October 23, 2025

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

Re: K250861
Trade/Device Name: Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: March 20, 2025
Received: March 21, 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,

BIFENG QIAN -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K250861

Device Name
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black)

Indications for Use *(Describe)*

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black) is a non-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, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid. The gloves were tested for use with chemotherapy drugs and fentanyl citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Concentration	Minimum Breakthrough Detection Time in Minutes
Azacytidine (25.0 mg/ml)	>240
Carmustine (3.3 mg/ml)	25.0
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Docetaxel (10.0 mg/ml)	>240
Doxorubicin HCl (2.0 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Gemcitabine (38.0 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0mg/ml)	>240
Oxaliplatin (5.0 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	55.7
Vinorelbine (10.0 mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240

Testing showed a minimum breakthrough time of 25.0 minutes with Carmustine and 55.7 minutes with Thiotepa
Warning: Do not use with Carmustine

Fentanyl Citrate Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100 mcg/2ml	>240
Fentanyl Citrate mixed with Simulated Gastric Acid at a 50:50 ratio	>240

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."

510(k) SUMMARY

K250861

FOR

NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS, FENTANYL CITRATE, SIMULATED GASTRIC ACID AND FENTANYL IN SIMULATED GASTRIC ACID (BLACK)

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

SUBMISSION APPLICANT

Date Prepared	:	October 10th, 2025
Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia
Establishment Registration Number	:	3011200663

SUBMISSION CORRESPONDENT AND/OR PREPARER

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

DEVICE IDENTIFICATION

Common Name of the Device	:	Patient Examination Glove
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black)
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	Tradename	Product Code
K200019	Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black)	LZA, LZC, QDO

DESCRIPTION OF THE DEVICE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black) is a disposable single-use, non-sterile, Black and powder- free ambidextrous glove made from nitrile butadiene rubber.

INDICATIONS FOR USE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black) is a non-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, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid. The gloves were tested for use with chemotherapy drugs and fentanyl citrate 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
Azacytidine (25.0 mg/ml)	> 240
Carmustine (3.3 mg/ml)	25.0
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (20.0 mg/ml)	> 240
Carboplatin (10.0 mg/ml)	> 240
Dacarbazine (10.0 mg/ml)	> 240
Docetaxel (10.0 mg/ml)	> 240
Doxorubicin HCl (2.0 mg/ml)	> 240
Epirubicin (2.0 mg/ml)	> 240
Etoposide (20.0 mg/ml)	> 240
Fluorouracil (50.0 mg/ml)	> 240
Gemcitabine (38.0 mg/ml)	> 240
Ifosfamide (50 mg/ml)	> 240
Irinotecan (20.0 mg/ml)	> 240
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Mitoxantrone (2.0 mg/ml)	> 240
Oncovin (1.0mg/ml)	> 240
Oxaliplatin (5.0 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240

Thiotepa (10.0 mg/ml)	55.7
Vinorelbine (10.0 mg/ml)	> 240
Vincristine Sulfate (1.0 mg/ml)	> 240

Testing showed a minimum breakthrough time of 25.0 minutes with Carmustine and 55.7 minutes with Thiotepa

Warning: Do not use with Carmustine

Fentanyl Citrate Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100 mcg/2ml	> 240
Fentanyl Citrate mixed with Simulated Gastric Acid at a 50:50 ratio	>240

