February 29, 2024

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

Re: K240051
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue), 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, ODQ, OPJ
Dated: January 6, 2024
Received: January 8, 2024

Dear Tinglong Chai:

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)*
K240051

Device Name
Powder Free Nitrile Examination Gloves (Blue), 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 select other drugs using ASTM D6978-05(2019)
The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time in 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)	29.1
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cytarabine, 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 , 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 Phosphate, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine HCL, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan HCL, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan HCL, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 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, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	78.3
Topotecan HCL, 1mg/ml (1,000ppm)	>240
Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate & other drugs	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection, 100mcg/2mg	>240

Chloroquine 50mg/ml (50,000ppm)	>240
Cyclosporin A 100 mg/ml (100,000 ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 29.1 minutes, Thiotepa: 78.3 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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510K Summary

The assigned 510(K) numbers: K240051

Date Prepared: February 29, 2024

1. Owner's Identification:

Lingshi Hongruida Health Protection Technology Co., Ltd.
Yangjiayuan, Liangdu Town, Lingshi County, Jinzhong City, Shanxi Province, 031300, China
Tel:86-311-66179668
Contact: Mr. Chai Tinglong, General Manager
Email: janicema@hongrayusa.com or fdareg@hongray.com.cn

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Blue), 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:

Lingshi Hongruida Health Protection Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue)， Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K223320)

4. Device Description:

Powder Free Nitrile Examination Gloves (Blue), 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 D6319-19 and have been tested for resistance to permeation by chemotherapy drugs, Fentanyl Citrate, and select other drugs as per ASTM D6978-05(2019). The gloves are single use, disposable, and non-sterile.

5. Device Modification

The proposed modification to the predicate device is adding additional Chemotherapy drugs. We have tested the proposed device (exactly same as predicate device) for use with chemotherapy drugs as per ASTM D6978 and gotten the testing report to support this claim. Please note that there are no differences with these two gloves from materials, manufacturing process and bench performance.

6. 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 select other drugs using ASTM D6978-05(2019)
The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum Breakthrough Detection Time in 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)	29.1
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cytarabine, 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 , 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 Phosphate, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine HCL, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan HCL, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan HCL, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 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, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	78.3
Topotecan HCL, 1mg/ml (1,000ppm)	>240
Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Fentanyl Citrate & other drugs	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240
Chloroquine 50mg/ml (50,000ppm)	>240
Cyclosporin A 100 mg/ml (100,000 ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240

*Please note that the following drugs have extremely low permeation times:
Carmustine: 29.1 minutes, Thiotepa: 78.3 minutes
Warning: Do not use with Carmustine and Thiotepa.

7. <u>Comparison of Subject Device and Predicate Device:</u>

510K Summary

General Comparison Table:

	Proposed Device K240051	Predicate Device K223320	Result of comparison
Trade Name	Powder Free Nitrile Examination Gloves (Blue), 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	Same
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO	Same
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 select other 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 D6978-05(2019)	Same
Material	Nitrile	Nitrile	Same
Powdered or Powder Free	Powder Free	Powder Free	Same
Color	Blue	Blue	Same
Single use	Single use	Single use	Same
Chemotherapy Drugs and Fentanyl Citrate and other drugs Claim	See below comparison table	See below comparison table	See below comparison table

Technological Characteristic Comparison Table:

Technological Characteristics	Proposed Device K240051	Predicate Device K223320	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

510K Summary

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
Watertight (1000ml)	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	21 CFR 800.20 ASTM D5151 G-1, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Same
10993-23:2021 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2021 Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
10993-5:2009 Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systemic toxicity testing.	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systemic toxicity testing.	Same
ISO 10993-11:2017 Acute Systemic toxicity study	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, Fentanyl Citrate & other drugs Permeation Comparison:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Result of comparison
	Proposed Device K240051	Predicate Device K223320	
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	/	Different*
Busulfan 6mg/ml (6,000 ppm)	>240	/	Different*
Carboplatin 10mg/ml (10,000 ppm)	>240	/	Different*
Carmustine 3.3 mg/ml (3,300 ppm)	29.1	13.5	Similar
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	Same
Cytarabine, 100 mg/ml (100,000 ppm)	>240	/	Different*
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	Same
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240	/	Different*
Docetaxel , 10 mg/ml (10,000 ppm)	>240	/	Different*
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	Same
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	/	Different*
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	Same
Fludarabine Phosphate, 25 mg/ml (25,000 ppm)	>240	/	Different*

Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	Same
Gemcitabine HCL, 38mg/ml (38,000ppm)	>240	/	Different*
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	/	Different*
Ifosfamide, 50mg/ml (50,000ppm)	>240	/	Different*
Irinotecan HCL, 20mg/ml (20,000ppm)	>240	/	Different*
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	/	Different*
Melphalan HCL, 5mg/ml (5,000ppm)	>240	/	Different*
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	Same
Mitomycin C, 0.5mg/ml (500ppm)	>240	/	Different*
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	/	Different*
Oxaliplatin, 5mg/ml (5,000ppm)	>240	/	Different*
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	Same
Paraplatin, 10mg/ml (10,000ppm)	>240	/	Different*
Rituximab, 10mg/ml (10,000ppm)	>240	/	Different*
Thiotepa, 10mg/ml (10,000ppm)	78.3	66.6	Similar
Topotecan HCL, 1mg/ml (1,000ppm)	>240	/	Different*
Trisenox (Arsenic Trioxide), 1mg/ml (1,000ppm)	>240	/	Different*
Velcade (Bortezomib), 1mg/ml (1,000ppm)	>240	/	Different*
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	/	Different*

Fentanyl Citrate & other drugs	Minimum BDT (Minutes)		Result of comparison
	Subject Device K240051	Predicate Device K223320	
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	Same
Chloroquine 50mg/ml (50,000ppm)	>240	/	Different*
Cyclosporin A 100 mg/ml (100,000 ppm)	>240	/	Different*
Retrovir, 10mg/ml (10,000ppm)	>240	/	Different*

**This different is support with test report and will be indicated on labeling, so this different does not raise questions of safety and effectiveness of subject device.*

8. 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	Test Performed	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) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Water leak test	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&-23	Irritation and Skin Sensitization	Skin sensitization and Skin irritation	non-sensitization and Non-irritation
ISO 10993-5:2009	Cytotoxicity	Cytotoxicity reactivity	showed potential toxicity to L929 cells.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	no evidence of acute systemic toxicity.

9. Summary of Clinical Information

No clinical testing was submitted for the subject device.

10. 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.