December 20, 2023

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

Re: K232444
Trade/Device Name: Sterile Powder Free Latex Surgical Gloves, 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, OPJ
Dated: November 20, 2023
Received: November 20, 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 (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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232444

Device Name
Sterile Powder Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
The 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.

Chemotherapy Drug	Minimum Breakthrough Detection Time (BDT) in Minutes
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	14.0
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 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
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 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
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thio Tepa, 10mg/ml (10,000ppm)	16.1
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU): 14.0 minutes, Thiotepa: 16.1 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: _K232444_
Date Prepared: December 16, 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
Email: fdareg@hongray.com.cn
Contact: Mrs. Wu Yuli
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611
Email: janicema@hongrayusa.com

2. Name of the Device:

Trade Name: Sterile Powder Free Latex Surgical Gloves, 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, OPJ
Device Class: Class 1

3. Predicate Device Information:

Primary Predicate Device:
Careplus (M) SDN BHD
ENCORE Latex Textured Surgical Gloves, Powder Free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs (K202765).

Reference device:
Medline Industries, Inc.
Signature Latex and Signature Latex Micro, Powder-Free, Surgical Glove, Tested for Use with Chemotherapy Drugs with a Protein Content Label Claim of <50µg/dm2 per Glove of Extractable Protein (K202668)
This reference device is being used to support inclusion of additional chemotherapy drugs that were not tested in the predicate.

4. Device Description:

Sterile Powder Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs is a disposable single-use, sterile, natural-colored and powder-free surgical glove made from rubber latex. They are in different sizes - 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0. Gloves meet the specification of ASTM D3577-19 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05(2019).

5. Indications for Use:

The glove is intended to be worn by operating room personnel to protect surgical wound from contamination. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978.

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240

Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	14.0
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 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
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 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
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thio Tepa, 10mg/ml (10,000ppm)	16.1
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU): 14.0 minutes, Thiotepa: 16.1 minutes
Warning: Do not use with Carmustine and Thiotepa

6. Comparison table of Subject Device and Predicate Device:

Items	Subject Device K232444	Predicate Device K202765	Remark
Trade Name	Sterile Powder Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs	ENCORE Latex Textured Surgical Gloves, Powder Free with Protein Content Labeling Claim (50 micrograms or less) and Tested for use with Chemotherapy drugs	Similar*
Product Code	KGO, LZC, OPJ	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	Sterile Powder Free Latex Surgical Gloves, Tested for Use with Chemotherapy Drugs 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.	Powder Free Surgical Gloves are sterile disposable devices intended to be worn by operating room personnel to protect surgical wound from contamination. These gloves were tested for use with chemotherapy drugs as per ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy.	Same
Type of use	Over the counter use	Over the counter use	Same
Materials	Latex	Latex	Same

Color	Natural	Natural	Same
Single Use/Disposable	Single Use	Single Use	Same
Sterility	Sterile	Sterile	Same
Sterilization method	Radiation sterilization	Radiation sterilization	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	Same
Shelf-life/expiration date	3 years	Not available	Different**
Freedom from holes	Meets ASTM D3577-19 requirements of AQL 1.5	Meets ASTM D3577-19 requirements of AQL 1.5	Same
Length	5.5: ≥ 245 mm 6-9: ≥ 265 mm	5.5: ≥ 245 mm 6-9: ≥ 265 mm	Same
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)	Same
Thickness	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Cuff Thickness: ≥ 0.10 mm Palm Thickness: ≥ 0.10 mm Finger Thickness: ≥ 0.10 mm	Same
Physical Properties	Tensile Strength Before Aging: ≥ 24 MPa Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation Before Aging: ≥ 750 % Ultimate Elongation After Aging: ≥ 560 %	Tensile Strength Before Aging: ≥ 24 MPa Tensile Strength After Aging: ≥ 18 MPa Ultimate Elongation Before Aging: ≥ 750 % Ultimate Elongation After Aging: ≥ 560 %	Same
Powder residual	Residual Powder: ≤ 2 mg per glove	Residual Powder: ≤ 2 mg per glove	Same
In Vitro Cytotoxicity	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.	Under the conditions of this study, the test material is cytotoxic (grade 4) at undiluted, 1:2, 1:4, 1:8 dilutions; and Non-cytotoxic, grade 2 at 1:16 dilution, grade 0 at 1:32 and 1:64 dilutions	Same
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 this study, the test material both inner and outer surface did not reveal systemic toxicity	Same
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 this study, the test material did not cause and irritant response.	Same
Dermal Sensitization	Under the conditions of this study, the test article extract showed no significant evidence of causing skin	Under the conditions of this study, the test material did not produce a skin sensitization effect.	Same

	sensitization		
Material-Mediated Pyrogenicity Test	The test article meets the requirements of pyrogen test.	Non-Pyrogenic	Same
Endotoxin	<20 EU/glove	Not available	Different***
Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	/
Protein Label Claim	No protein claim	Contains 50 micrograms or less of total water extractable protein per gram.	Different****