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device
K250861</th><th>Predicate Device
(K200019)</th><th>Discussion</th></tr>
<tr><td>Trade Name</td><td>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black)</td><td>Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black)</td><td>Similar</td></tr>
<tr><td>Applicant</td><td>Hartalega NGC Sdn. Bhd.</td><td>Hartalega NGC Sdn. Bhd.</td><td>Same</td></tr>
<tr><td>Product Code</td><td>LZA, LZC, QDO</td><td>LZA, LZC, QDO</td><td>Same</td></tr>
<tr><td>Classification</td><td>1</td><td>1</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 880.6250</td><td>21 CFR 880.6250</td><td>Same</td></tr>
<tr><td>Regulation Name</td><td>Non-Powder Patient Examination Glove</td><td>Non-Powder Patient Examination Glove</td><td>Same</td></tr>
<tr><td>Indications for Use</td><td>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black) is a non-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, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid.</td><td>Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black) is a non-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.</td><td>Similar</td></tr>
<tr><td>Test Chemotherapy Drugs and Fentanyl Citrate</td><td>
<table>
<tr><th>Chemotherapy Drug and Fentanyl Citrate Concentration</th><th>Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><td>Azacytidine (25.0 mg/ml)</td><td>240</td></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>25.0</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>Carboplatin (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Docetaxel (10.0 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>Azacytidine (25.0 mg/ml)</td><td>240</td></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>25.0</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>Carboplatin (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Docetaxel (10.0 mg/ml)</td><td>240</td></tr>
</table>
</td><td>The performance level for Carmustine and Thiotepa between subject device and predicate device is same.

Additional Chemotherapy drug was tested on the subject device.</td></tr>
</table>

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K200019)</th><th>Discussion</th></tr>
<tr><td></td><td>
<table>
<tr><td>Doxorubicin HCl (2.0 mg/ml)</td><td>240</td></tr>
<tr><td>Epirubicin (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>Gemcitabine (38.0 mg/ml)</td><td>240</td></tr>
<tr><td>Ifosfamide (50 mg/ml)</td><td>240</td></tr>
<tr><td>Irinotecan (20.0 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>Mitoxantrone (2.0 mg/ml)</td><td>240</td></tr>
<tr><td>Oncovin (1.0mg/ml)</td><td>240</td></tr>
<tr><td>Oxaliplatin (5.0 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>55.7</td></tr>
<tr><td>Vinorelbine (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>240</td></tr>
<tr><td>Fentanyl Citrate Injection, (100 mcg/2ml)</td><td>240</td></tr>
<tr><td>Fentanyl Citrate mixed with Simulated Gastric Acid at a 50:50 ratio</td><td>240</td></tr>
</table>
Testing showed a minimum breakthrough time of 25.0 minutes with Carmustine and 55.7 minutes with Thiotepa
Warning: Do not use with Carmustine</td><td>
<table>
<tr><td>Doxorubicin HCl (2.0 mg/ml)</td><td>240</td></tr>
<tr><td>Epirubicin (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>Gemcitabine (38.0 mg/ml)</td><td>240</td></tr>
<tr><td>Ifosfamide (50 mg/ml)</td><td>240</td></tr>
<tr><td>Irinotecan (20.0 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>Mitoxantrone (2.0 mg/ml)</td><td>240</td></tr>
<tr><td>Oncovin (1.0mg/ml)</td><td>240</td></tr>
<tr><td>Oxaliplatin (5.0 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>55.7</td></tr>
<tr><td>Vinorelbine (10.0 mg/ml)</td><td>240</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>240</td></tr>
<tr><td>Fentanyl Citrate Injection, (100 mcg/2ml)</td><td>240</td></tr>
</table>
Please note that Carmustine and Thiotepa have extremely low permeation times of 25.0 minutes and 55.7 minutes.
Warning: Do not use with Carmustine</td><td></td></tr>
<tr><td>**Type of use**</td><td>Over the counter use</td><td>Over the counter use</td><td>Same</td></tr>
<tr><td>**Materials**</td><td>Nitrile</td><td>Nitrile</td><td>Same</td></tr>
<tr><td>**Color**</td><td>Black</td><td>Black</td><td>Same</td></tr>
</table>

