December 15, 2022

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

Re: K222892
Trade/Device Name: Powder Free Polyurethane Examination Gloves, Blue color, 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, OPJ
Dated: August 30, 2022
Received: September 23, 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,

Bifeng Qian -S

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
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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)*
K222892

Device Name
Powder Free Polyurethane Examination Gloves, Blue color, Tested for use with Chemotherapy 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 using ASTM D6978-05(2019)

Chemotherapy Drug	Minimum Breakthrough Detection Time (BDT) in Minutes
Carmustine 3.3 mg/ml (3,300 ppm)	24.0
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	0.6

* Please note that the following drugs have extremely low permeation times:
Carmustine: 24.0 minutes, Thiotepa: 0.6 minutes

Warning: Do not use with Carmustine or 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.

Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Product: Powder Free Polyurethane Examination Gloves, Blue color, Tested for use with Chemotherapy Drugs

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: K222892

Date Prepared: November 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
Email: kathyliu@hongrayusa.com or fdareg@hongray.com.cn

2. **Name of the Device:**

Trade Name: Powder Free Polyurethane Examination Gloves, Blue color, Tested for use with Chemotherapy Drugs
Common Name: Exam Gloves
Classification Name: Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA, LZC, OPJ
Device Class: Class I

3. **Predicate Device Information:**

Central Medicare Sdn Bhd.
Non Sterile Powder Free Polyurethane Examination Gloves (Blue and Black colors)- (K203036)

Reference device:

Inner Mongolia Cureguard Medical Technology Co.,Ltd.
Disposable Nitrile Examination Glove (Tested for use with Chemotherapy Drug) (K222642)

4. **Device Description:**

Powder Free Polyurethane Examination Gloves, Blue color, tested for use with Chemotherapy Drugs are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of nitrile rubber materials and are powder free. They are ambidextrous and come in different sizes—XS, S, M, L, XL and XXL. Gloves meet the specification of ASTM D6319-19

and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05(2019).

5. **Intended Use/Indication for Use**

A patient examination 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 using ASTM D6978-05(2019)

Chemotherapy Drug	Minimum Breakthrough Detection Time (BDT) in Minutes
Carmustine 3.3 mg/ml (3,300 ppm)	24.0
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	0.6

* Please note that the following drugs have extremely low permeation times:
Carmustine: 24.0 minutes, Thiotepa: 0.6 minutes
Warning: Do not use with Carmustine and Thiotepa.

6.Comparison of Subject Device and Predicate Device:

The proposed and predicate device share the same technological characteristics and design by both meeting the standard specification ASTM D6319-19.

Biocompatibility study was performed on the proposed device. Under the conditions of the studies, the proposed devices are not sensitizers, irritants or systemic toxicity.

The proposed and predicate device are made from Polyurethane synthetic latex. The technological characteristics and design for the proposed device have been confirmed and the standard requirements that are appropriate for powder free polyurethane examinations gloves (ASTMD6319-19) have been met.

The following table of the device properties is a summary to show the technological characteristics of the proposed devices in relation to the predicate device:

General Comparison Table:

	Proposed Device K222892	Predicate Device K203036	Reference Device K222642	Comparison
Trade Name	Powder Free Polyurethane Examination Gloves, Blue color, Tested for	Non Sterile Powder Free Polyurethane Examination Gloves (Blue and Black colors)	Disposable Nitrile Examination Glove (Tested for use with Chemotherapy Drug)	Similar

	use with Chemotherapy Drugs			
Product Code	LZA, LZC, OPJ	LZA	LZA, LZC	Same as K222642
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	I	Same
Indications for Use	Powder Free Polyurethane Examination Gloves, Blue color, Tested for use with Chemotherapy Drugs 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 using ASTM D6978	Non Sterile Powder Free Polyurethane Examination Gloves (Blue and Black colors) is a patient medical exam glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.	A patient Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs	Same
Material	Polyurethane	Polyurethane	Nitrile	Same as K203036
Powder or Powder Free	Powder Free	Powder Free	Powder Free	Same
Color	Blue	Blue and Black	Blue	Similar
Single use	Single use	Single use	Single use	Same
Design Feature	Ambidextrous	Ambidextrous	Ambidextrous	Same
Labeling Information	Single-use indication, powder free, device name, glove size, quantity, Polyurethane Examination Gloves, Non Sterile, tested for use with Chemo-drugs	Single-use indication, powder free, device name, glove size, quantity, Polyurethane Examination Gloves, Non Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Similar

Technological Characteristic Comparison Table:

Technological Characteristics	Proposed Device K222892	Predicate Device K203036	Reference Device K222642	Comparison
Length	Minimum 230mm	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)				
XS	70±10	70±10	70±10	Same
S	80±10	80±10	80±10	Same
M	95±10	95±10	95±10	Same
L	110±10	110±10	110±10	Same
XL	120±10	120±10	120±10	Same
XXL	130±10	N/A	N/A	Different
Thickness(mm)				
Finger	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Palm	Minimum 0.05	Minimum 0.05	Minimum 0.05	Same
Tensile Strength, Before Aging	14MPa, min	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	400%, min	Same
Watertight (1000ml)	21 CFR 800.20 ASTM D5151 AQL 2.5	21 CFR 800.20 ASTM D5151	21 CFR 800.20 ASTM D5151	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	Same
ISO 10993-10&23 Skin Irritation and Sensitization Study	Under the conditions of the study, not an irritant, not a sensitizer	Under the conditions of the study, the subject device is non-irritating and non-sensitization	Under the conditions of the study, not an irritant, not a sensitizer	Same
ISO 10993-5 Cytotoxicity Test	showed potential toxicity to L929 cells	N/A	Under conditions of the study, device extract is cytotoxic.	Similar
ISO 10993-11Acute systemic toxicity	no evidence of acute systemic toxicity	N/A	Under conditions of the study, device extract is non-toxic.	Same

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Comparison
	Proposed Device K222892	Reference Device K222642	
Carmustine 3.3 mg/ml (3,300 ppm)	24.0	22.0	Similar
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	Same
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	N/A	Different
Mitomycin C (0.5 mg/ml)	N/A	>240	Different
Vincristine sulfate (1.0 mg/ml)	N/A	>240	Different
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	Same
Thiotepa, 10mg/ml (10,000ppm)	0.6	59.2	Similar

7. 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 230mm for all sizes	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	AQL 2.5	Pass
ASTM D6319- 19 ASTM D6124-06 (2017	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	Permeation by Chemotherapy Drugs	Refer the above table	Pass

ISO 10993-10 &23:2021	Irritation And Skin Sensitization	No Skin sensitization and No Skin irritation	Is non-sensitization and Non-irritation
ISO 10993-5:2009	Cytotoxicity	Not Cytotoxic	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.

- 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 2017), 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 device is as safe, as effective, and performs as well as or better than the legally marketed device.