May 13, 2023

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

Re: K230217
Trade/Device Name: Sterile Polyisoprene Powder Free Surgical Glove, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Non-Powdered Surgeon's Glove
Regulatory Class: Class I, reserved
Product Code: KGO, LZC
Dated: April 11, 2023
Received: April 12, 2023

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
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)*
K230217

Device Name
Sterile Polyisoprene Powder Free Surgical Glove, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05(Reapproved 2019).

Chemotherapy Drug	Minimum Breakthrough Detection Time (BDT) in Minutes
Carmustine (3.3mg/ml)	25.4
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Doxorubicin HCL (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	23.3
Vincristine Sulfate (1mg/ml)	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU): 25.4 minutes, Thiotepa: 23.3 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.

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: K230217
Date Prepared: March 25, 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: Ms. Kathy Liu, Project Manager
Grand Work Plastic Products Co., Ltd
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611

2. Name of the Device:

Trade Name: Sterile Polyisoprene Powder Free Surgical Glove, Tested for Use with Chemotherapy Drugs
Common Name: Surgeon's Glove
Classification Name: Surgeon's Glove
Classification Regulation: 21 CFR 878.4460
Product Code: KGO, LZC
Device Class: Class I

3. Predicate Device Information:

Hartalega NGC SDN BHD
Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs (Natural) (K221718)

4. Device Description:

Sterile Polyisoprene Powder Free Surgical Glove, tested for Use with Chemotherapy Drugs is a disposable single-use, sterile, Cream-colored and powder-free surgical glove made from synthetic polyisoprene latex.

5. Indications for Use:

This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (Reapproved 2019).

Chemotherapy Drug	Minimum BDT (Minutes)
Carmustine (3.3mg/ml)	25.4
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Doxorubicin HCL (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Methotrexate (25mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	23.3

Vincristine Sulfate (1 mg/ml)	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU): 25.4 minutes, Thiotepa: 23.3 minutes
Warning: Do not use with Carmustine and Thiotepa

6. Comparison table of Subject Device and Predicate Device:

Items	Subject Device K230217	Predicate Device K221718	Remark
Trade Name	Sterile Polyisoprene Powder Free Surgical Glove, Tested for Use with Chemotherapy Drugs	Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs (Natural)	Similar
Product Code	KGO, LZC	KGO, LZC	Same
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	Same
Classification	I	I	Same
Regulation Name	Surgeon's Glove	Surgeon's Glove	Same
Indications for Use	This glove is intended to be worn by operating room personnel to protect a surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (Reapproved 2019).	Polyisoprene Powder Free Surgical Glove Tested for Use with Chemotherapy Drugs is intended to be worn by operating room personnel to protect surgical wound from contamination. It is also tested for use against Chemotherapy Drugs. The gloves were tested for use with chemotherapy drugs as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Similar
Type of use	Over the counter use	Over the counter use	Same
Materials	Polyisoprene	Polyisoprene	Same
Color	Cream	Natural	Different
Design	• Single Use • Sterile • Powder-Free • Hand Specific • Beaded cuff	• Single Use • Sterile • Powder-Free • Hand Specific • Beaded cuff	Same
Sterility	Sterile	Sterile	Same
Sterilization	Radiation 10^{-6} SAL	Radiation 10^{-6} SAL	Same
Freedom from holes	Meets ASTM D3577-19 requirements of AQL 1.5	Meets ASTM D3577-19 requirements of AQL 1.5	Similar
Length	Length (mm): ≥ 265 mm	Length (mm): ≥ 265 mm	Similar
Dimensions	5.5: 70 ± 6 (mm) 6.0: 76 ± 6 (mm) 6.5: 83 ± 6 (mm) 7.0: 89 ± 6 (mm) 7.5: 95 ± 6 (mm) 8.0: 102 ± 6 (mm) 8.5: 108 ± 6 (mm) 9.0: 114 ± 6 (mm)	5.5: 70 ± 6 (mm) 6.0: 76 ± 6 (mm) 6.5: 83 ± 6 (mm) 7.0: 89 ± 6 (mm) 7.5: 95 ± 6 (mm) 8.0: 102 ± 6 (mm) 8.5: 108 ± 6 (mm) 9.0: 114 ± 6 (mm)	Similar
Thickness	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm	Similar

	Finger Thickness: ≥ 0.10 mm	Finger Thickness: ≥ 0.10 mm	
Physical Properties	Tensile Strength Before Aging: ≥ 17 MPa Tensile Strength After Aging: ≥ 12 MPa Ultimate Elongation Before Aging: ≥ 650 % Ultimate Elongation After Aging: ≥ 490 %	Tensile Strength Before Aging: ≥ 17 MPa Tensile Strength After Aging: ≥ 12 MPa Ultimate Elongation Before Aging: ≥ 650 % Ultimate Elongation After Aging: ≥ 490 %	Similar
Powder residual	Residual Powder: ≤ 2 mg per glove	Residual Powder: ≤ 2 mg per glove	Similar
In Vitro Cytotoxicity	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.	Under the conditions of the study, the device was found to be cytotoxic	Similar
Primary Skin Irritation	The test result showed that the polar and non-polar extract of the final test sample score is less 1.0, the requirements of the test are met.	Under the conditions of the study, the device is not an irritant	Similar
Dermal Sensitization	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization	Under the conditions of the study, the device is not a sensitizer	Similar
Acute Systemic Toxicity	Under the conditions of this study, there was no evidence of Acute systemic toxicity from the extract. The test article extract met the requirements of this study.	Under the conditions of the study, there was no evidence of systemic toxicity	Similar
Pyrogenicity Test	Under the conditions of this study, no rabbit shows an individual rise in temperature of 0.5ºC or more, the test article Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use with Chemotherapy Drugs meets the requirements of pyrogen test.	Under the conditions of the study, the test article was non-pyrogenic	Similar
Endotoxin Test	≤0.5 units/pair of gloves	Not Performed	Different
Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	Similar

