August 2, 2024

Kanglongda Vietnam Protection Technology Company Limited
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401
China

Re: K241970
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (XS,S,M,L,XL,XXL)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, OPJ, QDO, LZC
Dated: July 3, 2024
Received: July 5, 2024

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241970

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

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves (Blue) , Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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:
Carmustine 3.3 mg/ml(3,300 ppm) 27.7
(35.5,27.7,27.7)
Cisplatin 1 mg/ml (1,000 ppm) >240min
Cyclophosphamide 20 mg/ml (20,000 ppm) >240min
Dacarbazine 10mg/ml (10,000 ppm) >240min
Doxorubicin HCl 2 mg/ml(2,000 ppm) >240min
Etoposide 20 mg/ml (20,000 ppm) >240min
Fluorouracil 50mg/ml(50,000 ppm) >240min
Gemcitabine HCl 38 mg/ml (38,000 ppm) >240min
Ifosfamide 50mg/ml (50,000 ppm) >240min
Methotrexate 25mg/ml (25,000 ppm) >240min
Mitomycin C 0.5 mg/ml(500 ppm) >240min
Mitoxantrone HCl 2 mg/ml (2,000 ppm) >240min
Paclitaxel 6 mg/ml (6,000 ppm) >240min
Thiotepa 10 mg/ml (10,000 ppm) 59.4(67.5,59.4,65.9)
Vincristine Sulfate 1 mg/ml (1,000 ppm) >240min
The tested non-chemotherapy drugs are:
Fentanyl Citrate injection 100mcg/2ml >240min
Note: Carmustine and Thiotepa have extremely low permeation times of 27.7 and 59.4 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

The assigned 510(k) Number:_____K241970_____

1. Date of Preparation: 07/31/2024

2. Submitter

KANGLONGDA Vietnam Protection Technology Company Limited

Lot CN 05, Viglacera - Phong Dien Industrial Park, Phong Hoa Commune, Phong Dien District, Thua Thien Hue Province, Vietnam, 49316

Contact Person: Yuxiang Yao

Position: Batching Supervisor

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Email: yaoyuxiang_1212@126.com

3. 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

Fax: +86-10-56335780

Email: information@believe-med.com

4. Subject Device Identification

Trade Name: Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Common Name: Medical Examination Glove

Regulatory Information:

Classification: I

Product Code: LZA, LZC, OPJ, QDO

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

5. Predicate Device Identification

Predicate Device:

510(k) Number: K202356

Product Name: Powder free Nitrile Examination Gloves (Blue, Violet Blue, White, Cobalt Blue)

Manufacturer: Kanglongda Vietnam Protection Technology Company Limited

Regulatory Information:

Classification: I

Product Code: LZA

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Common Name: Nitrile Patient Examination Gloves (Powder Free)

Reference Device:

510(k) Number: K240629

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

Manufacturer: Xingyu Medical Tech Co., Ltd

Regulatory Information:

Classification: I

Product Code: LZA, LZC, OPJ, QDO

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Common Name: Nitrile Patient Examination Gloves (Powder Free)

6. Device Description

The Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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 gloves. The gloves are offered in six sizes: XS、S、M、L、XL、XXL, packed in a paper box.

The proposed 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. The proposed device was

modification from the legally marketed (existing) device "Powder free Nitrile Examination Gloves (Blue, Violet Blue, White, Cobalt Blue)"/K202356, manufactured by "KANGLONGDA VIETNAM PROTECTION TECHNOLOGY COMPANY LIMITED", same as the sponsor of this submission.
There are two modifications, one is to add a large model XXL, and the other is to add the "Tested for Use with Chemotherapy Drugs and Fentanyl Citrate" indications for use than the legally marketed (existing) device. Testing has been conducted on the proposed device passed as per ASTM D6978-05, ASTM D6319-19, ASTM D5151-19, ASTMD 6124-06.
The materials and the manufacturing process technology are the same.

We selected K240629 as our reference device and K202356 as our predicate device. Detailed comparison information can be found in the 510k Summary.

7. Indications For Use

The Powder Free Nitrile Examination Gloves(Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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:		
Carmustine	3.3 mg/ml(3,300 ppm)	27.7 (35.5,27.7,27.7)
Cisplatin	1 mg/ml (1,000 ppm)	>240min
Cyclophosphamide	20 mg/ml (20,000 ppm)	>240min
Dacarbazine	10mg/ml (10,000 ppm)	>240min
Doxorubicin HCl	2 mg/ml(2,000 ppm)	>240min
Etoposide	20 mg/ml (20,000 ppm)	>240min
Fluorouracil	50mg/ml(50,000 ppm)	>240min
Gemcitabine HCl	38 mg/ml (38,000 ppm)	>240min
Ifosfamide	50mg/ml (50,000 ppm)	>240min
Methotrexate	25mg/ml (25,000 ppm)	>240min
Mitomycin C	0.5 mg/ml(500 ppm)	>240min
Mitoxantrone HCl	2 mg/ml (2,000 ppm)	>240min
Paclitaxel	6 mg/ml (6,000 ppm)	>240min
Thiotepa	10 mg/ml (10,000 ppm)	59.4(67.5,59.4,65.9)
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240min

The tested non-chemotherapy drugs are:		
Fentanyl Citrate injection	100mcg/2ml	＞240min

Note: Carmustine and Thiotepa have extremely low permeation times of 27.7 and 59.4 minutes respectively.

