May 11, 2022

Grand Work Plastic Products Co., Ltd
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K220250
Trade/Device Name: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: February 12, 2022
Received: February 17, 2022

Dear Kathy Liu:

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,

Clarence W. Murray, III, PhD
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)*
K220250

Device Name
Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
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 standards.

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

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

Product: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

510(K) SUMMARY

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

The assigned 510(K) number is: K220250

Date Prepared: January 20, 2022

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: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611

2. Name of the Device:

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

3. Predicate Device Information:

Riverstone Resources SDN BHD.
Nitrile Examination Glove, Sterile Tested for use with Chemotherapy Drugs Claim, White (K190725)

4. Device Description:

The subject device is Nitrile Examination Gloves Sterile with tested for use with Chemotherapy drugs claims. The subject device is a patient examination glove made from nitrile latex compound, blue color, powder free and sterile (Per 21 CFR 880.6250, class I). The device is direct contact and not to be worn for more than 24 hours. The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility per 10993-10, 10993-11 and permeability to chemotherapy drugs per ASTM D6978-05(2019).

5. Indications for Use:

A patient examination 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 provides protection against following chemotherapy drugs and the minimum breakthrough time are listed as follows.

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

Product: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

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

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

6. Specification for Nitrile Gloves:

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 and above AQL2.5 requirements
Powder-Content	≤ 2 mg per glove	≤ 2 mg, meet requirements

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

7. Technological Characteristic Comparison:

Characteristics	Subject Device	Predicate Device K190725	Comparison
Trade Name	Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Nitrile Examination Gloves Sterile Tested for Use with Chemotherapy Drugs claim, White	Similar
Product Code	LZA and LZC	LZA and LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same

Product: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

Class	I	I	Same
Indications for Use	Subject device is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	Predicate device is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	Same
Description	Sterile Examination glove made of Nitrile and color Blue and tested with chemotherapy Drugs	Sterile Examination glove made of Nitrile and color White and tested with chemotherapy Drugs	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Material use	Nitrile Synthetic Latex	Nitrile Synthetic Latex	Same
Color	Blue	White	Different
Sterility ISO 11737-2 EN ISO 11137-2	Sterility	Sterility	Same
Single used	Single used	Single used	Same
Non Sterile or Sterile	Sterile	Sterile	Same
10993-10:2010 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2010 Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
ISO 10993 Part 11 Acute Systemic Toxicity Test	Under the conditions of this study, there was no evidence of systemic toxicity.	Under the condition of this study, Nitrile Examination glove, sterile shows no adverse biological reaction	Same

Dimensions and Performance Comparison Table:

Technological Characteristics	Subject Device	Predicate Device K190725	Comparison
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	/	Different
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

Product: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	Same
Freedom from holes	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Same
Residual Powder	≤ 2 mg per glove	≤ 2 mg per glove	Same

Chemotherapy Permeation Comparison:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Comparison
	Subject Device	Predicate Device K190725	
Carmustine (BCNU) (3.3mg/ml)	54.3	39	Similar
Cyclophosphamide (20mg/ml)	>240	>240	Same
Cytarabine (1.0 mg/ml)	/	>240	Different
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	97.6	Similar
Methotrexate (25mg/ml)	>240	>240	Same
Cisplatin (1mg/ml)	>240	/	Exceed
Vincristine Sulfate (1.0 mg/ml)	>240	/	Exceed
Cytarabine HCL (100mg/ml)	>240	/	Exceed
Mitoxantrone (2.0 mg/ml)	>240	/	Exceed
Mitomycin C (0.5 mg/ml)	>240	/	Exceed
Ifosfamide (50.0 mg/ml)	>240	/	Exceed
Dacarbazine (10.0 mg/ml)	>240	/	Exceed

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:

Test Methodology	Purpose	Acceptance Criteria	Result Summary
ASTM D6319- 19	The purpose of the testing is to measure the dimensions of the subject device.	XS-70±10 S-80±10 M-95±10 L-110±10 XL-120±10 XXL-130±10	Meets
ASTM D6319-19	The purpose of the testing is to measure the physical properties of	Finger - Minimum 0.05	Meets

	the subject device.	Palm - Minimum 0.05 Tensile Strength, before aging - 14MPa, min Ultimate Elongation, Before Aging - 500%, min Tensile Strength, After Accelerated Aging - 14MPa, min Ultimate Elongation, After Accelerated Aging - 400%, mi	
ASTM D6319- 19 ASTM D5151-19	The purpose of the testing is to measure the freedom from holes of the subject device.	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Meets
ASTM D 6124-06(2017) ASTM D6319- 19	The purpose of the testing is to measure the residual powder on the subject device.	≤ 2 mg per glove	Meets
ISO 10993-10:2010	The purpose of the testing is to measure the primary skin irritation test of the subject device.	Under the conditions of the study the device extracts were not an irritant	Meets
ISO 10993-10:2010	The purpose of the testing is to measure the Dermal sensitization assay of the subject device.	Under the conditions of the study the device extracts were not a sensitizer	Meets
ISO 10993-11:2017	The purpose of the testing is to measure the Acute Systemic Toxicity of the subject device.	Under the conditions of this study, there was no evidence of systemic toxicity for the device extracts.	Meets

Product: Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

The subject device meets the applicable requirements for patient examination gloves with regards to dimension and sizes, physical properties, freedom from holes and powder Residuals as found in the following standards: ASTM D6139, ASTM D5151, ASTM D6124.The subject device passes biological reactivity testing for dermal sensitization, irritation and acute systemic toxicity with accordance ISO10993-10 and ISO 10993-11.

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 predicated device.