July 12, 2022

Grand Work Plastic Products Co., Ltd
Donggao Industrial Zone, Zanhuang, Hebei 050000, China
% Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K213574
Trade/Device Name: Nitrile Vinyl Blend 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: LZA
Dated: June 14, 2022
Received: June 16, 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, M.D., Ph.D.
Acting 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)*
K213574

Device Name
Nitrile Vinyl Blend Powder Free Examination Gloves (Black)

Indications for Use *(Describe)*
Nitrile Vinyl Blend 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.

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Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

K213574

Product: Nitrile Vinyl Blend Powder Free Examination Gloves (Black)

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: K213574

Date Prepared: July 12, 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: Nitrile Vinyl Blend Powder Free Examination Gloves (Black)
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA
Device Class: Class I

3. **Predicate Device Information:**

Grand Work Plastic Products Co., Ltd.
Vinyl Nitrile Co-Polymer Powder Free Examination Gloves (Blue)- (K051662)

4. **Device Description:**

Nitrile Vinyl Blend 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. They are ambidextrous and come in different sizes—XS, S, M, L and XL. The physical and performance characteristics of the devices meet all requirements of ASTM D6319-19 Standard Specification for Nitrile 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:

Grand Work Plastic Products Co. Ltd.'s Nitrile Vinyl Blend Powder Free Examination Gloves (Black) is safety and effectiveness as the Grand Work Plastic Products Co., Ltd.'s Vinyl Nitrile Co-Polymer Powder Free Examination Gloves (Blue)- (K051662). The subject device and predicate

Product: Nitrile Vinyl Blend Powder Free Examination Gloves (Black)

device use a similar plastic flexible barrier film to achieve a device for the intended use. And the properties between the subject device and the predicate device are compared in the following table:

General Comparison Table:

#	Proposed Device K213574	Predicate Device K051662	Remark
Trade Name	Nitrile Vinyl Blend Powder Free Examination Gloves (Black)	Vinyl Nitrile Co-Polymer Powder Free Examination Gloves (Blue)	Similar
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Nitrile Vinyl Blend 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.	Vinyl Nitrile Co-Polymer Powder Free Examination Gloves (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand 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
Labeling Information	Single-use, powder free glove size, quantity, Examination Gloves, Non Sterile	Single-use, powder free glove size, quantity, Examination Gloves, Non Sterile	Same

Dimensions and Performance Comparison Table:

Technological Characteristics	Proposed Device	Predicate Device	Remark
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

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L	110±10	110±10	Same
XL	120±10	120±10	Same
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
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
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 potential toxicity	/	Exceed
ISO 10993 Part 11 Acute Systemic Toxicity Test	Under the conditions of this study, there was no evidence of systemic toxicity.	/	Exceed

Grand Work Plastic Products Co., Ltd.'s Nitrile Vinyl Blend Powder Free Examination Gloves (Black) shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D6319-19, biocompatibility requirement and FDA requirements and the labeling claims for the product. It performs as well as the legally marketed predicate device.

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 complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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- 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
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
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Test method	Purpose	Acceptance Criteria	Results
ASTM D6319- 19	Length	All size: Minimum 230mm	XS: 230-245mm S: 230-245mm M: 230-245mm L: 230-245mm XL: 230-247 mm
ASTM D6319- 19	Palm Width	XS：70±10mm	76-78mm
		S：80±10mm	86-88 mm
		M:95±10mm	96 -98mm
		L:110±10mm	106-110 mm
		XL：120±10mm	116-118 mm
ASTM D6319- 19	Thickness	Finger: 0.05mm (min)	0.06-0.08mm
		Palm: 0.05mm (min)	0.07-0.09mm
ASTM D6319-19 ASTN D412-16	Tensile Strength, Before Aging	14MPa, min	14.2-16.9 MPa
ASTM D6319-19 ASTN D412-16	Tensile Strength, After Accelerated Aging	14MPa, min	14.1-16.2MPa
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, Before Aging	500%, min	500-520%
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, After Accelerated Aging	400%, min	400-480%
ASTM D 5151-19 ASTM D6319- 19	Freedom from holes	G-I, AQL 2.5	XS: 0/125 S:0/125 M: 0/125 L:1/125 XL: 1/125
ASTM D 6124-06(2017) ASTM D6319- 19	Powder-Content	≤ 2 mg per glove	XS:0.35mg S: 0.41mg M: 0.47mg L: 0.55mg

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			XL：066mg
ISO 10993-10:2010	Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant
ISO 10993-10:2010	Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer
ISO 10993-5:2009	Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity	Under the conditions of this study, the test article extract showed potential toxicity
ISO 10993-11:2017	Systemic toxicity	Under the conditions of this study, there was no evidence of systemic toxicity.	Under the conditions of this study, there was no evidence of systemic toxicity.

8. Clinical Performance Data

N/A

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.