**The trade name will be indicated on labeling and it does not raise concerns of safety and does not affect the substantial equivalence in effectiveness and safety.*
***The shelf life will be indicated on labeling, so this different does not raise safety and effectiveness concerns.*
****The endotoxin is the required test item on surgical gloves and it will be supported with test report, so the difference does not raise concerns of safety and effectiveness.*
*****The protein claim will not be indicated on labeling of subject device, so the difference does not raise concerns of safety and effectiveness and does not affect the substantial equivalence in effectiveness and safety.*

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)			Remark (Compare with K202668)
	Subject Device K232444	Predicate Device K202765	Reference Device K202668	
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240	/	>240	Same
Busulfan 6mg/ml (6,000 ppm)	>240	/	>240	Same
Carboplatin 10mg/ml (10,000 ppm)	>240	/	>240	Same
Carmustine (BCNU)3.3 mg/ml (3,300 ppm)	14.0	13.2	12.6	Similar
Cisplatin 1mg/ml (1,000 ppm)	>240	/	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	>240	Same
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240	/	>240	Same
Dacarbazine 10 mg/ml (10,000 ppm)	>240	/	>240	Same
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	>240	Same
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	>240	Same
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240	/	>240	Same
Fludarabine, 25 mg/ml (25,000 ppm)	>240	/	>240	Same
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	>240	Same
Idarubicin HCL, 1mg/ml (1,000ppm)	>240	/	>240	Same
Ifosfamide, 50mg/ml (50,000ppm)	>240	/	>240	Same
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240	/	>240	Same
Melphalan, 5mg/ml (5,000ppm)	>240	/	>240	Same
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	>240	Same
Mitomycin C, 0.5mg/ml (500ppm)	>240	/	>240	Same
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240	/	>240	Same
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	>240	Same
Paraplatin, 10mg/ml (10,000ppm)	>240	/	>240	Same
Rituximab, 10mg/ml (10,000ppm)	>240	/	>240	Same
Thio Tepa, 10mg/ml (10,000ppm)	16.1	12.0	22.4	Similar
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	>240	Same

Note: The permeation times of Carmustine and Thio Tepa will be listed on labeling and will add the warning "Do not use with Carmustine and Thiotepa", so this similar does not raise concerns 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 (2022) Standard Test Method for Residual Powder on Medical Gloves
• ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
• ASTM D5712-15 (2020) Standard Test Method for the Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method
• 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

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	/
--Length	5.5: ≥ 245 mm 6-9: ≥ 265 mm	283-308mm	Pass
--Palm Width (size)	(mm)	Average value in mm	/
5.5	70±6	72	Pass
6.0	76±6	76	Pass
6.5	83±6	83	Pass
7.0	89±6	88	Pass
7.5	95±6	95	Pass
8.0	102±6	101	Pass
8.5	108±6	105	Pass
9.0	114±6	110	Pass
--Thickness		Average value in mm	
Finger	Minimum 0.10	0.20-0.26	Pass
Palm	Minimum 0.10	0.19-0.24	Pass
Cuff	Minimum 0.10	0.16-0.19	Pass
Physical Properties	ASTM D3577-19	Meets ASTM D3577-19	
Tensile Strength, Before Aging	24MPa, min	Average 24-29 MPa	Pass
Ultimate Elongation, Before Aging	750%, min	Average 750-851%	Pass
Stress at 500% Elongation	5.5 MPa, max	Average 2.1-4.5MPa	Pass
Tensile Strength, After Accelerated Aging	18MPa, min	Average 18-25MPa	Pass
Ultimate Elongation, After Accelerated Aging	560%, min	Average 610-796 %	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	0.09-0.12mg per glove	Pass
Aqueous Extractable Protein Content	ASTM D3577-19 ASTM D5712-15 ≤ 200ug/dm^2	0.07-0.34ug/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.
Material-mediated Pyrogenicity Test 10993-11	Under the conditions of this study, no rabbit shows an individual rise in temperature of 0.5℃ or more, the test article meets the requirements of pyrogen test.
Endotoxin	<20 EU/glove

10 Clinical Performance Data:
Not applicable.

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.