March 31, 2022

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

Re: K220240
Trade/Device Name: Vinyl Co-Polymer Powder-free Examination Gloves, Black
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: January 25, 2022
Received: January 28, 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)*
K220240

Device Name
Vinyl Co-Polymer Powder-free Examination Gloves, Black

Indications for Use *(Describe)*
Vinyl Co-Polymer Powder-free Examination Gloves, Black is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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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Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Product: Vinyl Co-Polymer Powder-free Examination Gloves, Black

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: K220240
Date Prepared: March 24, 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: Vinyl Co-Polymer Powder-free Examination Gloves, Black
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LYZ
Device Class: Class I

3. Predicate Device Information:

Grand Work Plastic Products Co., Ltd.
Vinyl Co-Polymer Powder-free Examination Gloves, Blue color - (K142409)

4. Device Description:

Vinyl Co-Polymer Powder-free Examination Gloves, Black are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of vinyl and oil-based liquid nitrile rubber materials and are powder free. The physical and performance characteristics of the devices meet all requirements of ASTM D5250-19 Standard Specification for Vinyl Examination Gloves for Medical Application.

5. Intended Use of the Device:

A patient examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6. Comparison of Subject Device and Predicate Device:

The subject device will be known as Vinyl Co-Polymer Powder-free Examination Gloves, Black.

Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Product: Vinyl Co-Polymer Powder-free Examination Gloves, Black

The following tables are a comparison of the technological characteristics, biocompatibility of the subject and predicate devices.

General Comparison Table:

#	Subject Device (K220240)	Predicate Device (K142409)	Comparison
Trade Name	Vinyl Co-Polymer Powder-free Examination Gloves, Black	Vinyl Co-Polymer Powder-free Examination Gloves, Blue color	Similar
Product Code	LYZ	LYZ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Proposed Device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Predicate device is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Materials	vinyl and oil-based liquid nitrile rubber	vinyl and oil-based liquid nitrile rubber	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Black	Blue	Different
Single use	Single use	Single use	Same

Dimensions and Performance Comparison Table:

Technological Characteristics	Subject Device (K220240)	Predicate Device (K142409)	Comparison
Length	Minimum 230mm for all sizes	Minimum 230mm for all sizes	Same
Palm Width (size) (mm)			
XS	75±5	Not Applicable	Different
S	85±5	85±5	Same
M	95±5	95±5	Same
L	105±5	105±5	Same
XL	115±5	115±5	Same
Thickness(mm)			
Finger	Minimum 0.08	Minimum 0.05	Different

Product: Vinyl Co-Polymer Powder-free Examination Gloves, Black

Palm	Minimum 0.08	Minimum 0.08	Same
Tensile Strength, Before Aging	11MPa, min	11MPa, min	Same
Ultimate Elongation, Before Aging	300%, min	300%, min	Same
Tensile Strength, After Accelerated Aging	11MPa, min	11MPa, min	Same
Ultimate Elongation, After Accelerated Aging	300%, min	300%, min	Same
Freedom from holes	G-I, AQL 2.5	G-I, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	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
10993-5:2009 In Vitro Cytotoxicity Test	Under the conditions of this study, the test article extract showed no potential cytotoxicity to L929 cells.	/	Different
ISO 10993 Part 11 Acute Systemic Toxicity Test	It is concluded that the extracts (polar and non-polar) of the product did not show any systemic toxicity	/	Different

There are no significant differences between the two products and are identical in terms of intended use and have similar materials, design, and manufacturing methods.

7. Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards. The performance test data of the non-clinical tests for this glove are summarized below.

Test method	Purpose	Acceptance Criteria	Results
ASTM D5250- 19	Length	Minimum 230mm	All size ≥230
ASTM D5250- 19	Palm Width	XS：75±5mm	XS：76-78mm
		S：85±5mm	S：86-88mm
		M:95±5mm	M:96-98mm
		L:105±5mm	L:106-108mm
		XL：115±5mm	XL：116-118mm

Product: Vinyl Co-Polymer Powder-free Examination Gloves, Black

ASTM D5250- 19	Thickness	Finger: 0.08mm (min)	0.08mm
		Palm: 0.08mm (min)	0.08-0.10mm
ASTM D5250-19 ASTN D412-16	Tensile Strength, Before Aging	11MPa, min	13.5-17.8 MPa
ASTM D5250-19 ASTN D412-16	Tensile Strength, After Accelerated Aging	11MPa, min	13.1-17.6 MPa
ASTM D5250-19 ASTN D412-16	Ultimate Elongation, Before Aging	300%, min	320-430%
ASTM D5250-19 ASTN D412-16	Ultimate Elongation, After Accelerated Aging	300%, min	310-420%
ASTM D 5151-19 ASTM D65250- 19	Freedom from holes	G-I, AQL 2.5	Meets AQL2.5 requirements
ASTM D 6124-06(2017) ASTM D5250 19	Powder-Content	≤ 2 mg per glove	0.35-0.68 mg

8. Clinical Performance Data

No Clinical study is included in this submission.

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 K142409.