July 28, 2026

Hartalega NGC Sdn. Bhd.
Nor Akmar Yusoff
Manager
1, Persiaran Tanjung, Kawasan Perindustrian Tanjung
Sepang, Selangor 43900
Malaysia

Re: K260558
Trade/Device Name: Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC, QDO, OPJ
Dated: June 30, 2026
Received: June 30, 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,

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)*
K260558

Device Name
Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate;
Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
1) Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by operating personnel to protect surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

The glove was 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)	6.7
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)	11.5
Vincristine Sulfate (1.0 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 6.7 minutes with Carmustine and 11.5 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa

2) Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by operating personnel to protect surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

The glove was 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)	7.7
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)	12.8
Vincristine Sulfate (1.0 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 7.7 minutes with Carmustine and 12.8 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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510(k) SUMMARY FOR K260558

(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	:	July 22, 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	:	Surgeon's Glove
Trade Name (Proprietary Name)	:	• Device 1: Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate • Device 2: Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Device Class	:	1
Product Code	:	KGO, LZC, QDO, OPJ
Regulation Number	:	21 CFR 878.4460
Reason for 510(k) Submission	:	New device

PREDICATE DEVICE INFORMATION

1.	510(k) Number	:	K214074
	Manufacturer	:	Hartalega NGC Sdn. Bhd.
	Trade Name (Proprietary Name)	:	Latex Powder Free Surgical Glove with Protein Labelling Claim of 50 Microgram or Less Per Gram of Glove and Tested for Use with Chemotherapy Drugs
	Device Class	:	1
	Product Code	:	KGO, LZC
	Regulation Number	:	21 CFR 878.4460
2.	510(k) Number	:	K032464
	Manufacturer	:	WRP Asia Pacific Sdn. Bhd.
	Trade Name (Proprietary Name)	:	Powder Free Latex Surgical Glove Sterile, Coated with Aloe Vera and with Protein Content Labelling Claim (50 Micrograms or less)
	Device Class	:	1
	Product Code	:	KGO
	Regulation Number	:	21 CFR 878.4460

DESCRIPTION OF THE DEVICE:

- Device 1: Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, is disposable, single-use, sterile, hand specific and powder-free surgical gloves made from natural rubber latex.
- Device 2: Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, is disposable, single-use, sterile, hand specific and powder-free surgical gloves made from natural rubber latex.

INDICATIONS FOR USE:

1) Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by operating personnel to protect surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

The glove was 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)	6.7

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
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)	11.5
Vincristine Sulfate (1.0 mg/ml)	> 240

Caution: Testing showed a minimum breakthrough time of 6.7 minutes with Carmustine and 11.5 minutes with Thiotepa.

Warning: Do not use with Carmustine and Thiotepa

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

2) Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by operating personnel to protect a surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

The glove was 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)	7.7
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

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Methotrexate (25.0 mg/ml)	> 240
Mitomycin C (0.5 mg/ml)	> 240
Paclitaxel (6.0 mg/ml)	> 240
Thiotepa (10.0 mg/ml)	12.8
Vincristine Sulfate (1.0 mg/ml)	> 240

Caution: Testing showed a minimum breakthrough time of 7.7 minutes with Carmustine and 12.8 minutes with Thiotepa.

Warning: Do not use with Carmustine and Thiotepa

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

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE:

Characteristics and Parameters	Subject Device		Predicate Device		Discussion
	Subject Device[1]	**Subject Device[2]**	**Predicate Device[1] K214074**	**Predicate Device[2] K032464**	
Trade Name	Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Latex Powder Free Surgical Glove with Protein Labelling Claim of 50 Microgram or Less per Gram of Glove and Tested for Use with Chemotherapy Drugs	Powder Free Latex Surgical Glove Sterile, Coated with Aloe Vera and with Protein Content Labelling Claim (50 Micrograms or less)	Different
Applicant	Hartalega NGC Sdn. Bhd.	Hartalega NGC Sdn. Bhd.	Hartalega NGC Sdn. Bhd.	WRP Asia Pacific Sdn Bhd	Different applicant for the Predicate Device[2]
Product Code	KGO, LZC, QDO, OPJ	KGO, LZC, QDO, OPJ	KGO, LZC	KGO	Similar
Classification	1	1	1	1	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	Same
Regulation Name	Non-powdered surgeon's glove	Non-powdered surgeon's glove	Non-powdered surgeon's glove	Non-powdered surgeon's glove	Same
Indications for Use	Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by	Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate is made of natural rubber intended to be worn by	Latex Powder Free Surgical Glove with Protein Labelling Claim of 50 Microgram or Less per Gram of Glove and tested for Use with Chemotherapy Drugs is	The Powder Free Latex Surgical Gloves, Sterile, Coated with Aloe Vera and with Protein Content Labelling Claim (50 Micrograms or less) are made of	Subject Device[1] and Subject Device[2] have the same intended use as Predicate Device[1] K214074. Additional

