February 24, 2025

Lingshi Hongruida Health Protection Technology Co., Ltd.
Chai Tinglong
General Manager
Yangjiayuan, Liangdu Town, Lingshi County
Jinzhong, Shanxi 031300
China

Re: K243959
Trade/Device Name: Powder Free Nitrile Examination Gloves (Violet, Black, Green), 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, QDO, OPJ
Dated: February 14, 2025
Received: February 14, 2025

Dear Chai Tinglong:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*

Device Name

Powder Free Nitrile Examination Gloves (Violet, Black, Green), Tested For Use With Chemotherapy Drugs, Fentanyl Citrate and Select Other Drugs

Indications for Use *(Describe)*

The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate and Other Select Drugs using ASTM D6978-05(2019)

Chemotherapy Drug & Concentration	Minimum Breakthrough Detection Time in Minutes		
	Violet	Black	Green
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	>240	>240
Busulfan 6mg/ml (6,000 ppm)	>240	>240	>240
Carboplatin 10mg/ml (10,000 ppm)	>240	>240	>240
Carmustine 3.3 mg/ml (3,300 ppm)	15.3	12.6	11.7
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240
Cytarabine, 100 mg/ml (100,000 ppm)	>240	>240	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	>240	>240
Docetaxel , 10 mg/ml (10,000 ppm)	>240	>240	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240	>240	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240
Gemcitabine, 38mg/ml (38,000ppm)	>240	>240	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	>240	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240	>240	>240
Irinotecan HCL, 20mg/ml (20,000ppm)	>240	>240	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	>240	>240
Melphalan HCL, 5mg/ml (5,000ppm)	>240	>240	>240
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240	>240	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	>240	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240	>240	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240
Paraplatin, 10mg/ml (10,000ppm)	>240	>240	>240
Rituximab, 10mg/ml (10,000ppm)	>240	>240	>240
Thiotepa, 10mg/ml (10,000ppm)	36.4	15.4	33.0
Topotecan HCL, 1mg/ml (1,000ppm)	>240	>240	>240
Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240	>240	>240
Velcade (Bortezomib) 1mg/ml (1,000ppm)	>240	>240	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	>240

Fentanyl Citrate & Other Drugs	Minimum Breakthrough Detection Time in Minutes		
	Violet	Black	Green

Fentanyl Citrate Injection, 100mcg/2mg	>240	>240	>240
Chloroquine 50mg/ml (50,000ppm)	>240	>240	>240
Cyclosporin A 100 mg/ml (100,000 ppm)	>240	>240	>240
Retrovir, 10mg/ml (10,000ppm)	>240	>240	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 15.3 minutes, Thiotepa: 36.4 minutes (Violet);
Carmustine: 12.6 minutes, Thiotepa: 15.4 minutes (Black);
Carmustine: 11.7 minutes, Thiotepa: 33.0 minutes (Green);
Warning: Do not use with Carmustine and Thiotepa.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Lingshi Hongruida Health Protection Technology Co., Ltd.

Yangjiayuan, Liangdu Town, Lingshi County, Jinzhong City,
Shanxi Province, 031300, China

510K Summary

The assigned 510(K) numbers: K243959

Date Prepared: February 14, 2025

1. Owner's Identification:

Lingshi Hongruida Health Protection Technology Co., Ltd.
Yangjiayuan, Liangdu Town, Lingshi County, Jinzhong City, Shanxi Province, 031300, China
Contact: Mr. Chai Tinglong / General Manager
Tel: 0086-311-66179668
Email: fdareg@hongray.com.cn

2. Device Identification:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Violet, Black, Green), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Select Other Drugs
Common Name: Exam Gloves
Classification Name: Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Better Care Plastic Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K221269)

4. Device Description:

Powder Free Nitrile Examination Gloves (Violet, Black, Green), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Select Other Drugs 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 and have been tested for resistance to permeation by chemotherapy drugs, Fentanyl Citrate and Select Other Drugs as per ASTM D6978. The gloves are single use, disposable, and non-sterile.

