.0</td><td>0.20</td><td>0.23</td><td>0.16</td></tr><tr><td>6.5</td><td>0.20</td><td>0.23</td><td>0.16</td></tr><tr><td>7.0</td><td>0.19</td><td>0.23</td><td>0.15</td></tr><tr><td>7.5</td><td>0.20</td><td>0.24</td><td>0.15</td></tr><tr><td>8.0</td><td>0.19</td><td>0.23</td><td>0.15</td></tr><tr><td>8.5</td><td>0.20</td><td>0.24</td><td>0.16</td></tr><tr><td>9.0</td><td>0.20</td><td>0.24</td><td>0.15</td></tr></table></td>
</tr>
<tr>
<td>Physical Properties

ASTM D3577-19
Standard Specification for Rubber Surgical Gloves</td>
<td><table><tr><th>Parameter</th><th>Before Aging</th><th>After Aging</th></tr><tr><td>Tensile Strength</td><td>Min 17 MPa</td><td>Min 12 MPa</td></tr><tr><td>Ultimate Elongation</td><td>Min 650%</td><td>Min 490%</td></tr><tr><td>Stress at 500% Elongation</td><td>Max 7.0 MPa</td><td>N/A</td></tr></table></td>
<td>Meets ASTM D3577-19 requirements for tensile strength and elongation at break before and after accelerated aging. Similar to predicate device.

<u>Before Age</u>
Tensile Strength (MPa)
Average 17.9
Elongation at Break (%)
Average 952
Stress at 500% Elongation (MPa)
Average 2.2

<u>After Age</u>
Tensile Strength (MPa)
Average 15.2
Elongation at Break (%)
Average 940</td>
</tr>
<tr>
<td>Freedom from holes

ASTM D5151-19
Standard Test Method for Detection of Holes in Medical Gloves

ASTM D3577-19
Standard Specification for Rubber Surgical Gloves</td>
<td>AQL 1.5</td>
<td>Meets ASTM D3577-19 and ASTM D5151-19 requirements of AQL 1.5. Similar to predicate device.</td>
</tr>
<tr>
<td>Powder residual

ASTM D6124-06(2017)
Standard Test Method for Residual Powder on Medical Gloves

ASTM D3577-19
Standard Specification for Rubber Surgical Gloves</td>
<td>Powder Free; ≤ 2 mg per glove</td>
<td>Meets ASTM D3577-19 and ASTM D6124-06 (2017) requirements for Powder Free; ≤ 2 mg per glove. Similar to predicate device.

Average 0.34 mg/glove</td>
</tr>
<tr>
<td>Chemotherapy Drugs Permeation

ASTM D6978-05(2019)
Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs</td>
<td>Under the conditions of the study, no permeation.</td>
<td>See results in the Table above.</td>
</tr>
</table>

Pyrogenicity Test USP <151>	Under the conditions of the study, the test article was non-pyrogenic	Under the conditions of the study, the test article was non-pyrogenic

Biocompatibility

Test Methodology/ Standards	Acceptance Criteria of the Standards	Result Summary
In Vitro Cytotoxicity ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Under the conditions of the study, the device is not cytotoxic	Under the conditions of the study, the device was found to be cytotoxic and therefore the device were evaluated under ISO 10993-11 – Test for acute systemic toxicity. From Acute Systemic Toxicity test, none of the test articles were observed with signs of toxicity. Similar to predicate device
Primary Skin Irritation ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Under the conditions of the study, the device is not an irritant	Under the conditions of the study, the device is not an irritant. Similar to predicate device
Dermal Sensitization ISO 10993-10:2021 Biological evaluation of medical devices — Part 10: Tests for skin sensitization	Under the conditions of the study, the device is not a sensitizer	Under the conditions of the study, the device is not a sensitizer. Similar to predicate device
Acute Systemic Toxicity ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Under the conditions of the study, the device does not pose a toxicity concern	Under the conditions of the study, there was no signs of toxicity. Similar to predicate device

CLINICAL PERFORMANCE DATA:

Not applicable. There was no clinical data required to support the subject device as the indication for use is equivalent to the predicate device.

CONCLUSION:

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