June 17, 2026

Hartalega NGC Sdn. Bhd
Nor Akmar Yusoff
Manager - Regulatory Affairs
Contact Address

Re: K260867
Trade/Device Name: Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue); Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (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: May 22, 2026
Received: May 22, 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

Indications for Use

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

510(k) Number *(if known)*
K260867

Device Name
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue);
Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Black)

Indications for Use *(Describe)*
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (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 and Fentanyl Citrate.

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)	20.0
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	54.0
Vincristine Sulfate (1.0 mg/ml)	>240
5-Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/mL)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

Caution: Testing showed a minimum breakthrough time of 20.0 minutes with Carmustine and 54.0 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

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug 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 and Fentanyl Citrate.

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)	25.0
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (Cytoxan) (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 (Taxol) (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	55.7
Vincristine Sulfate (1.0 mg/ml)	>240
5-Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/mL)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

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

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510(k) SUMMARY

FOR K260867

NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUG AND FENTANYL CITRATE (BLUE)

NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUG AND FENTANYL CITRATE (BLACK)

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

SUBMITTER INFORMATION

Name	:	Hartalega NGC Sdn. Bhd.
Address	:	No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia
Phone Number	:	(603) 8707 3000
Fax Number	:	(603) 6280 2533
Contact Person	:	Kuan Mun Leong
Date Prepared	:	February 27, 2026

CORRESPONDENT AND/OR PREPARER INFORMATION

Contact Name	:	Nor Akmar Yusoff
Contact Title	:	Manager – Regulatory Affairs
Phone Number	:	(603) 8707 3000
Fax Number	:	(603) 6280 2533
Contact Email	:	akmar.yusoff@hartalega.com.my

DEVICE IDENTIFICATION

Common Name of the Device	:	Examination Glove
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue); Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)
Device Class	:	1
Product Code	:	LZA, LZC, QDO, OPJ
Regulation Number	:	21 CFR 880.6250

PREDICATE DEVICE INFORMATION

510(k) Number	:	K200019
Manufacturer	:	Hartalega NGC Sdn. Bhd.
Trade Name (Proprietary Name)	:	Nitrile Powder Free Examination Glove Tested for Use with

		Chemotherapy Drug and Fentanyl Citrate (Blue); Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)
Device Class	:	1
Product Code	:	LZA, LZC, QDO
Regulation Number	:	21 CFR 880.6250

DESCRIPTION OF THE DEVICE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (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 and fentanyl citrate as per ASTM D6978.

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black) is a disposable single-use, non- sterile, black-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 and fentanyl citrate as per ASTM D6978.

DEVICE MODIFICATION:

The proposed modification to the subject device is to add an expiration date (shelf-life) labelling claim for the Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue) and Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black). Refer below table for detail:

Trade Name (Proprietary Name)	Modification Detail
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue)	The change is limited solely to addition of an expiration date labelling claim and updated year 5 chemotherapy drug performance results. The proposed device remains identical to the predicate device with respect to materials, manufacturing process and packaging configuration. All other aspects including the Intended Use, Indication for Use and the technological characteristics remain unchanged.
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black).	The change is limited solely to addition of an expiration date labelling claim. The proposed device remains identical to the predicate device with respect to materials, manufacturing process and packaging configuration bench performance. All other aspects including the Intended Use, Indication for Use and the technological characteristics remain unchanged.

INDICATIONS FOR USE:

Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (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 and Fentanyl Citrate.

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)	20.0
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (Cytoxan) (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 (Taxol) (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	54.0
Vincristine Sulfate (1.0 mg/ml)	> 240
5-Azacytidine, 25 mg/ml	> 240
Carboplatin, 10 mg/ml	> 240
Docetaxel, 10 mg/ml	> 240
Epirubicin, 2 mg/ml	> 240
Gemcitabine, 38 mg/ml	> 240
Ifosfamide, 50 mg/ml	> 240
Irinotecan, 20 mg/ml	> 240
Mitoxantrone, 2 mg/ml	> 240
Oncovin, 1.0mg/ml	> 240
Oxaliplatin, 5 mg/ml	> 240
Vinorelbine, 10 mg/ml	> 240

Caution: Testing showed a minimum breakthrough time of 20.0 minutes with Carmustine and 54.0 minutes with Thiotepa.

Warning: Do not use with Carmustine.

