November 7, 2018

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

Re: K180381
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: September 26, 2018
Received: October 2, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180381

Device Name
Powder Free Vinyl Patient Examination Gloves

Indications for Use *(Describe)*
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.

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, China 042399

Trade Name: Powder Free Vinyl Patient Examination Gloves

510(K) SUMMARY

This summary of 510(K) is being submitted in accordance with 21 CFR 807.92.

The assigned 510(K) number is: _K180381__

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, China 042399

Tel: 86-311-66179653
Fax: 86-311-83616934

Contact: Ms. Kathy Liu, Project Manager or Ms Monica Yu
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611
Fax: 909-590-1511
Date Summary Prepared: November 5, 2018

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:**

Ever Light Plastic Products Co., Ltd.
Powder Free Vinyl Patient Examination Gloves (K142571)

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 D5250-06 (Reapproved 2015) Standard Specification For Poly(Vinyl Chloride) Gloves For Medical Application.

Trade Name: Powder Free Vinyl Patient Examination Gloves

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 Characteristic Comparison Table:
Shown below is the comparison of technological characteristic between the subject and predicate device.

Characteristics	Device Performance		Result of comparison
	Predicate device K142571	Subject Device K180381	
Product Code	LYZ	LYZ	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	There are no special labeling claims	Same
Device Materials	Vinyl	Vinyl	Same
Color	Clear	Clear	Similar
Specifications & Performance Data:			
physical Properties	11Mpa minimum Elongation 300% Meets ASTM D 5250-06 (2015)requirements	11Mpa minimum Elongation:300% Meets ASTM D 5250-06 (2015)requirements	Same
Freedom from pinholes	G -1,AQL 2.5 Meets ASTM D 5250-06 (2015)requirements	G -1,AQL 2.5 Meets ASTM D 5250-06 (2015)requirements	Same
Dimensions:	Meets ASTM D 5250-06 (2015)requirements	Meets ASTM D 5250-06 (2015)requirements	Same
Residual powder	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Same
Biocompatibility			
Primary skin	Under conditions of the	Under conditions of the	Same

Trade Name: Powder Free Vinyl Patient Examination Gloves

Characteristics	Device Performance		Result of comparison
	Predicate device K142571	Subject Device K180381	
irritation test	study, not an irritant	study, not an irritant	
Dermal sensitization assay	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Same
Cytotoxicity Test	/	Under the conditions of this study, not a cytotoxic potential	Different

Shanxi Hongjin Plastic Technology Co., Ltd's Powder Free Vinyl Patient Examination Gloves shares the same or similar technology characteristics compared to the predicate device.

7. **Discussion of Non-Clinical Tests**

Testing Items	FDA-recognized Standard Requirements	Inspection Level and AQL	Actual Testing Results	Conclusion
Overall Length (mm)	230 for all sizes minimum	S-2, AQL4.0	S: 233-241mm M:231-242mm L:230-244mm XL: 234-245mm	Pass
Width (mm)	S: 85±5	S-2, AQL4.0	87-88 mm	Pass
	M: 95±5		97-98 mm	
	L: 105±5		107-108 mm	
	XL: 115±5		118-119 mm	
Palm Thickness (mm)	0.08mm minimum	S-2, AQL4.0	0.08mm	Pass
Finger Thickness (mm)	0.05mm minimum	S-2, AQL4.0	0.09-0.11mm	Pass
Tensile Strength (Mpa)				
Before aging	11Mpa minimum	S-2, AQL4.0	14.4-17.1Mpa	Pass
After aging	11Mpa minimum		14.1-16.9Mpa	Pass
Ultimate Elongation (%)				
Before aging	300% minimum	S-2, AQL4.0	390-480%	Pass
After aging	300% minimum		380-470%	Pass

Pinhole	2.5	G-I	meet AQL2.5 requirements	Pass
Residual Powder	Not more than 2mg per glove	N=5	0.20 mg/glove	Pass
(a) Primary Skin Irritation Test	Under conditions of the study, not an irritant		Under conditions of the study, not an irritant	
(b) Dermal Sensitization Study	Under conditions of the study, not an irritant		Under conditions of the study, not an irritant	
(c)Cytotoxicity Test	Under the conditions of this study, not a cytotoxic potential		Under the conditions of this study, not a cytotoxic potential	

8. **Discussion of Clinical Tests Performed:**
Not applicable

9. Conclusion:

Based on the performed nonclinical tests, demonstrate that the device is as safe, as effective, and performs as well as the legally marketed predicate device.