February 9, 2024

Luliang Hongruida Health Protection Technology Co., Ltd.
Guocai Zhang
General Manager
Zhaokua Area, Luliang Industrial Zone,
Qujing, Yunnan 655606
China

Re: K240072
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested For Use With Chemotherapy Drugs and Fentanyl Citrate
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: January 10, 2024
Received: January 10, 2024

Dear Guocai Zhang:

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
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240072

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

Indications for Use *(Describe)*
The glove is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, gloves were tested for use with Chemotherapy drugs and Fentanyl citrate in accordance with ASTM D6978.

Blue gloves:

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine 3.3 mg/ml (3,300 ppm)	25.5
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 HCL, 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
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin, 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/Carboplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	66.8
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib) , 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate	Minimum BDT (Minutes)
Fentanyl Citrate Injection (100mcg/2mL)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 25.5 minutes, Thiotepa: 66.8 minutes
Warning: Do not use with Carmustine and Thiotepa.

Purple-Blue gloves:

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine 3.3 mg/ml (3,300 ppm)	21.2
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 HCL, 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
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin, 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/Carboplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	36.3
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib) , 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate	Minimum BDT (Minutes)
Fentanyl Citrate Injection (100mcg/2mL)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 21.2 minutes, Thiotepa: 36.3 minutes
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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Luliang Hongruida Health Protection Technology Co., Ltd.

Zhaokua Area, Luliang Industrial Zone, Qujing City,
Yunnan Province, 655606 China

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

The assigned 510(K) numbers: K240072
Date Prepared: February 06, 2024

1. Owner's Identification:

Mr. Zhang Guocai
Luliang Hongruida Health Protection Technology Co., Ltd.
Zhaokua Area, Luliang Industrial Zone, Qujing City, Yunnan Province, 655606 China
Tel: 86-311-66179668

Contact: Mr. Zhang Guocai
Luliang Hongruida Health Protection Technology Co., Ltd.
Zhaokua Area, Luliang Industrial Zone, Qujing City, Yunnan Province, 655606 China
Tel: 909-590-1611
Email: fdareg@hongray.com.cn or janicema@hongrayusa.com

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name: Examination Gloves
Classification Name: Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA LZC QDO OPJ
Classification Panel: General Hospital and Personal use
Device Class: Class I

3. Predicate Device Information:

Luliang Hongruida Health Protection Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs (K213440)
Device Class: Class I
Product Code: LZA LZC

4. Device Description:

Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate Are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes—Extra Small, Small, Medium, Large, Extra Large and XXL. Gloves meet 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(2019).

5. Device Modification

The proposed modification to the predicate device is to add the claim that the subject device was tested for use with fentanyl citrate besides the claim of use with Chemotherapy drugs. The proposed device (exactly same as predicate device) was tested for use with fentanyl citrate as per ASTM D6978. There are no differences with these two gloves in materials, manufacturing process and bench performance.

6. Indications for Use:

The glove is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, gloves were tested for use with Chemotherapy drugs and fentanyl citrate in accordance with ASTM D6978.

Blue gloves

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine 3.3 mg/ml (3,300 ppm)	25.5
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 HCL, 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
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin, 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/Carboplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	66.8
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib) , 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate	Minimum BDT (Minutes)
Fentanyl Citrate Injection (100mcg/2mL)	>240

Luliang Hongruida Health Protection Technology Co., Ltd.
Zhaokua Area, Luliang Industrial Zone, Qujing City,
Yunnan Province, 655606 China

* Please note that the following drugs have extremely low permeation times:
Carmustine: 25.5 minutes, Thiotepa: 66.8 minutes
Warning: Do not use with Carmustine and Thiotepa.
Purple-Blue gloves

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine 3.3 mg/ml (3,300 ppm)	21.2
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 HCL, 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
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin, 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/Carboplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	36.3
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib) , 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate	Minimum BDT (Minutes)
Fentanyl Citrate Injection (100mcg/2mL)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 21.2 minutes, Thiotepa: 36.3 minutes
Warning: Do not use with Carmustine and Thiotepa.

