May 28, 2024

Xingyu Medical Tech Co., Ltd.
℅ Amanda Sun
Technical
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K240629
Trade/Device Name: Nitrile Disposable Examination Gloves, 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, OPJ, QDO
Dated: February 18, 2024
Received: March 6, 2024

Dear Amanda Sun:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K240629

Device Name
Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl

Indications for Use *(Describe)*
The Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
The tested drugs are:
Chemotherapy drug Concentration Minimum Breakthrough Detection Time
Bleomycin sulfate (15.0 mg/ml 15,000 ppm) 240 min
Carboplatin (10.0 mg/ml 10,000 ppm) 240 min
Carmustine (BCNU) (3.3mg/mL 3,300 ppm) 26.7
Cisplatin (1.0 mg/mL 1,000 ppm) 240 min
Cyclophosphamide (20.0 mg/mL 20,000 ppm) 240 min
Cytarabine (Cytosine) (100.0 mg/mL 100,000 ppm) 240 min
Dacarbazine (10.0 mg/mL 10,000 ppm) 240 min
Doxorubicin HCL (2.0 mg/mL 2,000 ppm) 240 min
Etoposide (Toposar) (20.0 mg/mL 20,000 ppm) 240 min
Fluorouracil (5 Flu) (50.0 mg/mL 50,000 ppm) 240 min
Idarubicin (1.0 mg/ml 1,000 ppm) 240 min
Ifosfamide (50.0 mg/mL 50,000 ppm) 240 min
Mechlorethamine HCL (1.0 mg/ml 1,000 ppm) 240 min
Methotrexate (25.0 mg/mL 25,000 ppm) 240 min
Mitomycin C (0.5 mg/mL 500 ppm) 240 min
Mitoxantrone HCL (2.0 mg/mL 2,000 ppm 240 min
Paclitaxel (6.0 mg/mL 6,000 ppm) 240 min
Thiotepa (10.0 mg/mL 10,000 ppm) 37.6
Vincristine Sulfate (1.0 mg/mL 1,000 ppm 240 min

Non Chemotherapy Drug
MESNA (100.0 mg/mL 100,000 ppm) 240 min
Trisenox (1.0 mg/ml 1,000 ppm) 240 min
Fentanyl Citrate Injection (100 mcg/2mL) 240 min

Note: Carmustine and Thiotepa have extremely low permeation times of 26.7 and 37.6 minutes respectively.
Warning: Do Not Use with Carmustine, 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

K240629

Summary Preparation Date: May 14, 2024

A. Applicant:

Name: Xingyu Medical Tech Co., Ltd.
Address: No.2189 Yaoqian Road, Gaomi Economic Development Zone, Weifang City, Shandong Province, China
Contact: Ms. Carrie Lee
Title: QA Manager
Tel: +86-0536-2588123
Email: medical@xingyugloves.com

Submission Correspondent:
Primary contact: Ms. Amanda Sun
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
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Email: jingyu.sun@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: zxfda@sungoglobal.com

B. Device:

Trade Name: Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl
Common Name: Nitrile Patient Examination Gloves (Powder Free)
Size(s): S, M, L, XL

Regulatory Information
Classification Name: Non-Powdered Patient Examination Glove
Classification: Class I
Product code: LZA, LZC, OPJ, QDO
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device:

Primary Predicate Device:
K232266
Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Better Care Plastic Technology Co., Ltd.

Reference Device
K212578
Nitrile disposable examination gloves
Xingyu Medical Tech Co., Ltd.

D. Indications for use of the device:

The Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

The tested drugs are:

Drugs	Concentration	Minimum Breakthrough Detection Time
The tested chemotherapy drugs are:		
Bleomycin sulfate	(15.0 mg/ml 15,000 ppm)	＞240 min
Carboplatin	(10.0 mg/ml 10,000 ppm)	＞240 min
Carmustine (BCNU)	(3.3mg/mL 3,300 ppm)	26.7
Cisplatin	(1.0 mg/mL 1,000 ppm)	＞240 min
Cyclophosphamide	(20.0 mg/mL 20,000 ppm)	＞240 min
Cytarabine (Cytosine)	(100.0 mg/mL 100,000 ppm)	＞240 min
Dacarbazine	(10.0 mg/mL 10,000 ppm)	＞240 min
Doxorubicin HCL	(2.0 mg/mL 2,000 ppm)	＞240 min
Etoposide (Toposar)	(20.0 mg/mL 20,000 ppm)	＞240 min
Fluorouracil (5 Flu)	(50.0 mg/mL 50,000 ppm)	＞240 min
Idarubicin	(1.0 mg/ml 1,000 ppm)	＞240 min
Ifosfamide	(50.0 mg/mL 50,000 ppm)	＞240 min
Mechlorethamine HCL	(1.0 mg/ml 1,000 ppm)	＞240 min
Methotrexate	(25.0 mg/mL 25,000 ppm)	＞240 min
Mitomycin C	(0.5 mg/mL 500 ppm)	＞240 min
Mitoxantrone HCL	(2.0 mg/mL 2,000 ppm	＞240 min
Paclitaxel	(6.0 mg/mL 6,000 ppm)	＞240 min