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

Nitrile Powder Free Examination Glove 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 and Fentanyl Citrate.

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)	25.0
Cisplatin (1.0 mg/ml)	> 240
Cyclophosphamide (Cytoxan) (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 (Taxol) (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	55.7
Vincristine Sulfate (1.0 mg/ml)	> 240
5-Azacytidine, 25 mg/ml	> 240
Carboplatin, 10 mg/ml	> 240
Docetaxel, 10 mg/ml	> 240
Epirubicin, 2 mg/ml	> 240
Gemcitabine, 38 mg/ml	> 240
Ifosfamide, 50 mg/ml	> 240
Irinotecan, 20 mg/ml	> 240
Mitoxantrone, 2 mg/ml	> 240
Oncovin, 1.0mg/ml	> 240
Oxaliplatin, 5 mg/ml	> 240
Vinorelbine, 10 mg/ml	> 240

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

Warning: Do not use with Carmustine.

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

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</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 Drug and Fentanyl Citrate (Blue),
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)</td><td>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue),
Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)</td><td>Same</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, OPJ</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-Powdered Patient Examination Glove</td><td>Non-Powdered Patient Examination Glove</td><td>Same</td></tr>
<tr><td>Indications for Use</td><td><u>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue)</u>
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.</td><td><u>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Blue)</u>
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.</td><td>Same</td></tr>
<tr><td>Chemotherapy Drug and Fentanyl Citrate Performance</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>20.0</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td></tr>
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<tr><td>Etoposide (Toposar) (20.0 mg/ml)</td><td>> 240</td></tr>
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<tr><td>5-Azacytidine, 25 mg/ml</td><td>> 240</td></tr>
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</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>23.3</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Cyclophosphamide (Cytoxan) (20.0 mg/ml)</td><td>> 240</td></tr>
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<tr><td>Paclitaxel (Taxol) (6.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Thiotepa (10.0 mg/ml)</td><td>58.2</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>5-Azacytidine, 25 mg/ml</td><td>> 240</td></tr>
<tr><td>Carboplatin, 10 mg/ml</td><td>> 240</td></tr>
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<tr><td>Oxaliplatin, 5 mg/ml</td><td>> 240</td></tr>
</table>
</td><td>Different. Performance for Carmustine and Thiotepa were updated following the Year 5 chemotherapy drug and Fentanyl Citrate permeation testing result. Results showed minor numerical variation, however the results remain consistent with the established risk profile and existing warning or precaution statements. The planned labeling update does not modify existing warnings or</td></tr>
</table>

<table>
<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K200019)</th><th>Discussion</th></tr>
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<tr><td>Vinorelbine, 10 mg/ml</td><td>> 240</td></tr>
</table>
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<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>
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Caution: Testing showed an average breakthrough time of 20.0 minutes with Carmustine and 54.0 with Thiotepa
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<tr><td>Fentanyl Citrate Injection (100mcg/2ml)</td><td>> 240</td></tr>
</table>
Blue
Caution: Testing showed an average breakthrough time of 23.3 minutes with Carmustine and 58.2 with Thiotepa
Warning: Do not use with Carmustine</td><td>precautions and does not introduce any new or increased risks to users. The labeling update reflects updated test data only, and the glove continues to perform as intended, maintaining its established functional and safety characteristics.</td></tr>
<tr><td>Indication for Use</td><td><u>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)</u>
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.</td><td><u>Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drug and Fentanyl Citrate (Black)</u>
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.</td><td>Same</td></tr>
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</td><td>Same</td></tr>
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<tr><th>Characteristics and Parameters</th><th>Subject Device</th><th>Predicate Device (K200019)</th><th>Discussion</th></tr>
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<tr><td>Ifosfamide, 50 mg/ml</td><td>> 240</td></tr>
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<tr><td>Fentanyl Citrate Injection (100mcg/2ml)</td><td>> 240</td></tr>
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<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>Blue
Black</td><td>Blue
Black</td><td>Same</td></tr>
<tr><td>Design</td><td>• Single Use
• Non-Sterile
• Powder-Free
• Ambidextrous</td><td>• Single Use
• Non-Sterile
• Powder-Free
• Ambidextrous</td><td>Same</td></tr>
<tr><td>Sterility</td><td>Non-Sterile</td><td>Non-Sterile</td><td>Same</td></tr>
<tr><td>Freedom from holes</td><td>Meets ASTM D5151-19 (2023): AQL 2.5</td><td>Meets ASTM D5151-06(2015): AQL 2.5</td><td>Same</td></tr>
<tr><td>Length</td><td>Meets ASTM D6319-19 (2023):
Overall Length: ≥ 230 mm</td><td>Meets ASTM D6319-10 (2015):
Overall Length: ≥ 230 mm</td><td>Same</td></tr>
<tr><td>Width</td><td>Meets ASTM D6319-19 (2023):
XS: 60 – 80 (mm)
S: 70 – 90 (mm)
M: 85 – 105 (mm)
L: 100 – 120 (mm)
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<tr><td>Thickness</td><td>Meets ASTM D6319-19 (2023):
Palm Thickness: ≥ 0.05 mm
Finger Thickness: ≥ 0.05 mm</td><td>Meets ASTM D6319-10 (2015):
Palm Thickness: ≥ 0.05 mm
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Characteristics and Parameters	Subject Device	Predicate Device (K200019)	Discussion
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 (2017): 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
Acute Oral Toxicity Study ISO 10993-11	Under the conditions of the study, the device does not induce acute systemic toxicity response.	Under the conditions of the study, the device does not induce acute systemic toxicity response.	Same
Expiration date labelling claim	5 years of shelf life	-	The subject and predicate devices are identical in all technological characteristics. The only modification is the addition of a 5-year expiration date labeling claim on both blue and black glove variants. Additionally, for blue glove variant the Carmustine and Thiotepa chemotherapy performance result have been updated to reflect the Year 5 permeation data. This update does not introduce any new warnings or precautionary

