October 26, 2023

Zhonghong Pulin Medical Products Co.,Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608,No.738,Shangcheng Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K230662
Trade/Device Name: Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, And Select Other Drugs
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: September 26, 2023
Received: September 26, 2023

Dear Boyle 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

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

Indications for Use

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

510(k) Number *(if known)*
K230662

Device Name
Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, And Select Other Drugs

Indications for Use *(Describe)*
A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.
In addition, these gloves were tested for use with chemotherapy drugs, Fentanyl Citrate, and select other drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough Detection Time (minutes)
Bendamustine HCl	5 mg/ml (5,000 ppm)	> 240
Bleomycin Sulfate	15 mg/ml (15,000 ppm)	> 240
Busulfan	6 mg/ml(6,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Carfilzomib	2 mg/ml (2,000 ppm)	> 240
Carmustine	3.3 mg/ml (3,300 ppm)	21.1 (24.2, 21.1, 25.3)
Cetuximab	2 mg/ml (2,000 ppm)	> 240
Cisplatin	1 mg/ml (1000 ppm)	> 240
Cladribine	1 mg/ml (1000 ppm)	> 240
Cyclophosphamide	20 mg/ml (20.000 ppm)	> 240
Cytarabine(Cytosine)	10 mg/ml(10,000 ppm)	> 240
Cytovene(Ganciclovir)	10 mg/ml(10,000 ppm)	> 240
Dacarbazine	10 mg/ml(10,000 ppm)	> 240
Daunorubicin HCl	5 mg/ml (5,000 ppm)	> 240
Decitabine	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 HCI (Ellence)	20 mg/ml (20,000 ppm)	> 240
Etoposide	20 mg/ml (20,000 ppm)	> 240
Fludarabine	25.0 mg/ml (25,000 ppm)	> 240
Fluorouracil	50 mg/ml,(50,000 ppm)	> 240
Fulvestrant	50 mg/ml(50,000 ppm)	> 240
Gemcitabine	38 mg/ml (38,000 ppm)	> 240
Idarubicin HCL	1.0 mg/ml (1,000 ppm)	> 240
lfosfamide	50 mg/ml (50,000 ppm)	> 240
lrinotecan HCl	20 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCl	1 mg/mI(1,000 ppm)	> 240
Melphalan	5 mg/ml(5000 ppm)	> 240
Methotrexate	25 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone HCL	2 mg/ml (2,000 ppm)	> 240
Oxaliplatin	5 mg/ml (5,000 ppm)	> 240
Paclitaxel	6 mg/ml (6,000 ppm)	> 240
Paraplatin	10 mg/ml (10,000 ppm)	> 240

Pemetrexed	25 mg/ml (25,000 ppm)	> 240
Raltitrexed	0.5 mg/ml (500 ppm)	> 240
Rituximab	10 mg/ml (10,000 ppm)	> 240
Temsirolimus	25 mg/ml (25,000 ppm)	> 240
Thiotepa	10 mg/ml(10,000 ppm)	74.9 (74.9, 96.7, 79.0)
Topotecan	1 mg/ml (1,000 ppm)	> 240
Trisenox (Arsenic Trioxide)	1 mg/ml (1,000 ppm)	> 240
Vinblastine,	1 mg/ml (1,000 ppm)	> 240
Vincristine sulfate (Oncovin)	1 g/ml (1,000 ppm)	> 240
Vinorelbine	10 mg/ml(10,000 ppm)	> 240

Fentanyl Citrate and other Drugs	Concentration	Breakthrough Detection Time (minutes)
Chloroquine	50 mg/m (50,000 ppm)	> 240
Cyclosporin A	100.0 mg/ml (100,000 ppm)	> 240
MESNA	100 mg/ml(100,000 ppm)	> 240
Retrovir	10 mg/ml(10,000 ppm)	> 240
Triclosan	3 mg/ml(3,000 ppm)	> 240
Zoledronic Acid	1 mg/25ml (40 ppm)	> 240
Fentanyl Citrate Injection	100mcg/2mL	> 240

Note: The maximum testing time is 240 minutes. And testing showed minimum breakthrough time of 21.1 minutes with Carmustine (3.3 mg/ml), 74.9 minutes with Thio Tepa (10 mg/ml).
Warning: Do not use with Carmustine and Thiotepa.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K230662

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

Name: Zhonghong Pulin Medical Products Co.,Ltd.
Address: West Industrial Park, BDA, Luannan County, Tangshan City, 063500 Hebei, P.R. China.
Phone Number: +86-18731635203
Contact: Li Yunjiao
Date of Preparation: 2023.10.23

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, And Select Other Drugs

Common name: Patient Examination Gloves

Classification name: Non-powdered patient examination glove

3.0 Classification

Production code: LZA, LZC, OPJ, QDO
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Name: Ever Global (Vietnam) Enterprise Corp.
Device Trade Name:

