August 31, 2023

Shanxi Hongjin Plastic Technology Co., Ltd.
Ma Janice
Project Manager
Coal Bed Gas Industrial Zone, Qu'e Town
Daning County
Linfen, Shanxi 042300
China

Re: K232353
Trade/Device Name: Powder Free Nitrile 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: August 7, 2023
Received: August 7, 2023

Dear Ma Janice:

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)*
K232353

Device Name
Powder Free Nitrile Examination Gloves (Black)

Indications for Use *(Describe)*
The glove 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Shanxi Hongjin Plastic Technology Co., Ltd.

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

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) numbers: K232353

Date Prepared: August 07, 2023

1. Owner's Identification:

Mr. Wu Zhigang
Shanxi Hongjin Plastic Technology Co., Ltd.
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen Shanxi, 042300, China
Email: fdareg@hongray.com.cn

Contact: Mr. Wu Zhigang
Shanxi Hongjin Plastic Technology Co., Ltd.
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen Shanxi, 042300, China
Email: janicema@hongrayusa.com

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Black)
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 21 CFR 880.6250
Product Code: LZA
Classification Panel: General Hospital and Personal Use
Device Class: Class I

3. Predicate Device Information:

Shanxi Hongjin Plastic Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K230779)
Product Code: LZA
Classification Panel: General Hospital and Personal Use
Device Class: Class I

4. Device Description:

The subject device is a patient examination glove made from nitrile latex compound, powder free and non-sterile (Per 21 CFR 880.6250, class I). They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large and XXL. The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves.

5. Device Modification

The proposed modification to the predicate device is to delete the claim which tested for use with chemotherapy drugs and fentanyl citrate. There are no any differences with these two models of the gloves from materials, manufacturing process and bench performance.

6. Indications for Use:

The Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

7. Comparison of Technological Characteristics Between the Subject Device and Predicate Device:

General Comparison Table:

Items	Subject Device	Predicate Device K230779	Comparison
Trade Name	Powder Free Nitrile Examination Gloves (Black)	Powder Free Nitrile Examination Gloves (Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Different
Product Code	LZA	LZA, LZC, QDO, OPJ	Different
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978	Different
Material	Nitrile	Nitrile	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Color	Black	Black	Same
Single use	Single use	Single use	Same
Sterile	Non-Sterile	Non-Sterile	Same

This different will do not raise different questions of safety and effectiveness than the predicate device because all necessary information will be labeled on the packaging.

Technological Characteristic Comparison Table:

Technological Characteristics	Subject Device	Predicate Device K230779	Comparison
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
L	110±10	110±10	Same
XL	120±10	120±10	Same
XXL	130±10	130±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
Watertight (1000ml)	G-I, AQL 2.5	G-I, AQL 2.5	Same
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Same
10993-23:2021 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2021 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 Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.	Under the conditions of this study, the test article extract showed potential toxicity to L929 cells.	Same
ISO 10993-11:2017 Acute Systemic toxicity study	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.	Same

8. Summary of 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 met the performance criteria with the following standards:

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 230mm for all sizes	Pass
ASTM D6319- 19	Physical Dimensions Palm Width	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL：120±10mm XXL：130±10mm	Pass
ASTM D6319- 19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412-16(2021)	Physical Properties	Tensile Strength (Min14 MPa) and Elongation (Before Aging 500% and after aging 400%) Min	Pass
ASTM D6319- 19 ASTM D5151-19	Water leak test	AQL 2.5 (ISO 2859-1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	Max 2mg/glove	Pass
ISO 10993-10 &23:2021	Irritation and Skin Sensitization	Skin sensitization and Skin irritation	Is non-sensitization and Non-irritation
ISO 10993-5:2009	Cytotoxicity	Cytotoxicity reactivity	showed potential

			toxicity to L929 cells.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	no evidence of systemic toxicity.

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Irritation.
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

9. Clinical Performance Data

N/A

10. 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 predicated device.