<table>
<tr><th>Characteristics and Parameters</th><th colspan="2">Subject Device</th><th colspan="2">Predicate Device</th><th>Discussion</th></tr>
<tr><th></th><th>Subject Device[1]</th><th>Subject Device[2]</th><th>Predicate Device[1] K214074</th><th>Predicate Device[2] K032464</th><th></th></tr>
<tr><td></td><td>operating personnel to protect surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.</td><td>operating personnel to protect surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.</td><td>made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. It is also tested to be used against Chemotherapy Drugs.</td><td>natural rubber latex intended to be worn on the hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment.</td><td>Fentanyl Citrate resistance does not raise new questions of safety or effectiveness, as permeation performance testing have been conducted on both finished Subject Device[1] and Subject Device[2].

Although Predicate Device[2] K032464 was not tested for use with Chemotherapy Drugs and Fentanyl Citrate, this performance characteristic does not alter the intended use of the device.</td></tr>
<tr><td>Chemotherapy Performance</td><td>
<table>
<tr><td></td><td></td></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>6.7</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>
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<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>7.7</td></tr>
<tr><td>Cisplatin (1.0 mg/ml)</td><td>> 240</td></tr>
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<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</td><td>> 240</td></tr>
</table>
</td><td>
<table>
<tr><td></td><td></td></tr>
<tr><td>Carmustine (3.3 mg/ml)</td><td>12.5</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>
</table>
</td><td>N/A</td><td>Subject Device[1] and Subject Device[2] have the similar chemotherapy claim as Predicate Device[1] K214074. Chemotherapy drug resistance permeation performance testing have been conducted and demonstrated on the finished Subject Device[1] and Subject Device[2].

Additionally, necessary warning and caution statement for Subject</td></tr>
</table>

<table>
<tr><th>Characteristics and Parameters</th><th colspan="2">Subject Device</th><th colspan="2">Predicate Device</th><th>Discussion</th></tr>
<tr><th>Subject Device[1]</th><th>Subject Device[2]</th><th>Predicate Device[1] K214074</th><th>Predicate Device[2] K032464</th><th></th></tr>
<tr>
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<table>
<tr><td>Fluorouracil (50.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Methotrexate (25.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Mitomycin C (0.5 mg/ml)</td><td>> 240</td></tr>
<tr><td>Paclitaxel (6.0 mg/ml)</td><td>> 240</td></tr>
<tr><td>Thiotepa (10.0 mg/ml)</td><td>11.5</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
</table>
Caution: Testing showed a minimum breakthrough time of 6.7 minutes with Carmustine and 11.5 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa
<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>
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<table>
<tr><td>mg/ml)</td><td></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>12.8</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
</table>
Caution: Testing showed a minimum breakthrough time of 7.7 minutes with Carmustine and 12.8 minutes with Thiotepa.
Warning: Do not use with Carmustine and Thiotepa
<table>
<tr><td></td><td></td></tr>
<tr><td>Fentanyl Citrate Injection (100mcg/2ml)</td><td>> 240</td></tr>
</table>
</td>
<td>
<table>
<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>13.6</td></tr>
<tr><td>Vincristine Sulfate (1.0 mg/ml)</td><td>> 240</td></tr>
</table>
Caution: Please note that the following drugs have low permeation times: Carmustine (BCNU) 3.3 mg/ml 12.5 minutes; Thiotepa 10.0 mg/ml 13.6 minutes.
Warning: Please do not use with Carmustine (BCNU) and Thiotepa.

N/A
</td>
<td>NA</td>
<td>Device[1] and Subject Device[2] is included in the labelling to ensure safe use of the device by the end user to avoid raise of any safety concern.
Additional Fentanyl Citrate resistance does not raise new questions of safety or effectiveness, as permeation performance testing has been conducted on both finished Subject Device[1] and Subject Device[2].</td>
</tr>
<tr><td>Type of use</td><td>Over the counter use</td><td>Over the counter use</td><td>Over the counter use</td><td>Over the counter use</td><td>Same</td></tr>
</table>