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs and Fentanyl Citrate
510(k) number: K193555

5.0 Indication for Use

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.
In addition, these gloves were tested for use with chemotherapy drugs, Fentanyl Citrate, and select other drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough Detection Time (minutes)
Bendamustine HCl	5 mg/ml (5,000 ppm)	> 240
Bleomycin Sulfate	15 mg/ml (15,000 ppm)	> 240
Busulfan	6 mg/ml(6,000 ppm)	> 240
Carboplatin	10.0 mg/ml (10,000 ppm)	> 240
Carfilzomib	2 mg/ml (2,000 ppm)	> 240
Carmustine	3.3 mg/ml (3,300 ppm)	21.1 (24.2, 21.1, 25.3)
Cetuximab	2 mg/ml (2,000 ppm)	> 240
Cisplatin	1 mg/ml (1000 ppm)	> 240
Cladribine	1 mg/ml (1000 ppm)	> 240
Cyclophosphamide	20 mg/ml (20.000 ppm)	> 240
Cytarabine(Cytosine)	10 mg/ml(10,000 ppm)	> 240
Cytovene(Ganciclovir)	100.0 mg/ml (100,000 ppm)	> 240
Dacarbazine	10 mg/ml(10,000 ppm)	> 240
Daunorubicin HCl	5 mg/ml (5,000 ppm)	> 240
Decitabine	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 (Ellence)	20 mg/ml (20,000 ppm)	> 240
Etoposide	20 mg/ml (20,000 ppm)	> 240
Fludarabine	25.0 mg/ml (25,000 ppm)	> 240
Fluorouracil	50 mg/ml,(50,000 ppm)	> 240
Fulvestrant	50 mg/ml(50,000 ppm)	> 240
Gemcitabine	38 mg/ml (38,000 ppm)	> 240
Idarubicin HCL	1.0 mg/ml (1,000 ppm)	> 240
Ifosfamide	50 mg/ml (50,000 ppm)	> 240
Irinotecan HCl	20 mg/ml (20,000 ppm)	> 240
Mechlorethamine HCl	1 mg/ml(1,000 ppm)	> 240
Melphalan	5 mg/ml(5000 ppm)	> 240
Methotrexate	25 mg/ml (25,000 ppm)	> 240
Mitomycin C	0.5 mg/ml (500 ppm)	> 240
Mitoxantrone HCL	2 mg/ml (2,000 ppm)	> 240
Oxaliplatin	5 mg/ml (5,000 ppm)	> 240
Paclitaxel	6 mg/ml (6,000 ppm)	> 240
Paraplatin	10 mg/ml (10,000 ppm)	> 240
Pemetrexed	25 mg/ml (25,000 ppm)	> 240
Raltitrexed	0.5 mg/ml (500 ppm)	> 240
Rituximab	10 mg/ml (10,000 ppm)	> 240
Temsirolimus	25 mg/ml (25,000 ppm)	> 240
Thiotepa	10 mg/ml(10,000 ppm)	74.9 (74.9, 96.7, 79.0)
Topotecan	1 mg/ml (1,000 ppm)	> 240

Trisenox (Arsenic Trioxide)	1 mg/ml (1,000 ppm)	> 240
Vinblastine,	1 mg/ml (1,000 ppm)	> 240
Vincristine sulfate (Oncovin)	1 g/ml (1,000 ppm)	> 240
Vinorelbine	10 mg/ml(10,000 ppm)	> 240

Fentanyl Citrate and other Drugs	**Concentration**	**Breakthrough Detection Time (minutes)**
Chloroquine	50 mg/m (50,000 ppm)	> 240
Cyclosporin A	100.0 mg/ml (100,000 ppm)	> 240
MESNA	100 mg/ml(100,000 ppm)	> 240
Retrovir	10 mg/ml(10,000 ppm)	> 240
Triclosan	3 mg/ml(3,000 ppm)	> 240
Zoledronic Acid	1 mg/25ml (40 ppm)	> 240
Fentanyl Citrate Injection	100mcg/2mL	> 240

Note: The maximum testing time is 240 minutes. And testing showed minimum breakthrough time of 21.1 minutes with Carmustine (3.3 mg/ml), 74.9 minutes with Thio Tepa (10 mg/ml).
Warning: Do not use with Carmustine and Thiotepa.

6.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, blue colored, nitrile, and tested for use with chemotherapy drugs And Fentanyl Citrate. The design of the subject device is addressing the standards as ASTM D6124, ASTM D5151, ASTM D6319, ASTM D6978-05. The gloves have a minimum length of 270mm. The Subject device is non-sterile.

