July 17, 2021

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

Re: K211177
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: April 14, 2021
Received: April 20, 2021

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, 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)*
K211177

Device Name
Powder Free Vinyl Patient Examination Gloves

Indications for Use *(Describe)*
Powder Free Vinyl Patient Examination Gloves 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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Shijiazhuang Hongjun Plastic Manufacture Co., Ltd.

Xinye Industrial Zone, Wangtong Village, Wancheng Town, Gaoyi County,
Shijiazhuang City, Hebei Province, 051330 China

Product: Powder Free Vinyl Patient Examination Gloves

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: K211177

Date Prepared: July 16, 2021

1. Owner's Identification:

Mr. Lv Zhanmin
Shijiazhuang Hongjun Plastic Manufacture Co., Ltd.
Xinye Industrial Zone, Wangtong Village, Wancheng Town, Gaoyi County,
Shijiazhuang City, Hebei Province, 051330 China
Tel: 86-311-83610904

Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611

2. Name of the Device:

Trade Name: Powder Free Vinyl Patient Examination Gloves
Common Name: Exam Gloves
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:

Shanxi Hongjin Plastic Technology Co., Ltd
Powder Free Vinyl Patient Examination Gloves- (K180381)

4. Device Description:

Powder Free Vinyl Patient Examination Gloves Are Patient Examination Gloves, Disposable, single use only and non-sterile. The gloves are made of vinyl materials and are powder free. The physical and performance characteristics of the devices meet all requirements of ASTM D5250-19 Standard Specification for Poly (Vinyl Chloride) 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. Technological Characteristics Comparison:

Shijiazhuang Hongjun Plastic Manufacture Co., Ltd's Powder Free Vinyl Patient Examination Gloves is compared to the Shanxi Hongjin Plastic Technology Co., Ltd's Powder Free Vinyl Patient Examination Gloves- (K180381) in the table below.

Shijiazhuang Hongjun Plastic Manufacture Co., Ltd.
Xinye Industrial Zone, Wangtong Village, Wancheng Town, Gaoyi County,
Shijiazhuang City, Hebei Province, 051330 China

Product: Powder Free Vinyl Patient Examination Gloves

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
Product Code	/	LYZ	LYZ	Same
Size	/	S, M, L, XL	S, M, L, XL	Same
Intended Use	/	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.	Subject 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
Labeling	/	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	There are no special labeling claims and do not claim gloves as hypoallergenic on labels.	Same
Device Materials	/	Vinyl	Vinyl	Same
Color	/	Clear	Clear	Same
Device tolerances and specifications & Performance Data:				
Tensile strength: before and after aging	ASTM D 5250-19	11Mpa minimum	11Mpa minimum	Same
Ultimate elongation: before and after aging	ASTM D 5250-19	300% minimum	300% minimum	Same
Freedom from pinholes	ASTM D 5250-19	G-I, AQL2.5	G-I, AQL2.5	Same
Dimensions: Overall length, Width, Palm and Finger thickness	ASTM D 5250-19	Meets ASTM D 5250-19	Meets ASTM D 5250-19	Same
Residual powder	ASTM D 5250-19	Not more than 2mg per glove	Not more than 2mg per glove	Same
Biocompatibility				
Primary skin irritation test	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Same
Dermal sensitization	ISO 10993-10	Under conditions of	Under conditions of	Same

Product: Powder Free Vinyl Patient Examination Gloves

Characteristics	Standard	Device Performance		Result of comparison
		Predicate device	Subject Device	
assay		the study, not an irritant	the study, not an irritant	
Cytotoxicity Test	ISO 10993-5	Under the conditions of this study, no cytotoxic potential	Under the conditions of this study, no cytotoxic potential	Same

Shijiazhuang Hongjun Plastic Manufacture Co., Ltd's Powder Free Vinyl Patient Examination Gloves shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D5250-19, biocompatibility requirement and FDA requirements and the labeling claims for the product..

7. <u>Summary of Non-Clinical Tests:</u>

Characteristics	FDA-recognized Standard	Inspection Level and AQL	Performance Results	Conclusion
Overall Length (mm)	ASTM D 5250-19 230 for all sizes minimum	S-2, AQL4.0	S: 235-241mm M:233-240mm L:234-241mm XL: 236-242mm	Meets
Width (mm) ASTM D 5250-19	S: 85±5	S-2, AQL4.0	86-88 mm	Meets
	M: 95±5		96-98 mm	
	L: 105±5		106-108 mm	
	XL: 115±5		116-118 mm	
Palm Thickness (mm)	0.08mm minimum	S-2, AQL4.0	0.08mm	Meets
Finger Thickness (mm)	0.08mm minimum	S-2, AQL4.0	0.08-0.10mm	Meets
Tensile Strength (Mpa) ASTM D 5250-19				
Before aging	11Mpa minimum	S-2, AQL4.0	13.0-16.1Mpa	Meets
After aging	11Mpa minimum		13.0-15.8Mpa	Meets
Ultimate Elongation (%)				
Before aging	300% minimum	S-2, AQL4.0	310-410%	Meets
After aging	300% minimum		310-400%	Meets
Pinhole	ASTM D 5250-19 ASTM D5151-19 21CFR800.20	G-I, AQL2.5	125 glove sampled and 1 piece leaks	Meets
Residual Powder	ASTM D 5250-19 ASTM D6124-06 (Reapproved 2017)	Not more than 2mg per glove N=5	0.35-0.73mg	Meets
Primary Skin Irritation and Skin Sensitization	ISO 10993-10	/	Under conditions of the study, not an irritant	Meets

Cytotoxicity Test	ISO 10993-5	/	Under the conditions of this study, no cytotoxic potential	Meets

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.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- 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 D5250-19, Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application

8. Clinical Performance Data

N/A

9. Conclusion:

The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject device, Powder Free Vinyl Patient Examination Gloves (K211177) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Powder Free Vinyl Patient Examination Gloves (K180381).