Characteristics and Parameters	Subject Device		Predicate Device		Discussion
	Subject Device[1]	**Subject Device[2]**	**Predicate Device[1] K214074**	**Predicate Device[2] K032464**	
Materials	Natural Latex	Natural Latex	Natural Latex	Natural Latex	Same
Color	Natural	Natural	Natural	Natural	Same
Design	• Powder Free • Single Use • Sterile • Hand Specific • Beaded Cuff	• Powder Free • Single Use • Sterile • Hand Specific • Beaded Cuff	• Powder Free • Single Use • Sterile • Hand Specific • Beaded Cuff	• Powder Free • Single Use • Sterile • Hand Specific • Beaded Cuff	Same
Coating	N/A	Coats with Colloidal Oatmeal	N/A	Coats with Aloe Vera Coating	The Subject Device[2] includes an internal colloidal oatmeal coating, representing a technological difference compared to Predicate Device[1] K214074. However, this difference does not raise new questions of safety or effectiveness, as biocompatibility and performance testing have been conducted on the finished Subject Device[2]. The results demonstrate that Subject Device[2] performs as intended and meets applicable requirements. Additional Predicate Device[2] K032464 demonstrates prior FDA clearance of coated latex surgical gloves using Aloe Vera under the same regulation and product

Characteristics and Parameters	Subject Device		Predicate Device		Discussion
	Subject Device[1]	**Subject Device[2]**	**Predicate Device[1] K214074**	**Predicate Device[2] K032464**	
					code. Additionally, device under K143419* demonstrated prior FDA clearance of colloidal oatmeal coating for medical glove applications. Therefore, Predicate Device[2] K032464 and device under K143419 establish regulatory precedent for coated glove technologies and are not relied upon to support surgical use indications or chemotherapy drug resistance claims.
Sterility	Sterile	Sterile	Sterile	Sterile	Same
Sterilization	Radiation	Radiation	Radiation	Radiation	Same
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	10^{-6} SAL	10^{-6} SAL	Same
Freedom from holes	Meets ASTM D3577 – 19 requirements of AQL 1.5	Meets ASTM D3577 – 19 requirements of AQL 1.5	Meets ASTM D3577 – 19 requirements of AQL 1.5	Meets ASTM D3577-01a requirement of AQL 1.5	Subject Device[1] and Subject Device[2] meet the specification and applicable ASTM D3577 requirement, similar to Predicate Device[1] K214074
Length	Meets ASTM D3577-19: ≥ 265 mm	Meets ASTM D3577-19: ≥ 265 mm	Meets ASTM D3577-19: ≥ 265 mm	Meets ASTM D3577-01a: ≥ 265 mm	Same

Characteristics and Parameters	Subject Device		Predicate Device		Discussion
	Subject Device[1]	Subject Device[2]	Predicate Device[1] K214074	Predicate Device[2] K032464	
Width	Meets ASTM D3577-19: 5 ½: 70 ± 6 6: 76 ± 6 6 ½: 83 ± 6 7: 89 ± 6 7 ½: 95 ± 6 8: 102 ± 6 8 ½: 108 ± 6 9: 114 ± 6	Meets ASTM D3577-19: 5 ½: 70 ± 6 6: 76 ± 6 6 ½: 83 ± 6 7: 89 ± 6 7 ½: 95 ± 6 8: 102 ± 6 8 ½: 108 ± 6 9: 114 ± 6	Meets ASTM D3577-19: 5 ½: 70 ± 6 6: 76 ± 6 6 ½: 83 ± 6 7: 89 ± 6 7 ½: 95 ± 6 8: 102 ± 6 8 ½: 108 ± 6 9: 114 ± 6	Meets ASTM D3577-01a: 5 ½: 70 ± 6 6: 76 ± 6 6 ½: 83 ± 6 7: 89 ± 6 7 ½: 95 ± 6 8: 102 ± 6 8 ½: 108 ± 6 9: 114 ± 6	Same
Thickness	Meets ASTM D3577-19: Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Meets ASTM D3577-19: Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Meets ASTM D3577-19: Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Meets ASTM D3577-01a: Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Same
Physical Properties	Meets ASTM D3577-19: Tensile Strength Before Aging: ≥ 24 MPa Ultimate Elongation Before Aging: ≥ 750% Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation After Aging: ≥ 560%	Meets ASTM D3577-19: Tensile Strength Before Aging: ≥ 24 MPa Ultimate Elongation Before Aging: ≥ 750% Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation After Aging: ≥ 560%	Meets ASTM D3577-19: Tensile Strength Before Aging: ≥ 24 MPa Ultimate Elongation Before Aging: ≥ 750% Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation After Aging: ≥ 560%	Meets ASTM D3577-01a: Tensile Strength Before Aging: ≥ 24 MPa Ultimate Elongation Before Aging: ≥ 750% Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation After Aging: ≥ 560%	Similar
Powder residual	Meets ASTM D3577-19 & ASTM D6124-06(2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D3577-19 & ASTM D6124-06(2022): Residual Powder: ≤ 2 mg per glove	Meets ASTM D3577-19 & ASTM D6124-06(2017): Residual Powder: ≤ 2 mg per glove	Meets ASTM D3577-01a & ASTM D6124-01: Residual Powder: ≤ 2 mg per glove	Similar
Protein Test	Meets ASTM D3577-19 & ASTM D5712-15 (2020) Protein test: ≤ 200 μg/dm²	Meets ASTM D3577-19 & ASTM D5712-15 (2020) Protein test: ≤ 200 μg/dm²	Meets ASTM D3577-19 & ASTM D5712-15 (2020) test: ≤ 50 μg/g	Meets ASTM D3577-01a & ASTM D5712-99 Protein test: ≤ 50 μg/g	Subject Device[1] and Subject Device[2] meet the recommended aqueous soluble protein content limit in accordance with ASTM D3577-19.