7.0 Comparison of Technical Characteristics

General Comparison Table

Item	**Subject device** Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, And Select Other Drugs	**Predicate device** Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate	**Comparison**
510(k) number	K230662	K193555	/
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC, QDO	Similar
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Indications For Use	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to	Similar

	contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs, Fentanyl Citrate, and select other drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs.	
	Chemotherapy Drug Concentration Breakthrough Detection Time (minutes) Bendamustine HCl 5 mg/ml (5,000 ppm) > 240 Bleomycin Sulfate 15 mg/ml (15,000 ppm) > 240 Busulfan 6 mg/ml(6,000 ppm) > 240 Carboplatin 10.0 mg/ml (10,000 ppm) > 240 Carfilzomib 2 mg/ml (2,000 ppm) > 240 Carmustine 3.3 mg/ml (3,300 ppm) 21.1 (24.2, 21.1, 25.3) Cetuximab 2 mg/ml (2,000 ppm) > 240 Cisplatin 1 mg/ml (1000 ppm) > 240 Cladribine 1 mg/ml (1000 ppm) > 240 Cyclophosphamide 20 mg/ml (20.000 ppm) > 240 Cytarabine(Cytosine) 10 mg/ml(10,000 ppm) > 240 Cytovene(Ganciclovir) 10 mg/ml(10,000 ppm) > 240 Dacarbazine 10 mg/ml(10,000 ppm) > 240 Daunorubicin HCl 5 mg/ml (5,000 ppm) > 240 Decitabine 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 (Ellence) 20 mg/ml (20,000 ppm) > 240 Etoposide 20 mg/ml (20,000 ppm) > 240 Fludarabine 25.0 mg/ml (25,000 ppm) > 240 Fluorouracil 50 mg/ml,(50,000 ppm) > 240 Fulvestrant 50 mg/ml(50,000 ppm) > 240 Gemcitabine 38 mg/ml (38,000 ppm) > 240 Idarubicin HCL 1.0 mg/ml (1,000 ppm) > 240 Ifosfamide 50 mg/ml (50,000 ppm)	Test Chemotherapy Drug Concentration (mg/ml) Minimum Breakthrough Detection Time (Min.) 1 Arsenic Trioxide (1.0 mg/ml) > 240 2 Azacitidine (Vidaza) (25.0 mg/ml) > 240 3 Bendamustine HCl (5.0 mg/ml) > 240 4 Bleomycin Sulfate (15.0 mg/ml) > 240 5 Bortezomib (Velcade) (1.0 mg/ml) > 240 6 Busulfan (6.0 mg/ml) > 240 7 Carboplatin (10.0 mg/ml) > 240 8 Carfilzomib (2.0 mg/ml) > 240 9 Carmustine (BCNU), (3.3 mg/ml) 6.2 10 Cetuximab (Erbitux) (2.0 mg/ml) > 240 11 Chloroquine (50.0 mg/ml) > 240 12 Cisplatin (1.0 mg/ml) > 240 13 Cladribine (1.0 mg/ml) > 240 14 Cyclophosphamide (20.0 mg/ml) > 240 15 Cyclosporine A (100.0 mg/ml) > 240 16 Cytarabine (100.0 mg/ml) > 240 17 Cytovene (Ganciclovir) (10.0 mg/ml) > 240 18 Dacarbazine (10.0 mg/ml) > 240 19 Daunorubicin (5.0 mg/ml) > 240 20 Decitabine (5.0 mg/ml) > 240 21 Docetaxel (10.0 mg/ml) > 240 22 Doxorubicin Hydrochloride (2.0 mg/ml) > 240 23 Epirubicin (Ellence) (2.0 mg/ml) > 240 24 Etoposide (20.0 mg/ml) > 240 25 Fludarabine (25.0 mg/ml) > 240 26 Fluorouracil (50.0 mg/ml) > 240 27 Fulvestrant (50.0 mg/ml) > 240 28 Gemcitabine (38.0 mg/ml) > 240 29 Idarubicin (1.0 mg/ml) > 240	

