July 20, 2026

Hartalega NGC Sdn. Bhd.
Nor Akmar Yusoff
Manager - Regulatory Affairs
1, Persiaran Tanjung, Kawasan Perindustrian Tanjung
Sepang, Selangor Darul Ehsan 43900
Malaysia

Re: K254285
Trade/Device Name: Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs - Aqua Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs - Violet Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs - Dark Blue.

Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: June 25, 2026
Received: June 26, 2026

Dear Nor Akmar Yusoff:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*
K254285

Device Name
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue

Indications for Use *(Describe)*
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time Minutes
Carmustine (3.3 mg/ml)	10.3
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(Toposar)(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)	28.8
Vincristine Sulfate (1.0 mg/ml)	>240

Caution: Testing showed a minimum breakthrough time of 10.3 minutes with Carmustine and 28.8 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa.

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time Minutes
Carmustine (3.3 mg/ml)	10.2
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(Toposar)(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)	30.2
Vincristine Sulfate (1.0 mg/ml)	>240

Caution: Testing showed a minimum breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa.

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time Minutes
Carmustine (3.3 mg/ml)	7.3
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(Toposar)(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)	20.6
Vincristine Sulfate (1.0 mg/ml)	>240

Caution: Testing showed a minimum breakthrough time of 7.3 minutes with Carmustine and 20.6 minutes with Thiotepa.
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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SPECIAL 510(k) SUMMARY (K254285)

FOR

NITRILE POWDER FREE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS – AQUA BLUE

NITRILE POWDER FREE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS – VIOLET BLUE

NITRILE POWDER FREE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS – DARK BLUE

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

SUBMITTER INFORMATION

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Contact Person	:	Kuan Mun Leong
Date Prepared	:	June 22, 2026

CORRESPONDENT AND/OR PREPARER INFORMATION

Contact Name	:	Nor Akmar Yusoff
Contact Title	:	Manager – Regulatory Affairs
Phone Number	:	(603) 8707 3000
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DEVICE IDENTIFICATION

Common Name of the Device	:	Examination Glove
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue
Device Class	:	1
Product Code	:	LZA, LZC, OPJ
Regulation Number	:	21 CFR 880.6250

PREDICATE DEVICE INFORMATION:

510(k) Number	:	K162923
Manufacturer	:	Hartalega NGC Sdn. Bhd.
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue; Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Violet Blue
Device Class	:	1
Product Code	:	LZA, LZC
Regulation Number	:	21 CFR 880.6250

DESCRIPTION OF THE DEVICE:

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue is a disposable single-use, non- sterile, blue-colored and powder-free examination glove made from nitrile latex. Gloves meet the specification of ASTM D6319 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978.

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue is a disposable single-use, non- sterile, blue-colored and powder-free examination glove made from nitrile latex. Gloves meet the specification of ASTM D6319 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978.

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue is a disposable single-use, non- sterile, blue-colored and powder-free examination glove made from nitrile latex. Gloves meet the specification of ASTM D6319 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978.

DEVICE MODIFICATION:

The proposed modification to the predicate devices is the addition of an expiration date labeling claim only. The proposed devices remain identical to the predicate devices with respect to materials, manufacturing process, packaging configuration, and bench performance. All other aspects including the Intended Use, Indications for Use, and technological characteristics remain unchanged.

INDICATIONS FOR USE:

1) Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	10.3
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)	28.8
Vincristine Sulfate (1.0 mg/ml)	> 240

Caution: Testing showed a minimum breakthrough time of 10.3 minutes with Carmustine and 28.8 minutes with Thiotepa.

Warning: Do not use with Carmustine and Thiotepa.

2) Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	10.2
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)	30.2
Vincristine Sulfate (1.0 mg/ml)	> 240

Caution: Testing showed a minimum breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa.

Warning: Do not use with Carmustine and Thiotepa.

3) Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue 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.

The list of Chemotherapy Drugs tested (with breakthrough time) are:

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	7.3
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)	20.6
Vincristine Sulfate (1.0 mg/ml)	> 240

Caution: Testing showed a minimum breakthrough time of 7.3 minutes with Carmustine and 20.6 minutes with Thiotepa.