Thiotepa	(10.0 mg/mL 10,000 ppm)	37.6
Vincristine Sulfate	(1.0 mg/mL 1,000 ppm	＞240 min
The tested non-chemotherapy drugs are:		
MESNA	(100.0 mg/mL 100,000 ppm)	＞240 min
Trisenox (Arsenic Trioxide)	(1.0 mg/ml 1,000 ppm)	＞240 min
Fentanyl Citrate Injection	(100 mcg/2mL)	＞240 min

Note: Carmustine and Thiotepa have extremely low permeation times of 26.7 and 37.6 minutes respectively.

Warning: Do Not Use with Carmustine, Thiotepa

E. Device Description:

The Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are blue color, powder free, nitrile ambidextrous gloves. The gloves are offered in four sizes, small, medium and large, extra-large, packed in a paper box.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard and are tested for use with chemotherapy drugs and Fentanyl per ASTM D6978-05 (Reapproved 2019). The gloves are as same as the Nitrile disposable examination gloves (Model D5000) cleared under K212578 also produced by Xingyu Medical Tech Co., Ltd. The materials and the manufacturing process technology are the same. The proposed device is increased test of Chemotherapy Drug and Fentanyl. Testing has been conducted on the proposed device passed as per ASTM D6978-05 (Reapproved 2019).

F. Summary of Technological Characteristics

Table 2 Comparison of Proposed, Predicate Devices and Reference Device

Device	**Proposed Device**	**Predicate Device**	**Reference Device**	**Result**
510K #	K240629	K232266	K212578	N/A
Manufacturer	XINGYU MEDICAL TECH CO.,LTD	Better Care Plastic Technology Co., Ltd.	XINGYU MEDICAL TECH CO.,LTD	Different from Predicate Same as Reference

<table>
<tr><td>Product Name</td><td>Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl</td><td>Powder Free Nitrile Patient Examination Gloves, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate</td><td>Nitrile disposable examination gloves</td><td>-</td></tr>
<tr><td>Product Code</td><td>LZA (primary), LZC, OPJ, QDO</td><td>LZA (primary), LZC, OPJ, QDO</td><td>LZA</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td>21 CFR 880.6250</td><td>21 CFR 880.6250</td><td>21 CFR 880.6250</td><td>Same</td></tr>
<tr><td>Indications for use</td><td>The Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
The tested chemotherapy drugs are:
<table>
<tr><th>Drugs</th><th>Concentration</th><th>Minimum Breakthrough Detection Time</th></tr>
<tr><td colspan="3">The tested chemotherapy drugs are:</td></tr>
<tr><td>Bleomycin sulfate</td><td>(15.0 mg/ml 15,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Carboplatin</td><td>(10.0 mg/ml 10,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Carmustine (BCNU)</td><td>(3.3mg/mL 3,300 ppm)</td><td>26.7</td></tr>
<tr><td>Cisplatin</td><td>(1.0 mg/mL 1,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Cyclophosphamide</td><td>(20.0 mg/mL 20,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Cytarabine (Cytosine)</td><td>(100.0 mg/mL 100,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Dacarbazine</td><td>(10.0 mg/mL 10,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Doxorubicin HCL</td><td>(2.0 mg/mL 2,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Etoposide (Toposar)</td><td>(20.0 mg/mL 20,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Fluorouracil (5-Flu)</td><td>(50.0 mg/mL 50,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Idarubicin</td><td>(1.0 mg/ml 1,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Ifosfamide</td><td>(50.0 mg/mL 50,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Mechlorethamine HCL</td><td>(1.0 mg/ml 1,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Methotrexate</td><td>(25.0 mg/mL 25,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Mitomycin C</td><td>(0.5 mg/mL 500 ppm)</td><td>>240 min</td></tr>
<tr><td>Mitoxantrone HCL</td><td>(2.0 mg/mL 2,000 ppm</td><td>>240 min</td></tr>
<tr><td>Paclitaxel</td><td>(6.0 mg/mL 6,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Thiotepa</td><td>(10.0 mg/mL 10,000 ppm)</td><td>37.6</td></tr>
<tr><td>Vincristine Sulfate</td><td>(1.0 mg/mL 1,000 ppm</td><td>>240 min</td></tr>
<tr><td colspan="3">The tested non-chemotherapy drugs are:</td></tr>
<tr><td>MESNA</td><td>(100.0 mg/mL 100,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Trisenox (Arsenic Trioxide)</td><td>(1.0 mg/ml 1,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Fentanyl Citrate Injection</td><td>(100 mcg/2mL)</td><td>>240 min</td></tr>
</table>
Note: Carmustine and Thiotepa have extremely low permeation times of
26.7 and 37.6 minutes respectively.
Warning: Do Not Use with Carmustine, Thiotepa.</td><td>The device 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.
The following Chemotherapy Drugs have been tested with these gloves:
<table>
<tr><th>Chemotherapy Drug</th><th>Minimum Breakthroug Detection Time (BDT in Minutes</th></tr>
<tr><td>Bleomycin Sulfate 15mg/ml (15000 ppm)</td><td>>240</td></tr>
<tr><td>Busulfan 6mg/ml (6,000 ppm)</td><td>>240</td></tr>
<tr><td>Carboplatin 10mg/ml (10,000 ppm)</td><td>>240</td></tr>
<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>Ifosfamide, 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>Velcade, 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</td><td>Nitrile Disposable Examination Gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.</td><td>① Similar as K232266</td></tr>
</table>