	> 240 Irinotecan HCl 20 mg/ml (20,000 ppm) > 240 Mechlorethamine HCl 1 mg/ml(1,000 ppm) > 240 Melphalan 5 mg/ml(5000 ppm) > 240 Methotrexate 25 mg/ml (25,000 ppm) > 240 Mitomycin C 0.5 mg/ml (500 ppm) > 240 Mitoxantrone HCL 2 mg/ml (2,000 ppm) > 240 Oxaliplatin 5 mg/ml (5,000 ppm) > 240 Paclitaxel 6 mg/ml (6,000 ppm) > 240 Paraplatin 10 mg/ml (10,000 ppm) > 240 Pemetrexed 25 mg/ml (25,000 ppm) > 240 Raltitrexed 0.5 mg/ml (500 ppm) > 240 Rituximab 10 mg/ml (10,000 ppm) > 240 Temsirolimus 25 mg/ml (25,000 ppm) > 240 Thiotepa 10 mg/ml(10,000 ppm) 74.9 (74.9, 96.7, 79.0) Topotecan 1 mg/ml (1,000 ppm) > 240 Trisenox (Arsenic Trioxide) 1 mg/ml (1,000 ppm) > 240 Vinblastine, 1 mg/ml (1,000 ppm) > 240 Vincristine sulfate (Oncovin) 1 g/ml (1,000 ppm) > 240 Vinorelbine 10 mg/ml(10,000 ppm) > 240 Fentanyl Citrate and other Drugs Concentration Breakthrough Detection Time (minutes) Chloroquine 50 mg/m (50,000 ppm) > 240 Cyclosporin A 100.0 mg/ml (100,000 ppm) > 240 MESNA 100 mg/ml(100,000 ppm) > 240 Retrovir 10 mg/ml(10,000 ppm) > 240 Triclosan 3 mg/ml(3,000 ppm) > 240 Zoledronic Acid 1 mg/25ml (40 ppm) > 240 Fentanyl Citrate Injection 100mcg/2mL > 240 Note: The maximum testing time is 240 minutes. And testing showed minimum	30 Ifosfamide (50.0 mg/ml) > 240 31 Irinotecan (20.0 mg/ml) > 240 32 Mechlorethamine HCl (1.0 mg/ml) > 240 33 Melphalan (5.0 mg/ml) > 240 34 Methotrexate (25 mg/ml) > 240 35 Mesna (100 mg/ml) > 240 36 Mitomycin C (0.5 mg/ml) > 240 37 Mitoxantrone (2.0 mg/ml) > 240 38 Oxaliplatin (5.0 mg/ml) > 240 39 Paclitaxel (6.0mg/ml) > 240 40 Paraplatin (10.0 mg/ml) > 240 41 Pemetrexed (25.0 mg/ml) > 240 42 Pertuzumab (30.0 mg/ml) > 240 43 Raltitrexed (0.5 mg/ml) > 240 44 Retrovir (10.0 mg/ml) > 240 45 Rituximab (10.0 mg/ml) > 240 46 Temsirolimus (25.0 mg/ml) > 240 47 Thiotepa (10.0 mg/ml) 13.6 48 Topotecan HCl (1.0 mg/ml) > 240 49 Trastuzumab (21.0 mg/ml) > 240 50 Triclosan (2.0 mg/ml) > 240 51 Trisenox (1.0 mg/ml) > 240 52 Vinblastine (1.0 mg/ml) > 240 53 Vincristine Sulfate (1.0 mg/ml) > 240 54 Vinorelbine (10.0 mg/ml) > 240 55 Zoledronic Acid (0.8 mg/ml) > 240 Warning: do not use with Carmustine and Thiotepa. The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time: Carmustine (BCNU), 3.3 mg/ml 6.2 minutes Thiotepa, 10.0 mg/ml 13.6 minutes Fentanyl Permeation Resistance Claim - Under the testing conditions of ASTM D6978-05, Fentanyl Citrate Injection (100mcg/2mL) was found to have no breakthrough detected up to 240 minutes.	

	breakthrough time of 21.1 minutes with Carmustine (3.3 mg/ml), 74.9 minutes with Thio Tepa (10 mg/ml). Warning: Do not use with Carmustine and Thiotepa.		
Powdered or Power free	Powder free	Powder free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non-Sterile	Non-Sterile	Same
Main Material	Powder-Free Nitrile	Nitrile	Similar
Colors	Blue	Blue	Same

Device Dimensions Comparison Table

Subject device K230662 Comply with ASTM D6319	Designation	Size (mm)					
		XS	S	M	L	XL	XXL
	Length, mm	287-293	288-297	287-300	290-297	283-301	292-300
	Criteria	≥270	≥270	≥270	≥270	≥270	≥270
	Results	Pass	Pass	Pass	Pass	Pass	Pass
	Width, mm	78-80	84-86	96-97	105-107	113-115	122-124
	Criteria	70±10	80±10	95±10	110±10	120±10	130±10
	Results	Pass	Pass	Pass	Pass	Pass	Pass
	Thickness, mm:						
	Finger	（0.082-0.185）					
	Criteria	> 0.05					
	Results	pass					
	Palm	（0.065-0.123）					
	Criteria	0.05					
	Results	pass					
Predicate Device (K193555) Comply with ASTM D6319	Designation	Size (mm)					
		XS	S	M	L	XL	
	Length, mm	≥300	≥300	≥300	≥300	≥300	
	Criteria	≥220	≥220	≥230	≥230	≥230	
	Results	Pass	Pass	Pass	Pass	Pass	
	Width, mm	70±10	80±10	95±10	110±10	120±10	
	Criteria	70±10	80±10	95±10	110±10	120±10	
	Results	Pass	Pass	Pass	Pass	Pass	
	Thickness, mm:						
	Finger	0.05mm min.					
	Criteria	> 0.05					
	Results	pass					
	Palm	0.05mm min.					
	Criteria	0.05					
	Results	pass					
Remarks	Similar. The subject gloves have a minimum length of 270mm.						