Characteristics and Parameters	Subject Device		Predicate Device		Discussion
	Subject Device[1]	**Subject Device[2]**	**Predicate Device[1] K214074**	**Predicate Device[2] K032464**	
Antigenic Protein	Device antigenic protein content does not exceed the maximum limit as per recommendation in accordance with ASTM D3577-19 which is 10µg/dm^2	Device antigenic protein content does not exceed the maximum limit as per recommendation in accordance with ASTM D3577-19 which is 10µg/dm^2	Device antigenic protein content does not exceed the maximum limit as per recommendation in accordance with ASTM D3577-19 which is 10µg/dm^2	N/A	Subject Device[1] and Subject Device[2] meet the recommended antigenic protein content limit in accordance with ASTM D3577-19, similar to Predicate Device[1] K214074.
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	Under the conditions of the study, the device is not an irritant	Pass (Not a primary skin 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	Under the conditions of the study, the device is not a sensitizer	Pass (Not a primary skin irritant)	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	Under the conditions of this study, the device showed no evidence of acute systemic toxicity	N/A	Subject Device[1] and Subject Device[2] showed no evidence of acute systemic toxicity, similar to Predicate Device[1] K214074.

*Latex Powder Free Examination Gloves with Colloidal Oatmeal USP Skin Protectant with Protein Labeling Claim of 50 Microgram or Less per Gram of Glove and Latex Powder Free Examination Gloves with Colloidal Oatmeal USP Skin Protectant with Protein Labeling Claim of 50 Microgram or Less per Gram of Glove – Lemon Green

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.

Test	Purpose	Criteria	Result
Standard Test Method for Detection of Holes in Medical Gloves ASTM D5151-19	To demonstrate glove integrity	Freedom from holes AQL 1.5	Pass
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124 – 06 (Reapproved 2017) ASTM D6124 – 06 (Reapproved 2022)	To demonstrate the gloves are 'powder free'	Average less than 2 mg/glove	Pass
Dimensional Conformance ASTM D3577-19	To demonstrate appropriate dimensions for labeled sizes	Conforms to ASTM D3577 width, thickness, and length requirements for 5 ½, 6, 6 ½, 7, 7 ½, 8, 8 ½ and 9 AQL 4.0	Pass
Tensile Performance ASTM D3577-19	To demonstrate adequate tensile properties	Conforms to ASTM D3577 tensile strength of at least 24MPa and ultimate elongation of at least 750% requirements prior to aging, and tensile strength of at least 18MPa and ultimate elongation of at least 560% after accelerated aging AQL 4.0	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) Fentanyl Citrate Injection, 100 mcg/2mL	N/A	<u>Carmustine/ Thiotepa:</u> Minimum breakthrough time for Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate: Carmustine: 6.7 minutes Thiotepa: 11.5 minutes Minimum breakthrough time for Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate: Carmustine: 7.7 minutes Thiotepa: 12.8 minutes No breakthrough detected

Test	Purpose	Criteria	Result
			during 240-minute test duration for remaining tested chemotherapy drugs and fentanyl citrate

CLINICAL PERFORMANCE DATA:

Not applicable.

CONCLUSION:

The conclusions drawn from the non-clinical testing demonstrates that the subject devices (Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, and Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate) are as safe, as effective, and perform as well as or better than the legally marketed Predicate Device[1] (K214074) and Predicate Device[2] (K032464).