Warning: Do Not Use with Carmustine, Thiotepa

8. Technological Characteristic Comparison Summary

Table 1 Comparison of Technology Characteristics

ITEM	**Proposed Device (K241970)** Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	**Predicate Device(K202356)** Powder free Nitrile Examination Gloves (Blue, Violet Blue, White, Cobalt Blue)	**Reference Device (K240629)** Nitrile Disposable Examination Gloves, Tested for Use with Chemotherapy Drugs and Fentanyl	**Remark**
Product Code	LZA, LZC,OPJ, QDO	LZA	LZA, LZC, OPJ, QDO	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	I	SAME
Intended Use	The Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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: Drugs / Concentration / Minimum Breakthrough Detection Time The tested chemotherapy drugs are: Carmustine / 3.3 mg/ml(3,300 ppm) / 27.7 (35.5,27.7,27.7) Cisplatin / 1 mg/ml (1,000 ppm) / >240min Cyclophosphamide / 20mg/ml (20,000 ppm) / >240min Dacarbazine / 10mg/ml (10,000 ppm) / >240min Doxorubicin HCl / 2 mg/ml(2,000 ppm) / >240min Etoposide / 20 mg/ml (20,000 ppm) / >240min Fluorouracil / 50mg/ml (50,000 ppm) / >240min Gemcitabine HCl / 38 mg/ml (38,000 ppm) / >240min Ifosfamide / 50mg/ml (50,000 ppm) / >240min Methotrexate / 25mg/ml (25,000 ppm) / >240min Mitomycin C / 0.5 mg/ml(500 ppm) / >240min Mitoxantrone HCl / 2 mg/ml (2,000 ppm) / >240min Paclitaxel / 6 mg/ml (6,000 ppm) / >240min Thiotepa / 10mg/ml (10,000 ppm) / 59.4(67.5,59.4,65.9) Vincristine Sulfate / 1 mg/ml (1,000 ppm) / >240min The tested non-chemotherapy drugs are: Fentanyl Citrate injection / 100mcg/2ml / >240min Note: Carmustine and Thiotepa have extremely low permeation times of 27.7 and 59.4 minutes respectively.	The Powder free Nitrile Examination Gloves (Blue, Violet Blue, White, Cobalt Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	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: 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 Thiotep have extremely low permeation times of 26.7 and 37.6 minutes respectively.	Similar 1

		Warning: Do Not Use with Carmustine, Thiotepa		Warning: Do Not Use with Carmustine, Thiotepa.	
Powder free		Yes	Yes	Yes	SAME
Material		Nitrile	Nitrile	Nitrile	SAME
Color		Blue	Blue, Violet Blue, White, Cobalt Blue	Blue	SAME
OTC use		Yes	Yes	Yes	SAME
Sterility		Non-sterile	Non-sterile	Non-sterile	SAME
Use		Singe use	Single use	Singe use	SAME
Labeling claim		Tested for Use with Chemotherapy Drugs and Fentanyl	Not Tested for use with Chemotherapy Drugs and Fentanyl	Tested for Use with Chemotherapy Drugs and Fentanyl	SAME
Size and Dimensions (mm)		Length: Min 230mm for size XS-XXL Width: XS:70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10 XXL:130±10	Length: Min 230mm for size XS-XL Width: XS:70±10 S: 80±10 M: 95±10 L: 110±10 XL: 120±10	Length: Min 220mm for size S Min 230mm for size M-XL Width: S: 80±10 M: 95±10 L: 110±10 XL: 120±10	Different 1
Thickness (mm)		Finger:0.08-0.14±0.01 Palm:0.06-0.10 ±0.01	Finger:0.08-0.14±0.01 Palm:0.06-0.10 ±0.01	Finger: ≥0.05; Palm: ≥0.05	
Physical Properties	Before Aging	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	SAME
		Ultimate Elongation:500% min	Ultimate Elongation:500% min	Ultimate Elongation:500% min	SAME
	After Aging	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	Tensile Strength: 14MPa, min	SAME
		Ultimate Elongation:400% min	Ultimate Elongation:400% min	Ultimate Elongation:400% min	SAME
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151	Be free from holes when tested in accordance with ASTMD5151	Be free from holes when tested in accordance with ASTMD5151	SAME
Powder Content		Meet the requirements of ASTM D6124 Less than 2mg per glove	Meet the requirements of ASTM D6124 Less than 2mg per glove	Meet the requirements of ASTM D6124 Less than 2mg per glove	SAME