Performance Comparison Table

Item	Subject device K230662	Predicate device (K193555)	Remark

Physical Properties			Comply with ASTM D6319	Comply with ASTM D6319	Same
	Before Aging	Tensile Strength	(19.9-28.9)MPa	14MPa, min	Same
		Criteria	14MPa, min	14MPa, min	
		Results	Pass	Pass	
		Ultimate Elongation	(540-580)%	500% min	Same
		Criteria	500% min	500% min	
		Results	Pass	Pass	
	After Aging	Tensile Strength	(20.2-29.1)MPa	14MPa, min	Same
		Criteria	14MPa, min	14MPa, min	
		Results	Pass	Pass	
		Ultimate Elongation	(508-528)%	400%min	Same
		Criteria	400%min	400%min	
		Results	Pass	Pass	
Freedom from Holes			accordance with ASTMD5151	accordance with ASTMD5151	Same
		Criteria	AQL: 2.5 (ISO 2859)	G-1, AQL 2.5	
		Results	0 gloves of failure Pass	Pass	
Powder Content			Meet the requirements of ASTM D6319	Meet the requirements of ASTM D6319	Same
		Criteria	< 2.0mg per glove	< 2.0mg per glove	
		Results	1.9 mg/glove Pass	Pass	
Chemotherapy Drugs and Fentanyl Citrate Injection Tested with Minimum Breakthrough Detection Time as Tested per ASTM D6978			Bendamustine HCl 5 mg/ml (5,000 ppm) > 240 min.	Bendamustine HCl (5.0 mg/ml) > 240 min.	Same
			Bleomycin Sulfate 15 mg/ml (15,000 ppm) > 240 min.	Bleomycin Sulfate 15 mg/ml > 240 min.	Same
			Busulfan 6 mg/ml(6,000 ppm) > 240 min.	Busulfan 6 mg/ml > 240 min	Same
			Carboplatin 10.0 mg/ml (10,000 ppm) > 240 min.	Carboplatin 10 mg/ml > 240 min.	Same
			Carfilzomib 2 mg/ml (2,000 ppm) > 240 min.	Carfilzomib (2.0 mg/ml) > 240 min.	Same
			Carmustine 3.3 mg/ml (3,300 ppm) 21.1 (24.2, 21.1, 25.3)min.	Carmustine (BCNU) 3.3 mg/ml 37.5 min.	Similar
			Cetuximab 2 mg/ml (2,000 ppm) > 240 min.	Cetuximab (Erbitux) (2.0 mg/ml) > 240 min.	Same
			Chloroquine 50 mg/m (50,000 ppm) > 240 min.	Chloroquine (50.0 mg/ml) > 240 min.	Same
			Cisplatin 1 mg/ml(1,000 ppm) > 240 min.	Cisplatin 1.0 mg/ml > 240 min.	Same
			Cladribine 1 mg/ml (1000 ppm) > 240 min.	Cladribine (1.0 mg/ml) > 240 min.	Same
			Cyclophosphamide 20 mg/ml (20.000 ppm) > 240 min.	Cyclophosphamide (20.0 mg/ml) > 240 min	Same
			Cyclosporin A	Cyclosporin A	Same