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 (K162923)</th><th>Discussion</th></tr>
<tr><td>Trade Name</td><td>Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue</td><td>Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue;
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Violet Blue</td><td>Same, except that the subject device does not include the Dark Violet Blue color variant.</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, OPJ</td><td>LZA, LZC</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-Powdered Patient Examination Glove</td><td>Non-Powdered Patient Examination Glove</td><td>Same</td></tr>
<tr><td>Indications for Use</td><td>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.
<table>
<tr><th rowspan="2">Chemotherapy Drug and Concentration</th><th colspan="3">Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><th>Aqua Blue</th><th>Violet Blue</th><th>Dark Blue</th></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>10.3</td><td>10.2</td><td>7.3</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
<tr><td>Cyclophosphamide (20.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
<tr><td>Dacarbazine (10.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
<tr><td>Doxorubicin HCl (2.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
<tr><td>Etoposide (20.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
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It is also tested to be used against Chemotherapy Drugs.
<table>
<tr><th rowspan="2">Chemotherapy Drug and Concentration</th><th colspan="4">Minimum Breakthrough Detection Time in Minutes</th></tr>
<tr><th>Aqua Blue</th><th>Violet Blue</th><th>Dark Blue</th><th>Dark Violet Blue</th></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>10.3</td><td>10.2</td><td>7.3</td><td>0.2</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
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<tr><td>Paclitaxel (6.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td><td>> 240</td></tr>
</table></td><td>Similar, except that the subject device does not include the Dark Violet Blue color variant.</td></tr>
</table>

Characteristics and Parameters	Subject Device	Predicate Device (K162923)	Discussion
	<table><tr><td>Thiotepa (10.0 mg/ml)</td><td>28.2</td><td>30.2</td><td>20.6</td></tr><tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td></tr></table> **Aqua Blue** Caution: Testing showed a minimum breakthrough time of 10.3 minutes with Carmustine and 28.2 minutes with Thiotepa. Warning: Do not use with Carmustine and Thiotepa **Violet Blue** Caution: Testing showed a minimum breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa. Warning: Do not use with Carmustine and Thiotepa **Dark Blue** Caution: Testing showed a minimum breakthrough time of 7.3 minutes with Carmustine and 20.6 minutes with Thiotepa. Warning: Do not use with Carmustine and Thiotepa	<table><tr><td>Thiotepa (10.0 mg/ml)</td><td>28.2</td><td>30.2</td><td>20.6</td><td>10.3</td></tr><tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td><td>> 240</td><td>> 240</td><td>> 240</td></tr></table> **Aqua Blue** Caution: Testing showed an average breakthrough time of 10.3 minutes with Carmustine and 28.2 minutes with Thiotepa. Warning: Do not use with Carmustine Warning: Do not use with Thiotepa **Violet Blue** Caution: Testing showed an average breakthrough time of 10.2 minutes with Carmustine and 30.2 minutes with Thiotepa. Warning: Do not use with Carmustine Warning: Do not use with Thiotepa **Dark Blue** Caution: Testing showed an average breakthrough time of 7.3 minutes with Carmustine and 20.6 minutes with Thiotepa. Warning: Do not use with Carmustine Warning: Do not use with Thiotepa **Dark Violet Blue** Caution: Testing showed an average breakthrough time of 0.2 minutes with Carmustine and 10.3 minutes with Thiotepa. Warning: Do not use with Carmustine Warning: Do not use with Thiotepa	
Type of use	Over the counter use	Over the counter use	Same
Materials	Nitrile	Nitrile	Same
Color	Aqua Blue Violet Blue Dark Blue	Aqua Blue Violet Blue Dark Blue Dark Violet Blue	Same, except that the subject device does not include the Dark Violet Blue color variant.
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): AQL 2.5	Meets D5151-06 (2011): AQL 2.5	Same
Length	Meets ASTM D6319-19 (2023): ≥ 230 mm	Meets ASTM D6319-10 (2015): ≥ 230 mm	Same
Width	Meets ASTM D6319-19 (2023): XS- 60-80 mm S – 70-90 mm M – 85-105 mm L – 100- 120mm XL – 110-130 mm XXL – 115-135 mm	Meets ASTM D6319-10 (2015): XS- 60-80 mm S – 70-90 mm M – 85-105 mm L – 100- 120mm XL – 110-130 mm XXL – 115-135 mm	Same

Characteristics and Parameters	Subject Device	Predicate Device (K162923)	Discussion
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	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 D6319-10 (2015): 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): Residual Powder: ≤ 2 mg per glove	Meets ASTM D6319-10 (2015) & ASTM D6124-06 (2011): Residual Powder: ≤ 2 mg per glove	Same
Primary Skin Irritation ISO 10993-10/ 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
Expiration date labelling claim	5 years of shelf life	-	The subject and predicate devices are identical in all technological characteristics. The only difference is the addition of a 5-year expiration date labelling claim. Real-time aging data support this labeling change, and it does not affect the safety or effectiveness of the device.

