DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 5,2014

Grand Work Plastic Products Company Limited
C/O Ms. Kathy Liu
Hongray USA Medical Products Incorporated
3973 Schaefer Avenue
Chino, CA 91710

Re: K142409
Trade/Device Name: Vinyl Co-Polymer Powder-free Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: October 31, 2014
Received: November 5, 2014

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142409

Device Name
Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone Zanhuang, Hebei, China 050000

K142409

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: K142409

Date Summary Prepared: December 3, 2014

1. **Owner's Identification:**

Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone Zanhuang, Hebei, China 050000
Tel: +86-0311-83980225
Fax: +86-0311-83634221
Contact: Ms. May Jia
Position title: Project Manager

2. **Name of the Device:**

Trade Name: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital
Product Code: LYZ
Device Class: Class I

3. **Predicate Device Information:**

Grand Work Plastic Products Co., Ltd.
Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color (K061562)

4. **Device Description:**

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color 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. The physical and performance characteristics of the devices meet all requirements of ASTM D5250-06 (Reapproved 2011) 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 and Substantial Equivalence:**

Grand Work Plastic Products Co., Ltd.'s Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color is substantially equivalent in safety and effectiveness to the Grand Work Plastic Products Co., Ltd.'s Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color (K 061562). The subject device and predicate 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:

Characteristics	Device Performance		Result of comparison
	Predicate device K061562	Subject Device K142409	
Product Code	LYZ	LYZ	Similar
Indications For 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.	Similar
Labeling	It is Patient Examination Glove, Disposable, single use only and non-sterile	It is Patient Examination Glove, Disposable, single use only and non-sterile	Similar
Device Materials	Vinyl and oil-based liquid Nitrile compound The plasticizer type used is different.	Vinyl and oil-based liquid Nitrile compound The plasticizer type used is different.	Similar
Color	Blue	Blue	Similar

Device tolerances and specifications & Performance Data:

Characteristics	Stated Standard	Device Performance		Result of comparison
		Predicate device K061562	Subject Device K142409	
Tensile strength: before and after aging	K061562: 9Mpa min K142409 11Mpa min	Before aging:14 MPa After aging:14MPa	Before aging: 15.2Mpa After aging: 14.6Mpa	Similar & Both meet ASTM D5250 standard

K142409

Characteristics	Stated Standard	Device Performance		Result of comparison
		Predicate device K061562	Subject Device K142409	
Ultimate elongation: before and after aging	300% min	Before aging: 400% After aging:300%	Before aging: 390% After aging: 360%	Similar & Both meet ASTM D5250 standard
Freedom from pinholes	G-I, AQL2.5	G-I, AQL2.5	G-I, AQL1.5	Similar & Both meet ASTM D5250 standard
Overall length	230 for all sizes min	245mm	239mm	Similar & Both meet ASTM D5250 standard
Width	S: 85±5	82 mm	87 mm	
	M: 95±5	97mm	97 mm	
	L: 105±5	110mm	107 mm	
	XL: 115±5	120mm	118 mm	
Palm thickness	min0.08mm	0.10mm	0.08mm	
Finger thickness	min0.05mm	0.10mm	0.10mm	
Residual powder	Not more than 2mg per glove	Not more than 2mg per glove	Not more than 2mg per glove	Similar & Both meet ASTM D5250 standard
Biocompatibility				
Primary skin irritation test	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Similar
Dermal sensitization assay	ISO 10993-10	Under conditions of the study, not an irritant	Under conditions of the study, not an irritant	Similar

The two versions of standards referenced for predicate device and subject device are compared in the following table:

Testing Items	ASTM D5250-00$^{\varepsilon 4}$ for Predicate device K061562	ASTM D 5250-06(2011) for Subject Device K142409	Inspection level	Result of comparison
Overall Length	230 for all sizes min	230 for all sizes mini	S-2, AQL4.0	Same

(mm)				
Width (mm)	S: 85±5	S: 85±5	S-2, AQL4.0	Same
	M: 95±5	M: 95±5		
	L: 105±5	L: 105±5		
	XL: 115±5	XL: 115±5		
Palm Thickness (mm)	0.08mm min	0.08mm min	S-2, AQL4.0	Same
Finger Thickness (mm)	0.05mm min	0.05mm min	S-2, AQL4.0	Same
Tensile Before aging	9Mpa min	11Mpa min	S-2, AQL4.0	Exceed
Tensile After aging	9Mpa min	11Mpa min		Exceed
Elongation Before aging	300% min	300% min	S-2, AQL4.0	Same
Elongation After aging	300% min	300% min		Same
Pinhole	AQL 2.5	AQL 2.5	G-I	Same
Residual Powder	Not more than 2mg per glove	Not more than 2mg per glove	N=5	Same

Grand Work Plastic Products Co., Ltd.'s Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color shares the same or comparable technology characteristics compared to the predicate device. The subject device performs according to the glove performance standards ASTM D5250-06(2011), biocompatibility requirement and FDA requirements and the labeling claims for the product. It performs as well as the legally marketed predicate device.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as Follows:**

Testing Items	FDA-recognized Standard Requirements	Inspection Level and AQL	Testing Results	Conclusion
Overall Length (mm)	230 for all sizes min	S-2, AQL4.0	239mm	Pass
Width (mm)	S: 85±5	S-2, AQL4.0	S: 87	Pass
	M: 95±5		M: 97	
	L: 105±5		L: 107	
	XL: 115±5		XL: 118	

Palm Thickness (mm)	0.08mm min	S-2, AQL4.0	0.08mm	Pass
Finger Thickness (mm)	0.05mm min	S-2, AQL4.0	0.10mm	Pass
Tensile Strength (Mpa)				
Before aging	11Mpa min	S-2, AQL4.0	15.2Mpa min	Pass
After aging	11Mpa min		14.6Mpa min	Pass
Ultimate Elongation (%)				
Before aging	300% min	S-2, AQL4.0	390% min	Pass
After aging	300% min		360% min	Pass
Pinhole	2.5	G-I	AQL1.5	Pass
Residual Powder	Not more than 2mg per glove	N=5	Not more than 2mg per 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	

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

9. **Labeling:**
   It is Patient Examination Glove, Disposable, single use only and non-sterile
   There are no special labeling claims.

10. **Conclusions:**
    Grand Work Plastic Products Co., Ltd's Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color conform fully to ASTM D 5250-06（2011） standard as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data discussed above. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

    Drawn from the complete list of non-clinical tests, the device herein mentioned is as safe, as effective, and performs as well as the legally marketed predicate device.