	100 mg/ml (100,000 ppm) > 240 min.	(100.0 mg/ml) > 240 min.	
	Cytarabine(Cytosine) 100.0 mg/ml (100,000 ppm) > 240 min.	Cytarabine (100.0 mg/ml) > 240 min	Same
	Cytovene(Ganciclovir) 10 mg/ml(10,000 ppm) > 240 min.	Cytovene (Ganciclovir) (10.0 mg/ml) > 240 min.	Same
	Dacarbazine 10 mg/ml(10,000 ppm) > 240 min.	Dacarbazine (DTIC) 10.0 mg/ml > 240 min.	Same
	Daunorubicin HCl 5 mg/ml (5,000 ppm) > 240 min.	Daunorubicin 5 mg/mL > 240 min.	Same
	Decitabine 5 mg/ml(5,000 ppm) > 240 min.	Decitabine (5.0 mg/ml) > 240 min.	Same
	Docetaxel 10 mg/ml (10.000 ppm) > 240 min.	Docetaxel 10.0 mg/ml > 240 min	Same
	Doxorubicin HCl 2 mg/ml (2,000 ppm) > 240 min.	Doxorubicin HCl 2.0 mg/ml: > 240 min	Same
	Epirubicin HCl (Ellence) 2 mg/ml (2,000 ppm) > 240 min.	Epirubicin (Ellence) 2.0 mg/ml > 240 min.	Same
	Etoposide 20 mg/ml (20,000 ppm) > 240 min.	Etoposide, (20.0 mg/ml) > 240 min.	Same
	Fludarabine 25.0 mg/ml (25,000 ppm) > 240 min.	Fludarabine 25.0 mg/ml > 240 min.	Same
	Fluorouracil 50 mg/ml,(50,000 ppm) > 240 min.	Fluorouracil 50.0 mg/ml: > 240 min	Same
	Fulvestrant 50 mg/ml(50,000 ppm) > 240 min.	Fulvestrant (50.0 mg/ml) > 240 min	Same
	Gemcitabine 38 mg/ml (38,000 ppm) > 240 min.	Gemcitabine 38 mg/ml > 240 min.	Same
	Idarubicin HCL 1.0 mg/ml (1,000 ppm) > 240 min.	Idarubicin 1 mg/ml > 240 min.	Same
	Ifosfamide 50 mg/ml (50,000 ppm) > 240 min.	Ifosfamide 50.0 mg/ml > 240 min.	Same
	Irinotecan HCl 20 mg/ml (20,000 ppm) > 240 min.	Irinotecan 20.0 mg/ml > 240 min.	Same
	Mechlorethamine HCl 1 mg/ml(1,000 ppm) > 240 min.	Mechlorethamine HCl 1.0 g/ml > 240 min.	Same
	Melphalan 5 mg/ml(5000 ppm) > 240 min.	Melphalan 5 mg/ml > 240 min.	Same
	Methotrexate 25 mg/ml (25,000 ppm) > 240 min.	Methotrexate 25 mg/ml > 240 min.	Same
	MESNA 100 mg/ml(100,000 ppm)	Mesna (100 mg/ml)	Same

	> 240 min.	> 240 min.	
	Mitomycin C 0.5 mg/ml (500 ppm) > 240 min.	Mitromycin C. 0.5 mg/ml > 240	Same
	Mitoxantrone HCL 2 mg/ml (2,000 ppm) > 240 min.	Mitoxantrone 2.0 mg/ml > 240 min.	Same
	Oxaliplatin 5 mg/ml (5,000 ppm) > 240 min.	Oxaliplatin 5 mg/ml > 240 min.	Same
	Paclitaxel 6 mg/ml (6,000 ppm) > 240 min.	Paclitaxel (Taxol) 6.0 mg/ml > 240 min.	Same
	Paraplatin 10 mg/ml (10,000 ppm) > 240 min.	Paraplatin 10 mg/ml > 240 min.	Same
	Pemetrexed 25 mg/ml (25,000 ppm) > 240 min.	Pemetrexed (25.0 mg/ml) > 240 min.	Same
	Raltitrexed 0.5 mg/ml (500 ppm) > 240 min.	Raltitrexed (0.5 mg/ml) > 240 min.	Same
	Retrovir 10 mg/ml(10,000 ppm) > 240 min.	Retrovir 10 mg/ml > 240 min.	Same
	Rituximab 10 mg/ml (10,000 ppm) > 240 min.	Rituximab 10.0 mg/ml > 240 min.	Same
	Temsirolimus 25 mg/ml (25,000 ppm) > 240 min.	Temsirolimus (25.0 mg/ml) > 240 min.	Same
	Thiotepa 10 mg/ml(10,000 ppm) 74.9 (74.9, 96.7, 79.0)min.	Thiotepa 10.0 mg/ml 13.6min.	Similar
	Topotecan 1 mg/ml (1,000 ppm) > 240 min.	Topotecan HCl (1.0 mg/ml) > 240 min.	Same
	Triclosan 3 mg/ml(3,000 ppm) > 240 min.	Triclosan (2.0 mg/ml) > 240 min.	Similar
	Trisenox (Arsenic Trioxide) 1 mg/ml (1,000 ppm) > 240 min.	Trisenox 1.0 mg/ml > 240 min.	Same
	Vinblastine, 1 mg/ml (1,000 ppm) > 240 min.	Vinblastine, 1 mg/ml (1,000 ppm) > 240 min.	Same
	Vincristine sulfate (Oncovin) 1 g/ml (1,000 ppm) > 240 min.	Vincristine Sulfate 1.0 mg/ml > 240 min.	Same
	Vinorelbine 10 mg/ml(10,000 ppm) > 240 min.	Vinorelbine 10 mg/ml > 240 min.	Same
	Zoledronic Acid 1 mg/25ml (40 ppm) > 240 min.	Zoledronic Acid (0.8 mg/ml) > 240 min.	Similar
	Fentanyl Citrate Injection 100mcg/2mL > 240 min.	Fentanyl Citrate Injection, (100 mcg/2ml) > 240 min	Same