5. 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.
Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978-05(2019)
The following chemicals have been tested with these gloves:

Chemotherapy Drug & Concentration	Minimum Breakthrough Detection Time in Minutes		
	Violet	Black	Green
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	>240	>240
Busulfan 6mg/ml (6,000 ppm)	>240	>240	>240
Carboplatin 10mg/ml (10,000 ppm)	>240	>240	>240
Carmustine, 3.3 mg/ml (3,300 ppm)	15.3	12.6	11.7
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240

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Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240
Cytarabine, 100 mg/ml (100,000 ppm)	>240	>240	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	>240	>240
Docetaxel , 10 mg/ml (10,000 ppm)	>240	>240	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240
Fludarabine Phosphate, 25 mg/ml (25,000 ppm)	>240	>240	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240
Gemcitabine HCL, 38mg/ml (38,000ppm)	>240	>240	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	>240	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240	>240	>240
Irinotecan HCL, 20mg/ml (20,000ppm)	>240	>240	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	>240	>240
Melphalan HCL, 5mg/ml (5,000ppm)	>240	>240	>240
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240	>240	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	>240	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240	>240	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240
Paraplatin, 10mg/ml (10,000ppm)	>240	>240	>240
Rituximab, 10mg/ml (10,000ppm)	>240	>240	>240
Thiotepa, 10mg/ml (10,000ppm)	36.4	15.4	33.0
Topotecan HCL, 1mg/ml (1,000ppm)	>240	>240	>240
Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240	>240	>240
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240	>240	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	>240

Fentanyl Citrate and Other Drugs	Minimum Breakthrough Detection Time in Minutes		
	Violet	Black	Green
Fentanyl Citrate Injection, 100mcg/2mg	>240	>240	>240
Chloroquine 50mg/ml (50,000ppm)	>240	>240	>240
Cyclosporin A, 100 mg/ml (100,000 ppm)	>240	>240	>240
Retrovir, 10mg/ml (10,000ppm)	>240	>240	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 15.3 minutes, Thiotepa: 36.4 minutes (Violet);
Carmustine: 12.6 minutes, Thiotepa: 15.4 minutes (Black);
Carmustine: 11.7 minutes, Thiotepa: 33.0 minutes (Green);
Warning: Do not use with Carmustine and Thiotepa.

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6. Comparison of Subject Device and Predicate Device:

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs & Fentanyl Citrate of the subject and predicate devices.

General Comparison Table:

Characteristics and Parameters	Subject Device	Predicate Device K221269	Comparison Result
Trade Name	Powder Free Nitrile Examination Gloves (Violet, Black, Green), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate and Select Other Drugs	Powder Free Nitrile Examination Gloves (Blue),Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Similar
Product Code	LZA, LZC, QDO,OPJ	LZA, LZC,QDO	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. Gloves have been tested for use with chemotherapy drugs, Fentanyl Citrate and Other Select Drugs using ASTM D6978-05(2019)	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978	Similar
Material	Nitrile	Nitrile	Same
Color	Violet, Black, Green	Blue	Different**
Design	• Single Use • Non-sterile • Powder-Free • Ambidextrous	• Single Use • Non-sterile • Powder-Free • Ambidextrous	Same
Chemotherapy Drugs, Fentanyl Citrate and other select drugs Claim	See below comparison table	See below comparison table	/

** QDO and OPJ, both designated for Medical Gloves with Chemotherapy Labeling Claims - Test for Use with Chemotherapy Drugs, the subject device added the product code OPJ as per requirements but does not raise questions of safety and effectiveness.*

*** The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.*

Technological Characteristic Comparison Table:

Technological Characteristics	Subject Device	Predicate Device K221269	Comparison Result