Characteristics and Parameters	Subject Device	Predicate Device (K200019)	Discussion
			statements. Real-time aging data support the proposed labeling, and the modification 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 and Fentanyl Citrate 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 and Fentanyl Citrate (ASTM D6978)**	To confirm that 5-year real-time aging does not adversely affect chemotherapy drug and Fentanyl Citrate resistance	Continued support of previously cleared chemotherapy drugs and Fentanyl Citrate resistance labeling and/or warning/precautionary statements	No adverse impact on chemotherapy drug and fentanyl permeation performance was observed following 5 years of real-time aging. The results continue to support the previously cleared labeling claims for the black glove variant. For the blue glove variant, the labeling has been updated to reflect the 5-year real-time aged chemotherapy drug permeation

Testing Performed	Purpose	Criteria	Result
			results. The existing warning statement remains applicable and unchanged, as the updated results do not introduce new risks and continue to ensure end-user safety.

**Chemotherapy Drug and Fentanyl Citrate 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 (2017)	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, and XL AQL 4.0	Pass
Tensile Performance ASTM D6319-10 (2015)	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 4.0	Pass
Biocompatibility: Skin Irritation ISO 10993-10	To demonstrate low potential for skin irritation	Under the conditions of the study, not an irritant.	Pass

Test	Purpose	Criteria	Result
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 Oral Toxicity Study ISO 10993-11	To demonstrate low potential for acute systemic toxicity	Under the conditions of the study, the device does not induce acute systemic toxicity response.	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 (Cytoxan) (20 mg/ml) Dacarbazine (10 mg/ml) Doxorubicin Hydrochloride (2 mg/ml) Etoposide (Toposar) (20 mg/ml) Fluorouracil (50 mg/ml) Methotrexate (25 mg/ml) Mitomycin C (0.5 mg/ml) Paclitaxel (Taxol) (6 mg/ml) Thiotepa (10 mg/ml) Vincristine Sulfate (1 mg/ml) 5-Azacytidine, 25 mg/ml Carboplatin, 10 mg/ml Docetaxel, 10 mg/ml Epirubicin, 2 mg/ml Gemcitabine, 38 mg/ml Ifosfamide, 50 mg/ml Irinotecan, 20 mg/ml Mitoxantrone HCl, 2 mg/ml Oncovin, 1.0mg/ml Oxaliplatin, 5 mg/ml Vinorelbine, 10 mg/ml Fentanyl Citrate Injection, 100 mcg/2mL	N/A	**Carmustine Minimum breakthrough time:** Blue 23.3 minutes Black: 25.0 minutes **Thiotepa Minimum breakthrough time:** Blue: 58.2 minutes Black: 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 devices as the indication for use is equivalent to the predicate devices.

CONCLUSION:

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