Biocompatibility Evaluation Comparison Table

Items		Predicate device (K193555)	Subject device K230662	Remark
Material		Nitrile	Nitrile compounds	Similar
Bio-compatibility	Irritation	Comply with ISO10993-10	Comply with ISO10993-10	Similar
		Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	
	Sensitization	Comply with ISO10993-10	Comply with ISO10993-10	
		Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	
	Cytotoxicity	Comply with ISO10993-5	Comply with ISO10993-5	Similar
		Extraction conditions: 37°C and 72 hours	Test conditions: No descriptions in summary	
		Under the conditions of the study, the device is not shown cytotoxicity	Under conditions of the study, not cytotoxic	

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, and Select Other Drugs was conducted in accordance with the following standards:

ISO 10993-10:2010 *Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization.*

ISO 10993-5:2009 *Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity*

Performance Testing (Bench)

Physical performance qualities of the Subject device were evaluated per ASTM D6319-19, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

Permeation testing was conducted according to ASTM D6978-05 (Reapproved 2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs to support the addition of the labeling claim: Tested for use with chemotherapy drugs, fentanyl citrate, and select other drugs.

In summary, 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 D6124-06 (Reapproved 2017), *Standard Test Method for*

Residual Powder on Medical Gloves

- ASTM D5151-19, *Standard Test Method for Detection of Holes in Medical Gloves.*
- ASTM D6319-19, *Standard Specification for Nitrile Examination Gloves for Medical Application.*
- Assessment Of Resistance To Permeation By Chemotherapy Drugs And Fentanyl Citrate per ASTM D6978-05 (Reapproved 2019), *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

Table 1 Summary of Non-Clinical Testing

No.	Purpose of the Test	Standard	Acceptance Criteria	Results	Summary
	Methodology				
1	Test for skin sensitization potential	ISO 10993-10:20 10 Biological Evaluation Of Medical Devices - Part 10	Under the conditions of the testing, not a sensitizer	The primary irritation indexes of the polar and non-polar test group were both calculated to be 0.	Pass
2	Test for Irritation potential		Under the conditions of the testing, not an irritant.	The skin sensitization rates of polar and non-polar extract group were both determined with 0%.	Pass
3	Evaluate In Vitro Cytotoxicity potential	ISO 10993-5:2009	Under the conditions of the testing, non-cytotoxic.	The cell viability of the 100% test article extract was 86.2%	Pass
4	Measure residual powder on medical gloves	ASTM D6124-06 (Reapproved 2017)	powder residue limit of 2.0 mg/glove	1.9 mg/glove	Pass
5	Detection of holes in medical gloves	ASTM D5151-19	Freedom free holes AQL: 2.5 (ISO 2859-1)	0 gloves of failure	Pass
6	Evaluate physical dimensions	ASTM D6319-19, (7.4 & ASTM D3767-03(2 020))	XS: width 70±10mm Length ≥270 mm	Length: 287-293 mm Width: 78-80mm	Pass
			S: width 80±10mm Length ≥270 mm	Length: 288-297 mm Width: 84-86mm	Pass
			M: width 95±10mm Length ≥270 mm	Length: 287-300mm Width: 96-97mm	Pass
			L: width 110±10mm Length ≥270 mm	Length: 290-297 mm Width: 105-107mm	Pass
			XL: width 120±10mm Length ≥270 mm	Length: 283-301 mm Width: 113-115mm	Pass
			XXL: width 130±10mm Length ≥270 mm	Length: 292-300 mm Width: 122-124mm	Pass
	Thickness		Finger ≥0.05 mm Palm ≥0.05 mm	Finger :0.082-0.185mm Palm: 0.065-0.123mm	Pass
	Evaluate physical properties: Before aging				
	Tensile strength	ASTM D6319-19, 7.5& ASTM D412-16 (2021)	≥14MPa	(19.9-28.9)MPa	Pass
	Ultimate Elongation		≥500%	(540-580)%	Pass
	After Accelerated Aging				
	Tensile strength	ASTM D6319-19, 7.5& ASTM D412-16 (2021) &ASTM D573-04 (2019)	≥14MPa	(20.2-29.1)MPa	Pass
	Ultimate Elongation		≥400%	(508-528)%	Pass
7	Evaluate permeation characteristics	ASTM D6978	Bendamustine HCl 5 mg/ml (5,000 ppm) > 240 min.		> 240 min.