		.		
Size	S, M, L, XL	XS, S, M, L, XL, XXL	S, M, L, XL	② Similar as K232266
Powder Free	Yes	Yes	Yes	Same
Material	Nitrile	Nitrile	Nitrile	Same
Color	Blue	Blue	Blue	Same
OTC use	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Single Patient Use	Singe use	Singe use	Singe use	Same
Labeling claim	Tested for Use with Chemotherapy Drugs and Fentanyl	Tested for Use with Chemotherapy Drugs and Fentanyl	Not Tested for use with Chemotherapy Drugs and Fentanyl	Same as K232266
Dimensions (Length)	Min 220mm for size S Min 230mm for size M-XL	Min 220mm for size XS, S Min 230mm for size M-XXL	230 mm min for all size	② Similar as K232266
Dimensions (width)	S: 80±10 M: 95±10 L: 110±10 XL: 120±10	XS: 70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10 XXL: 130±10	S: 83-89 mm M: 88-100mm L: 103-111mm XL: 114-119mm	② Similar as K232266
Dimensions (thickness)	Minimum Palm ≥0.05 mm Minimum Finger ≥0.05 mm	Minimum Palm ≥0.05 mm Minimum Finger ≥0.05 mm	Minimum ≥ 0.09 (Finger) Minimum ≥0.05 mm(Palm)	Same as K232266
Physical properties	Complies with: ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Complies with: ASTM D6319-19 Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Same
Freedom from holes	Meets ASTM D 6319-19 Tested in accordance with ASTM D5151-19 with acceptable results	Meets ASTM D 6319-19 Tested in accordance with ASTM D5151-19 with acceptable results	Meets ASTM D 6319-19 Tested in accordance with ASTM D5151-19 with acceptable results	Same

