Grand Work Plastic Products Co., Ltd.
Wu Yuli
General Manager
Donggao Industrial Zone
Zanhuang, Hebei 050000
China

Re: K232039
Trade/Device Name: Sterile Powder Free Nitrile Examination Gloves (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, OPJ, QDO
Dated: July 5, 2023
Received: July 10, 2023

Dear Wu Yuli:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K232039

Device Name
Sterile Powder Free Nitrile Examination Gloves (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 or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with Chemotherapy drugs and fentanyl citrate in accordance with ASTM D6978.

Chemotherapy Drug	Minimum BDT (Minutes)
Carmustine (BCNU) (3.3mg/ml)	54.3
Cyclophosphamide (20mg/ml)	>240
Doxorubicin Hydrochloride (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	196.7
Methotrexate (25mg/ml)	>240
Cisplatin (1mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240
Cytarabine HCL (100mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240

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

Caution: Please note that the following drugs have low permeation times:
Carmustine (BCNU): 54.3 minutes, Thiotepa: 196.7 minutes

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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Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Hebei, 050000, 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) number is: K232039

Date Prepared: August 09, 2023

1. Owner's Identification:

Mrs. Wu Yuli
Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Hebei, 050000, China
Tel: 86-311-66179668

Contact: Mrs. Wu Yuli
Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Hebei, 050000, China
Tel: 86-311-66179668

2. Name of the Device:

Trade Name: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA, LZC, QDO, OPJ
Device Class: Class I

3. Predicate Device Information:

Grand Work Plastic Products Co., Ltd.
Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs (K220250)
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA, LZC
Device Class: Class I

4. Device Description:

The subject device is Nitrile Examination Gloves Sterile with tested for use with Chemotherapy drugs and fentanyl citrate claims. The subject device is a patient examination glove made from nitrile compound, blue color, powder free and sterile. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large and XXL. The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for permeability to chemotherapy drugs and fentanyl citrate per ASTM D6978-05(2019).

Specification for subject device:

Items	Acceptance Criteria	Results
Length	Minimum 230mm	All size ≥290
Palm Width	XS：70±10mm	76-78mm
	S：80±10mm	86-88 mm

	M:95±10mm	96 -98mm
	L:110±10mm	106-108 mm
	XL：120±10mm	116-118 mm
	XXL：130±10mm	126-128 mm
Thickness	Palm: 0.05mm (min)	0.09-0.11mm
	Finger: 0.05mm (min)	0.13-0.14mm
Tensile Strength, Before Aging	14MPa, min	15.8-20.8 MPa
Tensile Strength, After Accelerated Aging	14MPa, min	15.6-19.8 MPa
Ultimate Elongation, Before Aging	500%, min	500-560%
Ultimate Elongation, After Accelerated Aging	400%, min	400-500%
Freedom from holes	G-I, AQL 2.5	Meet AQL2.5 requirements
Powder-Content	≤ 2 mg per glove	≤ 2 mg, meet requirements

Gloves meet all the specification listed in ASTM D 6319-19.

5. Device Modification

The proposed modification to the predicate device is add the claim which tested for use with fentanyl citrate besides claim use with Chemotherapy drugs. We have tested the proposed device (exactly same as predicate device) for use with fentanyl citrate as per ASTM D6978 and gotten the testing report to support this claim. Please note that there are no any differences with these two gloves from 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 or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with Chemotherapy drugs and fentanyl citrate in accordance with ASTM D6978.

Chemotherapy Drug	Minimum BDT (Minutes)
Carmustine (BCNU) (3.3mg/ml)	54.3
Cyclophosphamide (20mg/ml)	>240
Doxorubicin Hydrochloride (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	196.7
Methotrexate (25mg/ml)	>240
Cisplatin (1mg/ml)	>240
Vincristine Sulfate (1.0 mg/ml)	>240
Cytarabine HCL (100mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Ifosfamide (50.0 mg/ml)	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240

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

Caution: Please note that the following drugs have low permeation times:
Carmustine (BCNU): 54.3 minutes, Thiotepa: 196.7 minutes

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

Items	Predicate Device K220250	Subject Device K232039	Result of comparison
Trade Name	Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Different*
Product Code	LZA, LZC	LZA, LZC, OPJ, QDO	Different*
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Description	Sterile Examination glove	Sterile Examination glove	Same
Indications for Use	Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978.	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition these gloves were tested for use with Chemotherapy drugs and fentanyl citrate 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	Blue	Same
Sterility	Sterile	Sterile	Same
Single use	Single use	Single use	Same
Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	/

**This different is support with test report and will be indicated on labeling.*

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Result of comparison
	Predicate Device K220250	Subject Device K232039	

Carmustine (BCNU) (3.3mg/ml)	54.3	54.3	Same
Cyclophosphamide (20mg/ml)	>240	>240	Same
Doxorubicin Hydrochloride (2 mg/ml)	>240	>240	Same
Etoposide (20mg/ml)	>240	>240	Same
Fluorouracil (50mg/ml)	>240	>240	Same
Paclitaxel (6mg/ml)	>240	>240	Same
Thiotepa (10mg/ml)	196.7	196.7	Same
Methotrexate (25mg/ml)	>240	>240	Same
Cisplatin (1mg/ml)	>240	>240	Same
Vincristine Sulfate (1.0 mg/ml)	>240	>240	Same
Cytarabine HCL (100mg/ml)	>240	>240	Same
Mitoxantrone (2.0 mg/ml)	>240	>240	Same
Mitomycin C (0.5 mg/ml)	>240	>240	Same
Ifosfamide (50.0 mg/ml)	>240	>240	Same
Dacarbazine (DTIC) (10.0 mg/ml)	>240	>240	Same

Opioid Drug and Concentration	Minimum BDT (Minutes)		Result of comparison
	Predicate Device K220250	Subject Device K232039	
Fentanyl Citrate Injection (100mcg/2mL)	/	>240	Different*

**This different is support with test report and will be indicated on labeling.*

Dimensions and Performance Comparison Table:

Technological Characteristics	Subject Device K232039	Predicate Device K220250	Remark
Length	Minimum 230mm	Minimum 230mm	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	In accordance with ASTM D	Same

	5151-19, following ASTM D6319- 19, G-I, AQL 2.5	5151-19, following ASTM D6319- 19, G-I, AQL 2.5	
Residual Powder	≤ 2 mg per glove	≤ 2 mg per glove	Same

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/Prupose	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for size XS and S, 230mm for size M, L, XL	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	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 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	no evidence of acute systemic toxicity.

8. Summary of Clinical Information:

No clinical testing was submitted for the subject device.

9. 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.