



June 3, 2026

S&S Glove Corporation
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Contact Address

Re: K260703

Trade/Device Name: Powder Free Blue Nitrile Examination Glove - Tested for Use with
Chemotherapy Drugs and Fentanyl
Powder Free Black Nitrile Examination Glove - Tested for Use with
Chemotherapy Drugs and Fentanyl

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: April 28, 2026

Received: April 28, 2026

Dear Ray Wang:

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

510(k) Number (if known)

K260703

Device Name

Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl;

Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl

Indications for Use (Describe)

Powder Free Blue Nitrile Examination Glove- Tested for Use with Chemotherapy Drugs and Fentanyl:

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05.

The following chemicals have been tested with these gloves:

Chemotherapy Drugs	Concentration mg/ml	Breakthrough Detection Time in Minutes
1 Carmustine,	3.3mg/ml (3,300 ppm)	22.7 min
2 Cisplatin,	1mg/ml (1,000 ppm)	>240min
3 Cyclophosphamide,	20mg/ml (20,000 ppm)	>240min
4 Dacarbazine (DTIC),	10mg/ml (10,000 ppm)	>240min
5 Doxorubicin HCl (Adriamycin),	2mg/ml (2,000 ppm)	>240min
6 Etoposide (Toposar),	20mg/ml (20,000 ppm)	>240min
7 Fluorouracil (5 Flu),	50mg/ml (50,000 ppm)	>240min
8 Methotrexate,	25mg/ml (25,000 ppm)	>240min
9 Mitomycin C,	0.5 mg/ml (500 ppm)	>240min
10 Mitoxantrone HCl,	2mg/ml (2,000 ppm)	>240min
11 Paclitaxel (Taxol),	6mg/ml (6,000 ppm)	>240min
12 Thio-Tepa,	10mg/ml (10,000 ppm)	11.1 min
13 Vincristine Sulphate,	1mg/ml (1,000 ppm)	>240 min

Non-chemotherapy Drugs	Concentration mg/ml	Breakthrough Detection Time in Minutes
1 Fentanyl Citrate,	100mcg/2ml	>240min

Testing showed an average breakthrough time of 11.1 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 22.7 minutes with Carmustine, 3.3mg/ml (3,300 ppm)

Warning: Do not use with Carmustine and Thiotepa

Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl:

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05.

The following chemicals have been tested with these gloves:

Chemotherapy Drugs	Concentration mg/ml	Breakthrough Detection Time in Minutes
1 Carmustine,	3.3mg/ml (3,300 ppm)	21.4 min
2 Cisplatin,	1mg/ml (1,000 ppm)	>240min
3 Cyclophosphamide,	20mg/ml (20,000 ppm)	>240min
4 Dacarbazine (DTIC),	10mg/ml (10,000 ppm)	>240min
5 Doxorubicin HCl (Adriamycin),	2mg/ml (2,000 ppm)	>240min
6 Etoposide (Toposar),	20mg/ml (20,000 ppm)	>240min
7 Fluorouracil (5 Flu),	50mg/ml (50,000 ppm)	>240min
8 Methotrexate,	25mg/ml (25,000 ppm)	>240min

9 Mitomycin C,	0.5 mg/ml (500 ppm)	>240min
10 Mitoxantrone HCl,	2mg/ml (2,000 ppm)	>240min
11 Paclitaxel (Taxol),	6mg/ml (6,000 ppm)	>240min
12 Thio-Tepa,	10mg/ml (10,000 ppm)	15.5 min
13 Vincristine Sulphate,	1mg/ml (1,000 ppm)	>240 min

Non-chemotherapy Drugs	Concentration mg/ml	Breakthrough Detection Time in Minutes
1 Fentanyl Citrate,	100mcg/2ml	>240min

Testing showed an average breakthrough time of 15.5 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 21.4 minutes with Carmustine, 3.3mg/ml (3,300 ppm).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

The assigned 510(k) Number: K260703

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Submission: 04/28/2026

2. Sponsor Identification

S&S GLOVE CORPORATION

Lot 4, D6 Street, Dat Do I Industrial Park, Dat Do Commune, Ho Chi Minh City, Vietnam