<table>
<tr>
<td>Residual Powder</td>
<td>Meet the requirements of ASTM D6124</td>
<td>Meet the requirements of ASTM D6124</td>
<td>Meet the requirements of ASTM D6124</td>
<td>Same</td>
</tr>
<tr>
<td>Chemotherapy and non-chemo therapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978</td>
<td>
<table>
<tr><th>Drugs</th><th>Concentration</th><th>Minimum Breakthrough Detection Time</th></tr>
<tr><td colspan="3">The tested chemotherapy drugs are:</td></tr>
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<tr><td>Carmustine (BCNU)</td><td>(3.3mg/mL 3,300 ppm)</td><td>26.7</td></tr>
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<tr><td>Cyclophosphamide</td><td>(20.0 mg/mL 20,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Cytarabine (Cytosine)</td><td>(100.0 mg/mL 100,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Dacarbazine</td><td>(10.0 mg/mL 10,000 ppm)</td><td>>240 min</td></tr>
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<tr><td>Vincristine Sulfate</td><td>(1.0 mg/mL 1,000 ppm</td><td>>240 min</td></tr>
<tr><td colspan="3">The tested non-chemotherapy drugs are:</td></tr>
<tr><td>MESNA</td><td>(100.0 mg/mL 100,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Trisenox (Arsenic Trioxide)</td><td>(1.0 mg/ml 1,000 ppm)</td><td>>240 min</td></tr>
<tr><td>Fentanyl Citrate Injection</td><td>(100 mcg/2mL)</td><td>>240 min</td></tr>
</table>
Note: Carmustine and Thiotepa have extremely low permeation times of 26.7 and 37.6 minutes respectively.
Warning: Do Not Use with Carmustine, Thiotepa.
</td>
<td>
<table>
<tr><th>Chemotherapy Drug</th><th>Minimum Breakthrough Detection Time (BDT) in Minutes</th></tr>
<tr><td>Bleomycin Sulfate 15mg/ml (15000 ppm)</td><td>>240</td></tr>
<tr><td>Busulfan 6mg/ml (6,000 ppm)</td><td>>240</td></tr>
<tr><td>Carboplatin 10mg/ml (10,000 ppm)</td><td>>240</td></tr>
<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>Ifosfamide, 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>Retroyir, 10mg/ml (10,000ppm)</td><td>>240</td></tr>
<tr><td>Rituxumab, 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>Velcade, 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.
</td>
<td>NA</td>
<td>① Different as K232266</td>
</tr>
<tr>
<td>Material</td>
<td>Nitrile</td>
<td>Nitrile</td>
<td>Nitrile</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility Sensitization ISO 10993-10</td>
<td>Under the conditions of the study, not an irritant Under the conditions of the study, not a sensitizer</td>
<td>Under the conditions of the study, not an irritant
Under the conditions of the study, not a sensitizer</td>
<td>Under the conditions of the study, not an irritant Under the conditions of the study, not a sensitizer</td>
<td>Same</td>
</tr>
<tr>
<td>Biocompatibility Cytotoxicity ISO 10993-5</td>
<td>Not Performed</td>
<td>Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.
Cytotoxicity concern was addressed by acute systematic toxicity testing.</td>
<td>Not Performed</td>
<td>②Different as K232266 Same as K212578</td>
</tr>
</table>

Biocompatibility Acute Systemic Toxicity ISO 10993-11	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Same

G. Summary of Non-Clinical Testing

➢ Biocompatibility

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the proposed device is Surface Device category, Skin Contact and duration of contact is A-Limited (≤24h). The following tests for the proposed device were conducted to evaluate the biocompatibility of Nitrile Disposable Examination Gloves as per Guidance for Industry and FDA Staff-Medical Glove Guidance Manual issued on January 22, 2008:

• ISO 10993-10: Primary Skin Irritation
• ISO 10993-10: Dermal Sensitization
• ISO 10993-11: Systemic Toxicity

➢ Performance Testing

Physical performance testing of the proposed device were conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*. Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. In addition, the proposed device was tested according to ASTM D6978-05 (Reapproved 2019) *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

• ASTM D6319-19 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 Standard Test Method for Detection of Holes in Medical Gloves
• ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

From the test result, we can find the product can meet the requirements as its intended use indicated.

Test Method	Purpose	Acceptance Criteria	Results
Dimensions (Length)(width) (thickness) ASTM D6319-19	The purpose of the test is to Evaluate the physical dimension of the glove	Length S:⩾220mm M,L,XL:⩾230mm	Pass
		Width S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm	Pass
		Palm: 0.05mm Finger: 0.05mm	Pass

Physical properties ASTM D6319-19	The purpose of the test is to evaluate the tensile strength and ultimate elongation before and after aging	Tensile Strength: Before Aging ≥14 MPa, min. After Aging ≥14 MPa, min. Elongation: Before Aging 500%, min. After Aging 400%, min.	Pass
Freedom from holes ASTM D5151-19	The purpose of the test is to detect holes in the gloves	No leakage at sampling level of G-1, AQL 2.5	Pass
Residual Powder ASTM D 6124-06 (2022)	The purpose of the test is to detect the powder residue in the glove	<2mg per glove	Pass
Permeation by Chemotherapy Drugs ASTM D 6978-05 (2019)	The purpose of the test is to detect the Permeation time by Chemotherapy Drugs and Fentanyl of the glove	Refer the above table 2	Pass
ISO 10993- 10:2021 Biocompatibility Skin Sensitization Test	determine the potential of glove to promote skin sensitization after repeated applications	No dermal reactions indicative of delayed contact hypersensitivity	Pass
Biocompatibility Acute Systemic Toxicity ISO 10993-11	Determine the potential of glove to be toxic after repeated exposure	Under the conditions of the study, the device extract does not induce acute systemic toxicity response.	Pass
CPSC standards regulated under the FHSA Act set forth in 16 CFR 1500.41,	determine the potential of glove to promote irritation reactions after repeated applications	Not dermal irritation reactions	Pass

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Nitrile Disposable Examination Gloves, tested for Use with Chemotherapy Drugs and Fentanyl is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K232266.