7. Comparison of Technological Characteristics Between the Subject Device and Predicate Device

Items	Subject Device K240072	Predicate Device K213440	Result of comparison
Trade Name	Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Powder Free Nitrile Examination Gloves (Blue, Purple-Blue), Tested for Use with Chemotherapy Drugs	Different*
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC	Different*
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	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. In additiongloves were tested for use with Chemotherapy drugs and fentanyl citrate in accordance with ASTM D6978.	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. In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978.	Different*
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Material use	Nitrile	Nitrile	Same
Color	Blue, Purple-Blue	Blue, Purple-Blue	Same
Sterility	Non-Sterile	Non-Sterile	Same
Single use	Single use	Single use	Same
Chemotherapy Drug and Fentanyl Citrate Permeation Claim	See below comparison table	See below comparison table	/

** The subject device and predicate device are exactly the same. The subject device was tested for use with Chemotherapy drugs and fentanyl citrate, but the predicate device was tested for use with Chemotherapy drugs only.*

Dimensions and Performance Comparison Table:

Technological Characteristics	Subject Device K240072	Predicate Device K213440	Result of comparison
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	Same
Palm Width (size) (mm)			
XS	70±10	70±10	Same
S	80±10	80±10	Same
M	95±10	95±10	Same

L	110±10	110±10	Same
XL	120±10	120±10	Same
XXL	130±10	130±10	Same
Thickness(mm)			
Finger	Minimum 0.05	Minimum 0.05	Same
Palm	Minimum 0.05	Minimum 0.05	Same
Tensile Strength, Before Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	Same
Freedom from holes	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Same
ISO 10993-10:2010 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
ISO 10993-10:2010 Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
ISO 10993-5:2009 Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity	Under the conditions of this study, the test article extract showed potential toxicity	Same
ISO 10993 Part 11 Systemic toxicity	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

Chemotherapy Permeation Comparison:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)				Result of comparison
	Subject Device K240072		Predicate Device K213440		
	Blue	Purple-Blue	Blue	Purple-Blue	
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	>240	>240	>240	Same
Busulfan 6mg/ml (6,000 ppm)	>240	>240	>240	>240	Same
Carboplatin 10mg/ml (10,000 ppm)	>240	>240	>240	>240	Same
Carmustine 3.3 mg/ml (3,300 ppm)	25.5	21.2	25.5	21.2	Same
Chloroquine 50mg/ml (50,000ppm)	>240	>240	>240	>240	Same
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240	>240	Same

Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	>240	Same
Cyclosporin 100 mg/ml (100,000 ppm)	>240	>240	>240	>240	Same
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240	>240	>240	>240	Same
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240	>240	Same
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	>240	>240	>240	Same
Docetaxel HCL, 10 mg/ml (10,000 ppm)	>240	>240	>240	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	>240	Same
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240	>240	Same
Fludarabine, 25 mg/ml (25,000 ppm)	>240	>240	>240	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	>240	Same
Gemcitabine, 38mg/ml (38,000ppm)	>240	>240	>240	>240	Same
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Ifosfamide, 50mg/ml (50,000ppm)	>240	>240	>240	>240	Same
Irinotecan, 20mg/ml (20,000ppm)	>240	>240	>240	>240	Same
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Melphalan, 5mg/ml (5,000ppm)	>240	>240	>240	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	>240	Same
Mitomycin, 0.5mg/ml (500ppm)	>240	>240	>240	>240	Same
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	>240	>240	>240	Same
Oxaliplatin, 5mg/ml (5,000ppm)	>240	>240	>240	>240	Same
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240	>240	Same
Paraplatin/Carboplatin, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same
Retrovir, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same
Rituximab, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same
Thiotepa, 10mg/ml (10,000ppm)	66.8	36.3	66.8	36.3	Same
Topotecan, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Trisenox, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Velcade (Bortezomib) , 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same

Fentanyl Citrate Permeation Comparison:

Fentanyl Citrate and Concentration	Minimum BDT (Minutes)				Result of comparison
	Subject Device K240072		Predicate Device K213440		
	Blue	Purple-Blue	Blue	Purple-Blue	
Fentanyl Citrate Injection (100mcg/2mL)	>240	>240	/	/	Different*

** The subject device and predicate device are exactly the same. The subject device was tested for use with Chemotherapy drugs and fentanyl citrate, but the predicate device was tested for use with Chemotherapy drugs only.*

8. Summary of Non-Clinical Testing

Non-clinical tests were performed to verify that the subject device will meet the acceptance criteria of the performance test shown below:

Referenced standards	Test Performed/Purpose	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for size XS and S, 230mm for size M, L, XL, 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 ASTM D412-16 (2021)	Physical Properties	Tensile Strength (Min14 Mpa) Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Freedom from holes	G-I, AQL 2.5	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	Chemotherapy Drugs, Opioid Drug Permeation	Refer the above tables	Pass
ISO 10993-10:2010	Irritation and Skin Sensitization	No Skin sensitization and Skin irritation	Is non-sensitization and Non-irritation
ISO 10993-5:2009 Cytotoxicity Test	Cytotoxicity Test	Under the conditions of this study, no cytotoxic potential	Under the conditions of this study, the test article extract showed potential toxicity
ISO 10993-11:2017 systemic toxicity	Acute systemic toxicity study	Subject showed no adverse biological reaction	Under the conditions of this study, there was no evidence of acute systemic toxicity.

9. Summary of Clinical Testing:

No clinical testing was submitted for the subject device.

10. Conclusion:

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 predicate device.