SUMMARY OF NON-CLINICAL TESTING:

The subject devices and the predicate devices share the same intended use, identical material and identical manufacturing, and therefore share the same chemotherapy drug permeation testing, biocompatibility characteristics and compliance with ASTM D6319.

The expiration date labeling claim is supported by 5-year real-time shelf-life testing. Real-time stability testing was conducted in accordance with applicable ASTM standards, including ASTM D7160, ASTM D6319, and ASTM D5151, and demonstrated continued compliance with physical property and barrier integrity requirements through the labeled shelf life.

Testing Performed	Purpose	Criteria	Result
Real-Time 5-Year Shelf-Life Testing (ASTM D7160) Physical Properties & Barrier Integrity ASTM D6319 & ASTM D5151	To demonstrate that long-term aging does not impact physical properties or barrier integrity	- Conform to ASTM D6319 tensile strength of at least minimum 14 MPa and ultimate elongation of at least minimum 500% - Freedom from holes per ASTM D5151 (AQL ≤2.5)	Pass
***Chemotherapy Drug Permeation** (ASTM D6978)	To confirm that 5-year real-time aging does not adversely affect chemotherapy drug resistance	Continued support of previously cleared chemotherapy drugs resistance labeling	No adverse impact on chemotherapy drug permeation performance was observed after 5 years of real-time aging; results continue to support the previously cleared labeling claims

**Chemotherapy drug permeation testing in accordance with ASTM D6978 was performed on gloves aged through the full 5-year real-time shelf life.*

The following testing was previously performed on the physically identical predicate device.

Test	Purpose	Criteria	Result
Standard Test Method for Detection of Holes in Medical Gloves ASTM D6319-10 (2015)	To demonstrate glove integrity	Freedom from holes AQL 2.5	Pass
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124-06 (2011)	To demonstrate the gloves are 'powder free'	Average less than 2 mg/glove	Pass
Dimensional Conformance ASTM D6319-10 (2015)	To demonstrate appropriate dimensions for labeled sizes	Conforms to ASTM D6319 width, thickness, and length requirements for XS, S, M, L, XL and XXL AQL 4	Pass
Tensile Performance ASTM D6319-10 (2015)	To demonstrate adequate tensile properties	Conforms to ASTM D6319 requirements with tensile strength of at least 14MPa and ultimate elongation of at least 500% prior to aging, and tensile strength of at least 14MPa and ultimate elongation of at least 400% after accelerated aging AQL 4	Pass
Biocompatibility: Skin Irritation ISO 10993-10	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
ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Demonstrate barrier properties of gloves to permeation of chemotherapy drugs: Carmustine (3.3 mg/ml) Cisplatin (1.0 mg/ml) Cyclophosphamide (20.0 mg/ml) Dacarbazine (10.0 mg/ml)	N/A	**Carmustine Minimum breakthrough time:** Aqua Blue: 10.3 min Violet Blue: 10.2 min Dark Blue: 7.3 min

Test	Purpose	Criteria	Result
	Doxorubicin HCl (2.0 mg/ml) Etoposide (20.0 mg/ml) Fluorouracil (50.0 mg/ml) Methotrexate (25.0 mg/ml) Mitomycin C (0.5 mg/ml) Paclitaxel (6.0 mg/ml) Thiotepa (10.0 mg/ml) Vincristine Sulfate (1.0 mg/ml)		**Thiotepa Minimum breakthrough time:** Aqua Blue: 28.2 min Violet Blue: 30.2 min Dark Blue: 20.6 min No breakthrough detected during 240-minute test duration for remaining tested chemotherapy drugs

CLINICAL PERFORMANCE DATA:

Not applicable. Clinical performance data were not required to support the subject devices, as the indications for use are equivalent to those of the predicate devices.

CONCLUSION:

The conclusion drawn from the non-clinical testing demonstrate that the subject devices are as safe, as effective, and performs as well as or better than the legally marketed predicate device K162923, Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Aqua Blue, Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Violet Blue and Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs – Dark Blue.