July 30, 2025

Hartalega NGC Sdn. Bhd.
Mahalia Liyana Mat Harun
Manager - Regulatory Affairs
No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung
Sepang, Selangor Darul Ehsan 43900
Malaysia

Re: K251319
Trade/Device Name: Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue); Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: July 3, 2025
Received: July 3, 2025

Dear Mahalia Liyana Mat Harun:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251319

Device Name
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue);
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) - Extended Cuff

Indications for Use *(Describe)*
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue); and Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) - Extended Cuff, is a sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs and fentanyl citrate as per ASTM D6978 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)	38.3
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Doxorubicin HCl (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Methotrexate (25.0 mg/ml)	> 240
Mytomycin C (0.5 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	78.6
Vincristine Sulfate (1.0 mg/ml)	> 240
Vidaza (5-Azacytidine), 25 mg/ml	>240
Busulfan, 6 mg/ml	>240
Carboplatin, 10 mg/ml	>240
Docetaxel, 10 mg/ml	>240
Epirubicin HCl, 2 mg/ml	>240
Gemcitabine HCl, 38 mg/ml	>240
Ifosfamide, 50 mg/ml	>240
Irinotecan, 20 mg/ml	>240
Mitoxantrone HCl, 2 mg/ml	>240
Oxaliplatin, 5 mg/ml	>240
Vinorelbine, 10 mg/ml	>240

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100mcg/2ml)	>240

Caution: Testing showed a minimum breakthrough time of 38.3 minutes with Carmustine and 78.6 minutes with Thiotepa.
Warning: Do not use with Carmustine

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.

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510(k) SUMMARY FOR K251319

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

APPLICANT INFORMATION

Date Prepared	:	July 29, 2025
Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia
Establishment Registration Number	:	3011200663

CORRESPONDENT AND/OR PREPARER INFORMATION

Contact Name	:	Mahalia Liyana Mat Harun
Contact Title	:	Manager – Regulatory Affairs
Phone Number	:	(603) 8707 3000
Fax Number	:	(603) 3271 0135
Contact Email	:	liyana.harun@hartalega.com.my

DEVICE IDENTIFICATION

Common Name of the Device	:	Examination Glove
Trade Name (Proprietary Name)	:	Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue), Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff
Device Class	:	1
Product Code	:	LZA, LZC, QDO, OPJ
Regulation Number	:	21 CFR 880.6250
Reason for 510(k) Submission	:	New device

PREDICATE DEVICE INFORMATION

510(k) Number	:	K201531
Manufacturer	:	Hartalega Sdn. Bhd.
Trade Name (Proprietary Name)	:	Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)
Device Class	:	1
Product Code	:	LZA, LZC
Regulation Number	:	21 CFR 880.6250

DESCRIPTION OF THE DEVICE:

Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) and Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff, are disposable, single-use, sterile, blue-colored, and powder-free examination gloves made from nitrile latex.

INDICATIONS FOR USE:

Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) and Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff, is a sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs and fentanyl citrate as per ASTM D6978 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)	38.3
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Doxorubicin HCl (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)	78.6
Vincristine Sulfate (1.0 mg/ml)	> 240
Vidaza (5-Azacytidine), 25 mg/ml	> 240

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Busulfan, 6 mg/ml	> 240
Carboplatin, 10 mg/ml	> 240
Docetaxel, 10 mg/ml	> 240
Epirubicin HCl, 2 mg/ml	> 240
Gemcitabine HCl, 38 mg/ml	> 240
Ifosfamide, 50 mg/ml	> 240
Irinotecan, 20 mg/ml	> 240
Mitoxantrone HCl, 2 mg/ml	> 240
Oxaliplatin, 5 mg/ml	> 240
Vinorelbine, 10 mg/ml	> 240

Caution: Testing showed a minimum breakthrough time of 38.3 minutes with Carmustine and 78.6 minutes with Thiotepa.

Warning: Do not use with Carmustine.