Characteristics and Parameters	Subject Device	Predicate Device (K200019)	Discussion
Design	• Single Use • Non-Sterile • Powder-Free • Ambidextrous	• Single Use • Non-Sterile • Powder-Free • Ambidextrous	Same
Sterility	Non-sterile	Non-sterile	Same
Freedom from holes	Meets ASTM D5151-19(2023) and ASTM D6319-19(2023): AQL 2.5	Meets ASTM D5151-19 and ASTM D6319-19: AQL 2.5	Same
Length	Meets ASTM D6319-19(2023) Length (mm): ≥ 230 mm	Meets ASTM D6319-19 Length (mm): ≥ 230 mm	Same
Dimensions	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 XXL: 120 - 140 mm	Meets ASTM D6319-19: XS: 60 - 80 mm S: 70 - 90 mm M: 85 - 105 mm L: 100 - 120 mm XL: 110 - 130 mm	Similar Adding XXL size to the subject device.
Thickness	Meets ASTM D6319-19(2023) Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm	Meets ASTM D6319-19 Palm Thickness: ≥ 0.05 mm Finger Thickness: ≥ 0.05 mm	Same
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 D6319-19: Tensile Strength Before Aging: ≥ 14 MPa Tensile Strength After Aging: ≥ 14 MPa Ultimate Elongation Before Aging: ≥ 500 % Ultimate Elongation After Aging: ≥ 400 %	Same
Powder residual	Meets ASTM D6319-19(2023) & ASTM D6124-06 (2022)	Meets ASTM D6319-19 & ASTM D6124-06 (2022) Residual Powder: ≤ 2 mg per glove	Same

Characteristics and Parameters	Subject Device	Predicate Device (K200019)	Discussion
	Residual Powder: ≤ 2 mg per glove		
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 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	Same

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 D6319-19(2023)** Standard Specification for Nitrile Examination Gloves for Medical Application
- **ASTM D5151-19(2023)** Standard Test Method for Detection of Holes in Medical Gloves
- **ASTM D6124-06(2022)** Standard Test Method for Residual Powder on Medical Gloves
- **ASTM D6978-05(2023)** Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- **ISO 10993-10:2021** Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- **ISO 10993-11:2017** Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- **ISO 10993-23:2021** Biological evaluation of medical devices - Part 10: Tests for irritation

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 2.5%	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 Toxicity ISO 10993-11	To demonstrate low acute toxicity	Under the conditions of the study, no acute 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: Azacytidine (25.0 mg/ml) Carmustine (3.3 mg/ml) Cisplatin (1.0 mg/ml)	N/A	Carmustine Minimum breakthrough time: 25.0 minutes Thiotepa Minimum breakthrough

Test	Purpose	Criteria	Result
	Carboplatin (10.0 mg/ml) Dacarbazine (10.0 mg/ml) Docetaxel (10.0 mg/ml) Doxorubicin HCl (2.0 mg/ml) Epirubicin (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Gemcitabine (38.0 mg/ml) Ifosfamide (50 mg/ml) Irinotecan (20.0 mg/ml) Methotrexate (25.0 mg/ml) Mitomycin C (0.5 mg/ml) Mitoxantrone (2.0 mg/ml) Oncovin (1.0mg/ml) Oxaliplatin (5.0 mg/ml) Paclitaxel (6.0 mg/ml) Thiotepa (10.0 mg/ml) Vinorelbine (10.0 mg/ml) Vincristine Sulfate (1.0 mg/ml) Fentanyl Citrate Injection, (100 mcg/2ml Fentanyl Citrate mixed with Simulated Gastric Acid at a 50:50 ratio2ml)		time: 55.7 minutes No breakthrough detected during 240-minute test duration for remaining tested chemotherapy drugs and fentanyl citrate

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. The substantial equivalent of the subject device is supported by the non-clinical data.

CONCLUSION:

The conclusions drawn from the non-clinical testing demonstrate that the subject device, Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid (Black), is as safe, as effective and performs as well as or better than the legally marketed predicate device, Nitrile Powder Free Examination Gloved Tested for Use with Chemotherapy Drugs and Fentanyl, Citrate (Black) K200019.