March 26, 2022

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

Re: K220229
Trade/Device Name: Powder Free Nitrile Examination Gloves, Orange
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: January 20, 2022
Received: January 27, 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)*
K220229

Device Name
Powder Free Nitrile Examination Gloves, Orange

Indications for Use *(Describe)*
Powder Free Nitrile Examination Gloves, Orange 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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Shanxi Hongjin Plastic Technology Co., Ltd.

Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, Shanxi Province

510(K) SUMMARY

The assigned 510(K) number: K220229
Date Prepared: January 20, 2022

1. Owner's Identification:

Mr. Wu Zhigang
Shanxi Hongjin Plastic Technology Co., Ltd.
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, Shanxi Province

Tel: 86-311-66766067
Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Avenue, Chino, CA 91710, USA
Tel: 909-590-1611
Email: kathyliu@hongrayusa.com or fdareg@126.com

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves, Orange
Common Name: Patient Examination Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 21 CFR 880.6250
Product Code: LZA
Classification Panel: General Hospital Device
Class: Class I

3. Predicate Device Information:

Wrp Asia Pacific Sdn Bhd
Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Orange) (K192635)

4. Device Description:

Powder Free Nitrile Examination Gloves, Orange are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of nitrile latex and are powder free. They are ambidextrous. 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. Indications for Use:

Powder Free Nitrile Examination Gloves, Orange is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

6. Comparison of Subject Device and Predicate Device:

The subject device will be known as Powder Free Nitrile Examination Gloves, Orange.
The following tables are summaries of the technological characteristics, biocompatibility of the subject and predicate devices.

General Comparison Table:

Characteristics	Standards	Subject Device K220229	Predicate Device K192635	Comparison Analysis
Material	ASTM D6319-19	Nitrile	Nitrile	Same
Color	-	Orange	Orange	Same
Texture	-	Hand textured	Hand textured	Same
Trade Name	-	Powder Free Nitrile Examination Gloves, Orange	Powder Free Nitrile Patient Examination Gloves, Non-Sterile (Orange)	Similar
Product Code	-	LZA	LZA	Same

510(K) SUMMARY

Regulation Number	-	21 CFR 880.6250	21 CFR 880.6250	Same
Class	-	I	I	Same
Physical Properties Before Aging Tensile Strength: Ultimate Elongation: After Aging Tensile Strength: Ultimate Elongation :	ASTM D6319-19	 14MPa min 500% min 14MPa min 400% min	 14MPa min 500% min 14MPa min 400% min	Same
Thickness - Finger - Palm	ASTM D6319-19	 0.16-0.22mm 0.15-0.18mm	 0.21-0.23mm 0.19-0.22mm	Different
Powder Free	ASTM D6124-06(2017)	≤ 2 mg/glove	≤ 2 mg/glove	Same
Biocompatibility Primary Skin Irritation Test	ISO 10993-10:2010	Under conditions of the study, not an irritant	Not a primary skin irritant	Same
Biocompatibility Dermal Sensitization Study	ISO 10993-10:2010	Under conditions of the study, not a sensitizer	Not a contact sensitizer	Same
Biocompatibility Cytotoxicity	ISO 10993-5:2009	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systematic toxicity testing.	Exhibit severe cytotoxicity reactivity at 100%, 66%, and 44% extract concentration. Moderate cytotoxicity reactivity at 30%, mild cytotoxicity reactivity at 20% and slight cytotoxicity reactivity at 15% extract concentrations. Cytotoxicity concern was addressed by acute systematic toxicity testing.	Same
Biocompatibility Acute Systemic Toxicity	ISO 10993-11:2017	It is concluded that the extracts (polar and non-polar) of the product did not show any systemic toxicity	It is concluded that the extracts (polar and non -polar) of the product did not show any systemic toxicity	Same
Watertight (1000ml)	ASTM D5151-19	Inspection Level 1, AQL 2.5	Inspection Level 1, AQL 1.5	Similar
Indications for Use	-	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Same
Size	Medical Glove Guidance Manual – Labeling	XS, S, M, L, XL, XXL	XS, S, M, L, XL	Similar
Single use	Medical Glove Guidance Manual – Labeling	Single use	Single use	Same

There are no significant differences between the two products and are identical in terms of intended use, materials, design, manufacturing methods except for size and thickness. The subject device is one more extra size XXL and thinner than predicate device.

510(K) SUMMARY

7. Summary of Non-Clinical Testing

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 powder free nitrile examination glove is summarized as per below.

Test method	Purpose	Acceptance Criteria	Results	Status
ASTM D6319- 19	Length	Minimum 230mm	All size ≥230	Pass
ASTM D6319- 19	Palm Width	XS：70±10mm	76-78mm	Pass
		S：80±10mm	86-88 mm	Pass
		M:95±10mm	96 -98mm	Pass
		L:110±10mm	106-108 mm	Pass
		XL：120±10mm	116-118 mm	Pass
		XXL：130±10mm	126-128 mm	Pass
ASTM D6319- 19	Thickness	Finger: 0.05mm (min)	0.15-0.18mm	Pass
		Palm: 0.05mm (min)	0.16-0.22mm	Pass
ASTM D6319-19 ASTN D412-16	Tensile Strength, Before Aging	14MPa, min	15.8-19.9Mpa	Pass
ASTM D6319-19 ASTN D412-16	Tensile Strength, After Accelerated Aging	14MPa, min	15.2-18.8Mpa	Pass
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, Before Aging	500%, min	500-550%	Pass
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, After Accelerated Aging	400%, min	430-500%	Pass
ASTM D 5151-19 ASTM D6319- 19	Freedom from holes	G-I, AQL 2.5	Meet and above AQL2.5 requirements	Pass
ASTM D 6124-06(2017) ASTM D6319- 19	Powder-Content	≤ 2 mg per glove	0.55-0.78 mg	Pass

8. Summary of Clinical Testing

No Clinical study is included in this submission.

9. 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 predicated device, K192635.