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Remark
	Subject Device K230217	Predicate Device K221718	
Carmustine (3.3mg/ml)	25.4	12.3	Similar
Cisplatin (1mg/ml)	>240	>240	Same
Cyclophosphamide (20mg/ml)	>240	>240	Same

Dacarbazine (10.0 mg/ml)	Not performed	>240	Different*
Doxorubicin HCL (2 mg/ml)	>240	>240	Same
Etoposide (20mg/ml)	>240	>240	Same
Fluorouracil (50mg/ml)	>240	>240	Same
Methotrexate (25mg/ml)	>240	>240	Same
Mitomycin C (0.5 mg/ml)	>240	>240	Same
Paclitaxel (6mg/ml)	>240	>240	Same
Thiotepa (10mg/ml)	23.3	17.4	Similar
Vincristine Sulfate (1 mg/ml)	>240	>240	Same

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

7 Summary of Non-Clinical Testing

Non-clinical testing was performed to verify that the subject device meets the acceptance criteria of the performance test and all design specifications. The test results demonstrated that the subject device complies with the following standards as shown below.

- ASTM D3577-19 Standard Specification for Rubber Surgical Gloves
- 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 D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-5 In Vitro Cytotoxicity
- ISO 10993-23 Primary Skin Irritation
- ISO 10993-10 Dermal Sensitization
- ISO 10993-11 Acute Systemic Toxicity
- ISO 10993-11 Pyrogen Test
- U.S. Pharmacopeia Sterility Test
- U.S. Pharmacopeia endotoxin test

8. Specification for subject Gloves:

Technological Characteristics	Standard/Test/FDA Guidance	Result Summary	Conclusion
Dimensions	ASTM D3577-19	Meets ASTM D3577 requirements for length, width and thickness	Same
--Length	Minimum 265mm	280-305mm	Pass
--Palm Width (size)	(mm)	Average value in mm	
5.5	70±6	73	Pass
6.0	76±6	79	Pass
6.5	83±6	84	Pass
7.0	89±6	90	Pass
7.5	95±6	96	Pass
8.0	102±6	101	Pass
8.5	108±6	108	Pass
9.0	114±6	114	Pass
--Thickness		Average value in mm	
Finger	Minimum 0.10	0.22-0.24	Pass
Palm	Minimum 0.10	0.22	Pass
Cuff	Minimum 0.10	0.17-0.18	Pass
Physical Properties	ASTM D3577-19	Meets ASTM D3577-19	
Tensile Strength, Before	17MPa, min	Average 20-21MPa	Pass

Aging			
Ultimate Elongation, Before Aging	650%, min	Average 780-823%	Pass
Stress at 500% Elongation	7.0 MPa, max	Average 2.5-3.1MPa	Pass
Tensile Strength, After Accelerated Aging	12 MPa, min	Average 18-20MPa	Pass
Ultimate Elongation, After Accelerated Aging	490%, min	Average 747-809 %	Pass
Freedom from holes	ASTM D3577-19 ASTM D 5151-19 requirements of AQL1.5	Meets AQL1.5	Pass
Powder-Free	ASTM D3577-19 ASTM D 6124-06(2022) ≤ 2 mg per glove	0.10-0.27 mg per glove	Pass
Aqueous Extractable Protein Content	ASTM D3577-19 ASTM D5712-15 ≤ 200ug/dm^2	<=50ug/dm^2	Pass
Sterility	10^{-6} SAL	10^{-6} SAL	Pass

9. Biocompatibility

Test	Result Summary
Skin Sensitization Test ISO 10993-10	Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization
Intracutaneous Reactivity Test ISO 10993-23	The test result showed that the polar and non-polar extract of the final test sample score is less 1.0, the requirements of the test are met.
Cytotoxicity Test ISO 10993-5	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.
Acute Systemic Toxicity Test 10993-11	Under the conditions of this study, there was no evidence of Acute systemic toxicity from the extract. The test article extract met the requirements of this study.
Pyrogen Test 10993-11	Under the conditions of this study, no rabbit shows an individual rise in temperature of 0.5ºC or more, the test article Sterile Polyisoprene Powder Free Surgical Gloves, Tested for Use with Chemotherapy Drugs meets the requirements of pyrogen test.

10. Clinical Performance Data:

Not applicable. There was no clinical data required to support the subject device as the indication for use is equivalent to the predicate device.

11. Conclusion:

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