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100 mcg/2ml	> 240

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

<table>
<tr><th rowspan="2">Characteristics and Parameters</th><th>Subject Device (1)</th><th>Subject Device (2)</th><th rowspan="2">Predicate Device (K201531)</th><th rowspan="2">Discussion</th></tr>
<tr><th>Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)</th><th>Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff</th></tr>
<tr><td>Trade Name</td><td>Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)</td><td>Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff</td><td>Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)</td><td>Similar</td></tr>
<tr><td>Applicant</td><td colspan="2">Hartalega NGC Sdn. Bhd.</td><td>Hartalega Sdn. Bhd.</td><td>Different</td></tr>
<tr><td>Product Code</td><td colspan="2">LZA, LZC, QDO, OPJ</td><td>LZA, LZC, QDO</td><td>Same</td></tr>
<tr><td>Classification</td><td colspan="2">1</td><td>1</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td colspan="2">21 CFR 880.6250</td><td>21 CFR 880.6250</td><td>Same</td></tr>
<tr><td>Regulation Name</td><td colspan="2">Non-Powdered Patient Examination Glove</td><td>Non-Powdered Patient Examination Glove</td><td>Same</td></tr>
<tr><td rowspan="2">Indications for Use</td><td colspan="2">Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue); and Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) - Extended Cuff, is a sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.
These gloves were tested for use with chemotherapy drugs and fentanyl citrate as per ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.</td><td>A sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.</td><td>Same</td></tr>
<tr><td colspan="2">
<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>38.3</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 HCl (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>78.6</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Vidaza (5-Azacytidine), 25 mg/ml</td><td>> 240</td></tr>
<tr><td>Busulfan, 6 mg/ml</td><td>> 240</td></tr>
<tr><td>Carboplatin, 10 mg/ml</td><td>> 240</td></tr>
<tr><td>Docetaxel, 10 mg/ml</td><td>> 240</td></tr>
<tr><td>Epirubicin HCl, 2 mg/ml</td><td>> 240</td></tr>
<tr><td>Gemcitabine HCl, 38 mg/ml</td><td>> 240</td></tr>
<tr><td>Ifosfamide, 50 mg/ml</td><td>> 240</td></tr>
<tr><td>Irinotecan, 20 mg/ml</td><td>> 240</td></tr>
<tr><td>Mitoxantrone HCl, 2 mg/ml</td><td>> 240</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>26.3</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 HCl (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>
</table>
</td><td>The performance level for Carmustine and Thiotepa between subject device and predicate device is comparable.

An additional 11 chemotherapy drugs were tested on the subject device</td></tr>
</table>

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device (1)
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)</th><th>Subject Device (2)
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff</th><th>Predicate Device (K201531)</th><th>Discussion</th></tr>
<tr><td></td><td colspan="2"><table><tr><td>Oxaliplatin, 5 mg/ml</td><td>> 240</td></tr><tr><td>Vinorelbine, 10 mg/ml</td><td>> 240</td></tr></table>
Caution: Testing showed a minimum breakthrough time of 38.3 minutes with Carmustine and 78.6 minutes with Thiotepa.

Warning: Do not use with Carmustine.</td><td><table><tr><td>Thiotepa (10.0 mg/ml)</td><td>97.1</td></tr><tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr></table>
Caution: Please note that Carmustine and Thiotepa have extremely low permeation times of 26.3 minutes and 97.1 minutes respectively.
Warning: Do not use with Carmustine and Thiotepa</td><td></td></tr>
<tr><td></td><td colspan="2"><table><tr><th>Fentanyl Citrate and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr><tr><td>Fentanyl Citrate Injection (100mcg/2ml)</td><td>> 240</td></tr></table></td><td><table><tr><th>Fentanyl Citrate and Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr><tr><td>Fentanyl Citrate Injection (100mcg/2ml)</td><td>> 240</td></tr></table></td><td>Same</td></tr>
<tr><td>Type of use</td><td colspan="2">Over the counter use</td><td>Over the counter use</td><td>Same</td></tr>
<tr><td>Materials</td><td colspan="2">Nitrile</td><td>Nitrile</td><td>Same</td></tr>
<tr><td>Color</td><td colspan="2">Blue</td><td>Blue</td><td>Same</td></tr>
<tr><td>Design</td><td colspan="2">• Single Use
• Sterile
• Powder-Free
• Ambidextrous</td><td>• Single Use
• Sterile
• Powder-Free
• Ambidextrous</td><td>Same</td></tr>
<tr><td>Sterility</td><td colspan="2">Sterile</td><td>Sterile</td><td>Same</td></tr>
<tr><td>Sterilization</td><td colspan="2">Radiation</td><td>Radiation</td><td>Same</td></tr>
<tr><td>Sterility Assurance Level (SAL)</td><td colspan="2">10^{-6} SAL</td><td>10^{-6} SAL</td><td>Same</td></tr>
<tr><td>Freedom from holes</td><td colspan="2">Meets ASTM D5151-19 (2023):
AQL 1.5</td><td>Meets ASTM D5151-06(2015):
AQL 1.5</td><td>Similar</td></tr>
<tr><td>Length</td><td>Meets ASTM D6319-19 (2023):
Overall Length: ≥ 230 mm</td><td>Meets ASTM D6319-19 (2023):
Overall Length: ≥ 260 mm</td><td>Meets ASTM D6319-10 (2015):
Overall Length: ≥ 230 mm</td><td>Both subject devices meet the overall length specification in accordance with ASTM D6319. Subject Device (2) features an extended cuff design, with a minimum length of 260 mm, compared to 230 mm for the predicate device. This dimensional difference does not impact the safety or performance of the subject device, as all devices comply with</td></tr>
</table>