Postal Code: 70000

Contact Person: Sang Duong Thanh

Position: General Manager

Tel: +84906338314

Email: sangdt@ssglove.vn

3. Designated Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.

Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China, 102401

Contact Person: Ray Wang

Position: General Manager

Tel: +86-18910677558

Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl; Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl

Size(s): XS, S, M, L, XL, XXL

Regulatory Information

Classification Name: Non-Powdered Patient Examination Glove

Classification: I

Product Code: LZA, LZC, QDO, OPJ

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-powdered patient examination glove

Review Panel: General Hospital

5. Identification of Predicate Device(s)

510(k) Number: K232266

Product Name: Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile,

Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Manufacturer: Better Care Plastic Technology Co., Ltd.

6. Device Description:

The Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl and Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl are disposable powder free nitrile examination gloves. There are two colors available: blue and black. They are ambidextrous and come in different sizes: XS, S, M, L, XL and XXL. The gloves are single use only, and provided non-sterile.

The proposed device meets the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05.

7. Indication For Use Statement:

➤ **Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl:**

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05. The following chemicals have been tested with these gloves:

No.	Chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Carmustine, 3.3mg/ml (3,300 ppm)	22.7 min
2	Cisplatin, 1mg/ml (1,000 ppm)	> 240min
3	Cyclophosphamide, 20mg/ml (20,000 ppm)	> 240min
4	Dacarbazine (DTIC), 10mg/ml (10,000 ppm)	> 240min
5	Doxorubicin HCl (Adriamycin), 2mg/ml (2,000 ppm)	> 240min
6	Etoposide (Toposar), 20mg/ml (20,000 ppm)	> 240min
7	Fluorouracil (5 Flu), 50mg/ml (50,000 ppm)	> 240min
8	Methotrexate, 25mg/ml (25,000 ppm)	> 240min
9	Mitomycin C, 0.5 mg/ml (500 ppm)	> 240min
10	Mitoxantrone HCl, 2mg/ml (2,000 ppm)	> 240min
11	Paclitaxel (Taxol), 6mg/ml (6,000 ppm)	> 240min
12	Thio-Tepa, 10mg/ml (10,000 ppm)	11.1 min
13	Vincristine Sulphate, 1mg/ml (1,000 ppm)	> 240 min
No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Fentanyl Citrate, 100mcg/2ml	> 240min

Testing showed an average breakthrough time of 11.1 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 22.7 minutes with Carmustine, 3.3mg/ml (3,300 ppm).

Warning: Do not use with Carmustine and Thiotepa

➤ **Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl:**

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05. The following chemicals have been tested with these gloves:

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No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes
1	Fentanyl Citrate, 100mcg/2ml	> 240min

Testing showed an average breakthrough time of 15.5 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 21.4 minutes with Carmustine, 3.3mg/ml (3,300 ppm).

Warning: Do not Use with Carmustine and Thiotepa

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device (K260703)		Predicate Device (K232266)	Remark								
Trade Name	Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl;	Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl.	Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate									
Product Code	LZA, LZC, QDO, OPJ		LZA, LZC, QDO, OPJ	SAME								
Classification Regulation	21 CFR 880.6250		21 CFR 880.6250	SAME								
Class	I		I	SAME								
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510(k) Summary