<table>
<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>
<tr><td>Carmustine</td><td>3.3 mg/ml(3,300 ppm)</td><td>27.7
(35.5,27.7,27.7)</td></tr>
<tr><td>Cisplatin</td><td>1 mg/ml (1,000 ppm)</td><td>>240min</td></tr>
<tr><td>Cyclophosphamide</td><td>20 mg/ml (20,000 ppm)</td><td>>240min</td></tr>
<tr><td>Dacarbazine</td><td>10mg/ml (10,000 ppm)</td><td>>240min</td></tr>
<tr><td>Doxorubicin HCl</td><td>2 mg/ml(2,000 ppm)</td><td>>240min</td></tr>
<tr><td>Etoposide</td><td>20 mg/ml (20,000 ppm)</td><td>>240min</td></tr>
<tr><td>Fluorouracil</td><td>30mg/ml (30,000 ppm)</td><td>>240min</td></tr>
<tr><td>Gemcitabine HCl</td><td>38 mg/ml (38,000 ppm)</td><td>>240min</td></tr>
<tr><td>Ifosfamide</td><td>50mg/ml (50,000 ppm)</td><td>>240min</td></tr>
<tr><td>Methotrexate</td><td>25mg/ml (25,000 ppm)</td><td>>240min</td></tr>
<tr><td>Mitomycin C</td><td>0.5 mg/ml(500 ppm)</td><td>>240min</td></tr>
<tr><td>Mitoxantrone HCl</td><td>2 mg/ml (2,000 ppm)</td><td>>240min</td></tr>
<tr><td>Paclitaxel</td><td>6 mg/ml (6,000 ppm)</td><td>>240min</td></tr>
<tr><td>Thiotepa</td><td>10 mg/ml (10,000 ppm)</td><td>59.4(87.5,59.4,63.9)</td></tr>
<tr><td>Vincristine Sulfate</td><td>1 mg/ml (1,000 ppm)</td><td>>240min</td></tr>
<tr><td colspan="3">The tested non-chemotherapy drugs are:</td></tr>
<tr><td>Fentanyl Citrate Injection</td><td>100mcg/2ml</td><td>>240min</td></tr>
</table>
Note: Carmustine and Thiotepa have extremely low permeation times of 27.7 and 59.4 minutes respectively.
Warning: Do Not Use with Carmustine, Thiotepa
</td>
<td>NA</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>
<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>Similar 2</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Irritation and Sensitization:Under the conditions of the study, not an irritant and not a sensitizer

Cytotoxicity:Under conditions of the study, not cytotoxic</td>
<td>Irritation and Sensitization:Under the conditions of the study, not an irritant and not a sensitizer

Cytotoxicity:Under conditions of the study, not cytotoxic</td>
<td>ISO 10993-10, under the conditions of the study, not an irritant or a sensitizer

ISO 10993-11, under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.</td>
<td>SAME</td>
</tr>
</table>

Similar 1-Indications for use

The proposed device and the reference device have same indications, only minor differences on different drugs and the penetration time of carmustine and thiotepa between the proposed device and the predicate device, which will not raise any new safety or performance.

Different 1-Size and dimension, Thickness

The size and dimension, Thickness of the proposed device is not exactly same as the predicate and reference device. However, the size and dimension, thickness of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user's hand. In addition, its dimension and thickness have been tested and met the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Similar 2-Chemotherapy and non-chemo therapy Drugs

Only minor differences on different drugs and the penetration time of carmustine and thiotepa between the proposed device and the reference device. And met the requirement of ASTM D6978-05. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

9. Summary of Non-Clinical Testing

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:

ISO 10993-10: 2021 Biological Evaluation Of Medical Devices - Part 10: Tests For Skin Sensitization

ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D6124-06 (Reapproved 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 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Table 2 Summary of non clinical performance testing

Test Method	**Purpose**	**Acceptance Criteria**	**Results**
ASTM D6319-19	Physical Dimensions Test	Length (mm): XS/S/M/L/XL/XXL: ≥230 Width(mm): XS: 70±10mm; S: 85±10mm; M: 95±10mm; L: 110±10 mm; XL: 120±10 mm XXL:130±10 mm	Pass

		Thickness (mm): Finger: ≥0.05; Palm: ≥0.05		Pass
ASTM D5151-19	Watertightness Test for Detection of Holes	Be free from holes when tested in accordance with ASTM D5151		Pass
ASTM D412	Physical Properties	Before Aging	Tensile Strength: 14MPa, min	Pass
			Ultimate Elongation:500% min	Pass
		After Aging	Tensile Strength: 14MPa, min	Pass
			Ultimate Elongation:400% min	Pass
ASTM D6124	Powder Content	Meet the requirements of Less than 2mg per glove		Pass
ASTMD 6978-05 (2019)	Detect the Permeation time by Chemotherapy Drugs and Fentanyl of the glove	Meet the requirements of ASTMD 6978-05.		Pass
ISO 10993-10	Irritation and Sensitization	Non-irritating; Non- sensitizer		Under the conditions of the study, not an irritant and not a sensitizer
ISO 10993-5	Cytotoxicity	Non Cytotoxic		Under conditions of the study, not cytotoxic.

10. Summary of Clinical Testing

    Not applicable

11. Conclusions

    The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device, K202356.