	me		Bleomycin Sulfate 15 mg/ml (15,000 ppm) > 240 min.	> 240 min.
			Busulfan 6 mg/ml(6,000 ppm) > 240 min.	> 240 min.
			Carboplatin 10.0 mg/ml (10,000 ppm) > 240 min.	> 240 min.
			Carfilzomib 2 mg/ml (2,000 ppm) > 240 min.	> 240 min.
			Carmustine 3.3 mg/ml (3,300 ppm) 21.1 (24.2, 21.1, 25.3)min.	21.1 min
			Cetuximab 2 mg/ml (2,000 ppm) > 240 min.	> 240 min.
			Chloroquine 50 mg/m (50,000 ppm) > 240 min.	> 240 min.
			Cisplatin 1 mg/ml(1,000 ppm) > 240 min.	> 240 min.
			Cladribine 1 mg/ml (1000 ppm) > 240 min.	> 240 min.
			Cyclophosphamide 20 mg/ml (20.000 ppm) > 240 min.	> 240 min.
			Cyclosporin A 100 mg/ml (100,000 ppm) > 240 min.	> 240 min.
			Cytarabine(Cytosine) 100.0 mg/ml (100,000 ppm) > 240 min.	> 240 min.
			Cytovene(Ganciclovir) 10 mg/ml(10,000 ppm) > 240 min.	> 240 min.
			Dacarbazine 10 mg/ml(10,000 ppm) > 240 min.	> 240 min.
			Daunorubicin HCl 5 mg/ml (5,000 ppm) > 240 min.	> 240 min.
			Decitabine 5 mg/ml(5,000 ppm) > 240 min.	> 240 min.
			Docetaxel 10 mg/ml (10.000 ppm) > 240 min.	> 240 min.
			Doxorubicin HCl 2 mg/ml (2,000 ppm) > 240 min.	> 240 min.
			Epirubicin HCl (Ellence) 2 mg/ml (2,000 ppm) > 240 min.	> 240 min.
			Etoposide 20 mg/ml (20,000 ppm) > 240 min.	> 240 min.
			Fludarabine 25.0 mg/ml (25,000 ppm) > 240 min.	> 240 min.
			Fluorouracil	> 240 min.

			50 mg/ml,(50,000 ppm) > 240 min.	
			Fulvestrant 50 mg/ml(50,000 ppm) > 240 min.	> 240 min.
			Gemcitabine 38 mg/ml (38,000 ppm) > 240 min.	> 240 min.
			Idarubicin HCL 1.0 mg/ml (1,000 ppm) > 240 min.	> 240 min.
			Ifosfamide 50 mg/ml (50,000 ppm) > 240 min.	> 240 min.
			Irinotecan HCl 20 mg/ml (20,000 ppm) > 240 min.	> 240 min.
			Mechlorethamine HCl 1 mg/ml(1,000 ppm) > 240 min.	> 240 min.
			Melphalan 5 mg/ml(5000 ppm) > 240 min.	> 240 min.
			Methotrexate 25 mg/ml (25,000 ppm) > 240 min.	> 240 min.
			MESNA 100 mg/ml(100,000 ppm) > 240 min.	> 240 min.
			Mitomycin C 0.5 mg/ml (500 ppm) > 240 min.	> 240 min.
			Mitoxantrone HCL 2 mg/ml (2,000 ppm) > 240 min.	> 240 min.
			Oxaliplatin 5 mg/ml (5,000 ppm) > 240 min.	> 240 min.
			Paclitaxel 6 mg/ml (6,000 ppm) > 240 min.	> 240 min.
			Paraplatin 10 mg/ml (10,000 ppm) > 240 min.	> 240 min.
			Pemetrexed 25 mg/ml (25,000 ppm) > 240 min.	> 240 min.
			Raltitrexed 0.5 mg/ml (500 ppm) > 240 min.	> 240 min.
			Retrovir 10 mg/ml(10,000 ppm) > 240 min.	> 240 min.
			Rituximab 10 mg/ml (10,000 ppm) > 240 min.	> 240 min.
			Temsirolimus 25 mg/ml (25,000 ppm) > 240 min.	> 240 min.
			Thiotepa 10 mg/ml(10,000 ppm) 74.9 (74.9, 96.7, 79.0)min.	74.9 min.
			Topotecan 1 mg/ml (1,000 ppm)	> 240 min.

			> 240 min.	
			Triclosan 3 mg/ml(3,000 ppm) > 240 min.	> 240 min.
			Trisenox (Arsenic Trioxide) 1 mg/ml (1,000 ppm) > 240 min.	> 240 min.
			Vinblastine, 1 mg/ml (1,000 ppm) > 240 min.	> 240 min.
			Vincristine sulfate (Oncovin) 1 g/ml (1,000 ppm) > 240 min.	> 240 min.
			Vinorelbine 10 mg/ml(10,000 ppm) > 240 min.	> 240 min.
			Zoledronic Acid 1 mg/25ml (40 ppm) > 240 min.	> 240 min.
			Fentanyl Citrate Injection 100mcg/2mL > 240 min.	> 240 min.

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Nitrile Exam Glove, Extended cuff, Tested For Use With Chemotherapy Drugs, Fentanyl Citrate, And Select Other Drugs is as safe, as effective, and performs as well as or better than the legally marketed predicate device K193555.