	<table><tr><th>No.</th><th>Chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr><tr><td>1</td><td>Carmustine, 3.3mg/ml (3,300 ppm)</td><td>22.7 min</td></tr><tr><td>2</td><td>Cisplatin, 1mg/ml (1,000 ppm)</td><td>> 240min</td></tr><tr><td>3</td><td>Cyclophosphamide, 20mg/ml (20,000 ppm)</td><td>> 240min</td></tr><tr><td>4</td><td>Dacarbazine (DTIC), 10mg/ml (10,000 ppm)</td><td>> 240min</td></tr><tr><td>5</td><td>Doxorubicin HCl (Adriamycin), 2mg/ml (2,000 ppm)</td><td>> 240min</td></tr><tr><td>6</td><td>Etoposide (Toposar), 20mg/ml (20,000 ppm)</td><td>> 240min</td></tr><tr><td>7</td><td>Fluorouracil (5 Flu), 50mg/ml (50,000 ppm)</td><td>> 240min</td></tr><tr><td>8</td><td>Methotrexate, 25mg/ml (25,000 ppm)</td><td>> 240min</td></tr><tr><td>9</td><td>Mitomycin C, 0.5 mg/ml (500 ppm)</td><td>> 240min</td></tr><tr><td>10</td><td>Mitoxantrone HCl, 2mg/ml (2,000 ppm)</td><td>> 240min</td></tr><tr><td>11</td><td>Paclitaxel (Taxol), 6mg/ml (6,000 ppm)</td><td>> 240min</td></tr><tr><td>12</td><td>Thio-Tepa, 10mg/ml (10,000 ppm)</td><td>11.1 min</td></tr><tr><td>13</td><td>Vincristine Sulphate, 1mg/ml (1,000 ppm)</td><td>> 240 min</td></tr><tr><th>No.</th><th>Non-chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr><tr><td>1</td><td>Fentanyl Citrate, 100mcg/2ml</td><td>> 240min</td></tr></table> Testing showed an average breakthrough time of 11.1 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 22.7 minutes with Carmustine, 3.3mg/ml (3,300 ppm)*Warning: Do not use with Carmustine and Thiotepa.	No.	Chemotherapy Drugs	Breakthrough Detection Time in Minutes	1	Carmustine, 3.3mg/ml (3,300 ppm)	22.7 min	2	Cisplatin, 1mg/ml (1,000 ppm)	> 240min	3	Cyclophosphamide, 20mg/ml (20,000 ppm)	> 240min	4	Dacarbazine (DTIC), 10mg/ml (10,000 ppm)	> 240min	5	Doxorubicin HCl (Adriamycin), 2mg/ml (2,000 ppm)	> 240min	6	Etoposide (Toposar), 20mg/ml (20,000 ppm)	> 240min	7	Fluorouracil (5 Flu), 50mg/ml (50,000 ppm)	> 240min	8	Methotrexate, 25mg/ml (25,000 ppm)	> 240min	9	Mitomycin C, 0.5 mg/ml (500 ppm)	> 240min	10	Mitoxantrone HCl, 2mg/ml (2,000 ppm)	> 240min	11	Paclitaxel (Taxol), 6mg/ml (6,000 ppm)	> 240min	12	Thio-Tepa, 10mg/ml (10,000 ppm)	11.1 min	13	Vincristine Sulphate, 1mg/ml (1,000 ppm)	> 240 min	No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes	1	Fentanyl Citrate, 100mcg/2ml	> 240min	<table><tr><th>No.</th><th>Chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr><tr><td>1</td><td>Carmustine, 3.3mg/ml (3,300 ppm)</td><td>21.4 min</td></tr><tr><td>2</td><td>Cisplatin, 1mg/ml (1,000 ppm)</td><td>> 240min</td></tr><tr><td>3</td><td>Cyclophosphamide, 20mg/ml (20,000 ppm)</td><td>> 240min</td></tr><tr><td>4</td><td>Dacarbazine (DTIC), 10mg/ml (10,000 ppm)</td><td>> 240min</td></tr><tr><td>5</td><td>Doxorubicin HCl (Adriamycin), 2mg/ml (2,000 ppm)</td><td>> 240min</td></tr><tr><td>6</td><td>Etoposide (Toposar), 20mg/ml (20,000 ppm)</td><td>> 