Characteristics and Parameters	Subject Device (1)	Subject Device (2)	Predicate Device (K201531)	Discussion
	Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)	**Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff**		
				applicable standard requirements.
Width	Meets ASTM D6319-19 (2023): XS: 60 – 80 (mm) S: 70 – 90 (mm) M: 85 – 105 (mm) L: 100 – 120 (mm) XL: 110 – 130 (mm)		Meets ASTM D6319-10 (2015): XS: 60 – 80 (mm) S: 70 – 90 (mm) M: 85 – 105 (mm) L: 100 – 120 (mm) XL: 110 – 130 (mm)	Similar
Thickness	Meets ASTM D6319-19 (2023): Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm		Meets ASTM D6319-10 (2015): Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm	Similar
Physical Properties	Meets ASTM D6319-19 (2023): Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %		Meets ASTM D6319-10 (2015) Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Similar
Powder residual	Meets ASTM D6319-19 (2023) & ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove		Meets ASTM D6124-06 (2017): Residual Powder: ≤ 2 mg per glove	Similar
Primary Skin Irritation ISO 10993-23	Under the conditions of the study, the device is not an irritant		Under the conditions of the study, the device is not an irritant	Same
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 is not a sensitizer	Same
Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, the device showed no evidence of acute systemic toxicity		Under the conditions of this study, the device showed no evidence of acute systemic toxicity	Same

SUMMARY OF NON-CLINICAL TESTING:

Non-clinical testing was performed to verify that the subject devices meet 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.

Test	Purpose	Criteria	Result
Standard Test Method for Detection of Holes in Medical Gloves ASTM D5151-19(R2023)	To demonstrate glove integrity	Freedom from holes AQL 1.5%	Pass
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124-06(R2022)	To demonstrate the gloves are 'powder free'	Average less than 2 mg/glove	Pass
Dimensional Conformance ASTM D6319(R2023)	To demonstrate appropriate dimensions for labeled sizes	Conforms to ASTM D6319 width, thickness, and length requirements for XS, S, M, L, and XL AQL 4%	Pass
Tensile Performance ASTM D6319(R2023)	To demonstrate adequate tensile properties	Conforms to ASTM D6319 tensile strength of at least 14MPa and ultimate elongation of at least 500% requirements prior to aging, and tensile strength of at least 14MPa and ultimate strength of at least 400% after accelerated aging AQL 4%	Pass
Biocompatibility: Skin Irritation ISO 10993-23	To demonstrate low potential for skin irritation	Under the conditions of the study, not an irritant.	Pass
Biocompatibility: Skin Sensitization ISO 10993-10	To demonstrate low potential for skin sensitization	Under the conditions of the study, not a sensitizer	Pass
Biocompatibility: Acute Systemic Toxicity ISO 10993-11	To demonstrate low acute systemic toxicity	Under the conditions of the study, no acute systemic toxicity.	Pass
ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	To demonstrate barrier properties of gloves to permeation of chemotherapy drugs and fentanyl citrate: Carmustine (3.3 mg/ml) Cisplatin (1 mg/ml) Cyclophosphamide (20 mg/ml) Dacarbazine (10 mg/ml) Doxorubicin HCl (2 mg/ml) Etoposide (20 mg/ml) Fluorouracil (50 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Paclitaxel (6 mg/ml) Thiotepa (10 mg/ml) Vincristine Sulfate (1 mg/ml) Vidaza (5-Azacytidine), 25 mg/ml Busulfan, 6 mg/ml Carboplatin, 10 mg/ml Docetaxel, 10 mg/ml Epirubicin HCl, 2 mg/ml	N/A	Carmustine Minimum breakthrough time: 38.3 minutes Thiotepa Minimum breakthrough time: 78.6 minutes No breakthrough detected during 240-minute test duration for remaining tested chemotherapy drugs and fentanyl citrate

Test	Purpose	Criteria	Result
	Gemcitabine HCl, 38 mg/ml Ifosfamide, 50 mg/ml Irinotecan, 20 mg/ml Mitoxantrone HCl, 2 mg/ml Oxaliplatin, 5 mg/ml Vinorelbine, 10 mg/ml Fentanyl Citrate Injection, 100 mcg/2mL		

CLINICAL PERFORMANCE DATA:

Not applicable.

CONCLUSION:

The conclusions drawn from the non-clinical testing demonstrates that the subject devices (Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue); and Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) – Extended Cuff) are as safe, as effective and perform as well as or better than the legally marketed predicate device K201531, Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs (Blue).