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Length (mm) (Minimum)	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	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) (Minimum)			
Finger	0.05	0.05	Same
Palm	0.05	0.05	Same
Tensile Strength, Before Aging, min	14MPa	14MPa	Same
Ultimate Elongation, Before Aging, min	500%	500%	Same
Tensile Strength, After Accelerated Aging, min	14MPa	14MPa	Same
Ultimate Elongation, After Accelerated Aging, min	400%	400%	Same
Freedom from holes	G-I, AQL 2.5	G-I, AQL 2.5	Same
Powder residual	≤ 2 mg per glove	≤ 2 mg per glove	Same
In vitro Cytotoxicity ISO 10993-5	The test article is considered cytotoxic under the conditions of this test. Cytotoxicity concern was addressed by Acute Systemic Injection Test.	Under the conditions of this study, the test article showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by Acute Systemic Toxicity testing.	Same
Acute Systemic Injection Test ISO 10993-11	The test result indicate that the requirements of the ISO Acute Systemic Injection Test have been met by the test article.	Under the conditions of this study, there was no evidence of systemic toxicity from the test article.	Same
Dermal Sensitization ISO 10993-10	Under the conditions of this protocol, the test article did not elicit a sensitization response.	Under the conditions of this study, the test article showed no significant evidence of causing skin sensitization	Same

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Primary Skin Irritation ISO 10993-23	The test result showed that the requirements of the ISO Intracutaneous Reactivity Test have been met by the test article.	The test result showed that the response of the test article was categorized as negligible under the test condition.	Same

Chemotherapy Permeation, Fentanyl Citrate, and Select Other Drugs Comparison Claim:

Chemotherapy Drug & Concentration	Minimum Breakthrough Detection Time (Minutes)				Comparison Result
	Subject Device			Predicate Device K221269	
	Violet	Black	Green		
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)	15.3	12.6	11.7	11.1	Similar
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	>240	Same
Cytarabine, 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 , 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 Phosphate, 25 mg/ml (25,000 ppm)	>240	>240	>240	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	>240	Same
Gemcitabine HCL, 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 HCL, 20mg/ml (20,000ppm)	>240	>240	>240	>240	Same
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Melphalan HCL, 5mg/ml (5,000ppm)	>240	>240	>240	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	>240	Same
Mitomycin C, 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, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same
Rituximab, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same
Thiotepa, 10mg/ml (10,000ppm)	36.4	15.4	33.0	21.6	Similar
Topotecan HCL, 1mg/ml (1,000ppm)	>240	>240	>240	>240	Same
Trisenox (Arsenic Trioxide), 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

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Fentanyl Citrate and Other Drugs	Minimum Breakthrough Detection Time (Minutes)				Comparison Result
	Subject Device			Predicate Device	
	Violet	Black	Green	K221269	
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	>240	>240	Same
Chloroquine 50mg/ml (50,000ppm)	>240	>240	>240	>240	Same
Cyclosporin A, 100 mg/ml (100,000 ppm)	>240	>240	>240	>240	Same
Retrovir, 10mg/ml (10,000ppm)	>240	>240	>240	>240	Same

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

7. Summary of Non-Clinical Performance Data

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

Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319- 19	To determine the length of the gloves	XS: ≥ 220 mm S: ≥ 220 mm M: ≥ 230 mm L: ≥ 230 mm XL: ≥ 230 mm XXL: ≥ 230 mm	Pass
ASTM D6319- 19	To determine the 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	To determine the Physical Dimensions (Thickness)	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412-16(2021)	To determine the Physical Properties	Tensile Strength (Min14 MPa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	To determine the Water leak test	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2022)	To determine the Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	chemical permeation testing	Refer to the above table	Pass
ISO 10993 Part 10-2021	Skin Sensitization Testing	Under the conditions of the study, the device is not a sensitizer	Under the conditions of this protocol, the test article did not elicit a sensitization response.
ISO 10993 Part 23-2021	Skin irritation Testing	Under the conditions of the study, the device is not an irritant	The test result showed that the requirements of the ISO Intracutaneous Reactivity

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			Test have been met by the test article.
ISO 10993-5:2009	Cytotoxicity testing	No Cytotoxicity reactivity	The test article is considered cytotoxic under the conditions of this test. Cytotoxicity concern was addressed by Acute Systemic Injection Test.
ISO 10993-11:2017	Acute systemic toxicity study	No systemic toxicity	The test result indicate that the requirements of the ISO Acute Systemic Injection Test have been met by the test article.

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reapproved 2022), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization.
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 10: Tests for Skin Irritation.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

8. Clinical Performance Data

N/A

9. Conclusion:

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