240min</td></tr><tr><td>7</td><td>Fluorouracil (5 Flu), 50mg/ml (50,000 ppm)</td><td>> 240min</td></tr><tr><td>8</td><td>Methotrexate, 25mg/ml (25,000 ppm)</td><td>> 240min</td></tr><tr><td>9</td><td>Mitomycin C, 0.5 mg/ml (500 ppm)</td><td>> 240min</td></tr><tr><td>10</td><td>Mitoxantrone HCl, 2mg/ml (2,000 ppm)</td><td>> 240min</td></tr><tr><td>11</td><td>Paclitaxel (Taxol), 6mg/ml (6,000 ppm)</td><td>> 240min</td></tr><tr><td>12</td><td>Thio-Tepa, 10mg/ml (10,000 ppm)</td><td>15.5 min</td></tr><tr><td>13</td><td>Vincristine Sulphate, 1mg/ml (1,000 ppm)</td><td>> 240 min</td></tr><tr><th>No.</th><th>Non-chemotherapy Drugs</th><th>Breakthrough Detection Time in Minutes</th></tr><tr><td>1</td><td>Fentanyl Citrate, 100mcg/2ml</td><td>> 240min</td></tr></table> Testing showed an average breakthrough time of 15.5 minutes with Thio-Tepa, 10mg/ml (10,000 ppm) and 21.4 minutes with Carmustine, 3.3mg/ml (3,300 ppm) *Warning: Do not use with Carmustine and Thiotepa.	No.	Chemotherapy Drugs	Breakthrough Detection Time in Minutes	1	Carmustine, 3.3mg/ml (3,300 ppm)	21.4 min	2	Cisplatin, 1mg/ml (1,000 ppm)	> 240min	3	Cyclophosphamide, 20mg/ml (20,000 ppm)	> 240min	4	Dacarbazine (DTIC), 10mg/ml (10,000 ppm)	> 240min	5	Doxorubicin HCl (Adriamycin), 2mg/ml (2,000 ppm)	> 240min	6	Etoposide (Toposar), 20mg/ml (20,000 ppm)	> 240min	7	Fluorouracil (5 Flu), 50mg/ml (50,000 ppm)	> 240min	8	Methotrexate, 25mg/ml (25,000 ppm)	> 240min	9	Mitomycin C, 0.5 mg/ml (500 ppm)	> 240min	10	Mitoxantrone HCl, 2mg/ml (2,000 ppm)	> 240min	11	Paclitaxel (Taxol), 6mg/ml (6,000 ppm)	> 240min	12	Thio-Tepa, 10mg/ml (10,000 ppm)	15.5 min	13	Vincristine Sulphate, 1mg/ml (1,000 ppm)	> 240 min	No.	Non-chemotherapy Drugs	Breakthrough Detection Time in Minutes	1	Fentanyl Citrate, 100mcg/2ml	> 240min	<table><tr><td>Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)</td><td>22.8</td></tr><tr><td>Chloroquine 50mg/ml (50,000ppm)</td><td>>240</td></tr><tr><td>Cisplatin 1mg/ml (1,000 ppm)</td><td>>240</td></tr><tr><td>Cyclophosphamide 20mg/ml (20,000 ppm)</td><td>>240</td></tr><tr><td>Cyclosporin 100 mg/ml (100,000 ppm)</td><td>>240</td></tr><tr><td>Cytarabine HCL, 100 mg/ml (100,000 ppm)</td><td>>240</td></tr><tr><td>Dacarbazine 10 mg/ml (10,000 ppm)</td><td>>240</td></tr><tr><td>Daunorubicin HCL, 5 mg/ml (5,000 ppm)</td><td>>240</td></tr><tr><td>Docetaxel, 10 mg/ml (10,000 ppm)</td><td>>240</td></tr><tr><td>Doxorubicin HCL, 2 mg/ml (2,000 ppm)</td><td>>240</td></tr><tr><td>Epirubicin HCL, 2 mg/ml (2,000 ppm)</td><td>>240</td></tr><tr><td>Etoposide, 20 mg/ml (20,000 ppm)</td><td>>240</td></tr><tr><td>Fludarabine, 25 mg/ml (25,000 ppm)</td><td>>240</td></tr><tr><td>Fluorouracil, 50mg/ml (50,000ppm)</td><td>>240</td></tr><tr><td>Gemcitabine, 38mg/ml (38,000ppm)</td><td>>240</td></tr><tr><td>Idarubicin HCL, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Ilofarnide, 50mg/ml (50,000ppm)</td><td>>240</td></tr><tr><td>Irinotecan, 20mg/ml (20,000ppm)</td><td>>240</td></tr><tr><td>Mechlorethamine HCL, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Melphalan, 5mg/ml (5,000ppm)</td><td>>240</td></tr><tr><td>Methotrexate, 25mg/ml (25,000ppm)</td><td>>240</td></tr><tr><td>Mitomycin C, 0.5mg/ml (500ppm)</td><td>>240</td></tr><tr><td>Mitoxantrone HCL, 2mg/ml (2,000ppm)</td><td>>240</td></tr><tr><td>Oxaliplatin, 5mg/ml (5,000ppm)</td><td>>240</td></tr><tr><td>Paclitaxel, 6mg/ml (6,000ppm)</td><td>>240</td></tr><tr><td>Paraplatin, 10mg/ml (10,000ppm)</td><td>>240</td></tr><tr><td>Retrovir, 10mg/ml (10,000ppm)</td><td>>240</td></tr><tr><td>Rituximab, 10mg/ml (10,000ppm)</td><td>>240</td></tr><tr><td>Thiotepa, 10mg/ml (10,000ppm)</td><td>46.9</td></tr><tr><td>Topotecan, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Trisenox, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Velsade, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Vincristine Sulfate, 1mg/ml (1,000ppm)</td><td>>240</td></tr><tr><td>Fentanyl Citrate Injection (100 mcg/2ml)</td><td>>240</td></tr></table> Please note that the following drugs have extremely low permeation times: Carmustine: 22.8 minutes, Thiotepa: 46.9 minutes, Or *Warning: Do not use with Carmustine and Thiotepa.	Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	22.8	Chloroquine 50mg/ml (50,000ppm)	>240	Cisplatin 1mg/ml (1,000 ppm)	>240	Cyclophosphamide 20mg/ml (20,000 ppm)	>240	Cyclosporin 100 mg/ml (100,000 ppm)	>240	Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240	Dacarbazine 10 mg/ml (10,000 ppm)	>240	Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	Docetaxel, 10 mg/ml (10,000 ppm)	>240	Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	Etoposide, 20 mg/ml (20,000 ppm)	>240	Fludarabine, 25 mg/ml (25,000 ppm)	>240	Fluorouracil, 50mg/ml (50,000ppm)	>240	Gemcitabine, 38mg/ml (38,000ppm)	>240	Idarubicin HCL, 1mg/ml (1,000ppm)	>240	Ilofarnide, 50mg/ml (50,000ppm)	>240	Irinotecan, 20mg/ml (20,000ppm)	>240	Mechlorethamine HCL, 1mg/ml (1,000ppm)	>240	Melphalan, 5mg/ml (5,000ppm)	>240	Methotrexate, 25mg/ml (25,000ppm)	>240	Mitomycin C, 0.5mg/ml (500ppm)	>240	Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	Oxaliplatin, 5mg/ml (5,000ppm)	>240	Paclitaxel, 6mg/ml (6,000ppm)	>240	Paraplatin, 10mg/ml (10,000ppm)	>240	Retrovir, 10mg/ml (10,000ppm)	>240	Rituximab, 10mg/ml (10,000ppm)	>240	Thiotepa, 10mg/ml (10,000ppm)	46.9	Topotecan, 1mg/ml (1,000ppm)	>240	Trisenox, 1mg/ml (1,000ppm)	>240	Velsade, 1mg/ml (1,000ppm)	>240	Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	Fentanyl Citrate Injection (100 mcg/2ml)	>240	
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Chemotherapy Drugs and Fentanyl Citrate Claim	Refer to Table 3	Refer to Table 3	Refer to Table 3	Analysis 1																																																																																																																																																																				

Table 2 Technological Characteristic Comparison

Technological Characteristics	Proposed Device (K260703)		Predicate Device (K232266)	Remark
	Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl;	Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl.	Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	
Physical Dimension:				
Length	Minimum 220mm for size XS and S, 230mm for size M, L, XL, XXL	Minimum 220mm for size XS and S, 230mm for size M, L, XL, XXL	Min 220mm for size XS, S Min 230mm for size M-XXL	SAME
Palm Width (size) (mm):				
XS	70±10	70±10	70±10	SAME
S	80±10	80±10	80±10	SAME
M	95±10	95±10	95±10	SAME
L	110±10	110±10	110±10	SAME
XL	120±10	120±10	120±10	SAME
XXL	130±10	130±10	130±10	SAME
Thickness (mm):				
Finger	Minimum 0.05	Minimum 0.05	Minimum 0.05	SAME
Palm	Minimum 0.05	Minimum 0.05	Minimum 0.05	SAME
Tensile Strength, Before Aging	14MPa, min	14MPa, min	14MPa, min	SAME
Ultimate Elongation, Before Aging	500%, min	500%, min	500%, min	SAME
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	14MPa, min	SAME
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	400%, min	SAME
Watertight (1000ml)	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	SAME
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	SAME

Table 3 Chemotherapy Permeation and Fentanyl Citrate Comparison

Tested Chemotherapy Drug and Fentanyl Citrate Concentration	Minimum BDT (Minutes)		
	Proposed Device (K260703)		Predicate Device (K232266)
	Powder Free Blue Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl;	Powder Free Black Nitrile Examination Glove - Tested for Use with Chemotherapy Drugs and Fentanyl.	Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Bleomycin Sulfate 15mg/ml (15000 ppm)			>240
Busulfan 6mg/ml (6,000 ppm)			>240
Carboplatin 10mg/ml (10,000 ppm)			>240
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	22.7	21.4	22.8
Chloroquine 50mg/ml (50,000ppm)			>240
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240
Cyclosporin 100 mg/ml (100,000 ppm)			>240
Cytarabine HCL, 100 mg/ml (100,000 ppm)			>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)			>240
Docetaxel, 10 mg/ml (10,000 ppm)			>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)			>240
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240
Fludarabine, 25 mg/ml (25,000 ppm)			>240
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240
Gemcitabine, 38mg/ml (38,000ppm)			>240
Idarubicin HCL, 1mg/ml (1,000ppm)			>240
Ifosfamide, 50mg/ml (50,000ppm)			>240
Irinotecan, 20mg/ml (20,000ppm)			>240
Mechlorethamine HCl, 1mg/ml (1,000ppm)			>240
Melphalan, 5mg/ml (5,000ppm)			>240

Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240	>240	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	>240	>240
Oxaliplatin, 5mg/ml (5,000ppm)			>240
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240
Paraplatin, 10mg/ml (10,000ppm)			>240
Retrovir, 10mg/ml (10,000ppm)			>240
Rituximab, 10mg/ml (10,000ppm)			>240
Thiotepa, 10mg/ml (10,000ppm)	11.1	15.5	46.9
Topotecan, 1mg/ml (1,000ppm)			>240
Trisenox, 1mg/ml (1,000ppm)			>240
Velcade, 1mg/ml (1,000ppm)			>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	>240
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	>240

Analysis #1:

Chemotherapy drugs and Fentanyl Citrate and the minimum breakthrough time of subject device will be listed on labeling, so this difference does not raise questions of safety and effectiveness.

Analysis #2:

The proposed device has one more color than the predicate device. However, the size specifications for the two colors of the proposed device are the same, with the only difference being the color. We have tested the biocompatibility and performance of the black gloves, and the results meet the requirements. The concentration test results of chemotherapy drugs and fentanyl according to ASTM D6978-05 have also been added to the label. Therefore, this difference will not affect the safety and effectiveness of the proposed device.

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ASTM D6319-19:2023, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06:2022, Standard Test Method for Residual Powder on Medical Gloves

- ASTM D5151-19:2023, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6978-05:2023 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319-19	Physical Dimensions Length	Min 220mm for size XS, S Min 230mm for size M-XXL	Pass
ASTM D6319-19	Physical Dimensions Palm Width	XS: 70±10mm, S: 80±10mm, M: 95±10mm, L: 110±10mm, XL:120±10mm, XXL:130±10mm	Pass
ASTM D6319-19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319-19	Physical Properties	Tensile Strength (Min 14MPa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319-19 ASTM D5151-19	Water leak test	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319-19 ASTM D6124-06	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05	Permeation by Chemotherapy Drugs	Refer above table	Pass
ISO 10993-11	Acute systemic toxicity study	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Pass
ISO 10993-10	Skin sensitization	Under the condition of the study, the device is not a sensitizer	Pass
ISO 10993-23	Irritation	Under the condition of the study, the device is not an irritant	Pass

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K232266).