DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 26, 2016

Xingyuan Plastic Products Co., Ltd.
% Mr. Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Rd.,
Chaoyang District
Beijing, 100024 CHINA

Re: K153159
Trade/Device Name: Vinyl Patient Examination Glove, Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: December 16, 2015
Received: December 18, 2015

Dear Mr. Ray Wang:

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 Industry and Consumer Education 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" (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 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Infection Control, and Dental Devices
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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)*

K153159

Device Name
Vinyl patient examination glove, Powder Free

Indications for Use *(Describe)*

The Vinyl patient examination glove, Powder Free, is a disposable device intended for medical purposes that is worn on the examiner's hands 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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Exhibit 2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K153159

1. Date of Preparation: 2016/01/26

2. Sponsor

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3. Submission Correspondent

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4. Proposed Device Identification

Trade Name: Vinyl patient examination glove, Powder Free
Device Name: Vinyl Patient Examination Gloves (Powder Free)
Common Name: Patient Examination Gloves

Classification: I
Product Code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Intended Use Statement:
The Vinyl patient examination glove, Powder Free, is a disposable device intended for medical

purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: k150224
Product Name: BLUE VINYL GLOVES POWDER FREE
Manufacturer: ZIBO SANYING TRADE CO., LTD

6. Device Description

The proposed device, Vinyl patient examination glove, Powder Free is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.
The proposed is Powder Free Vinyl Patient Examination Gloves without color, and includes variations of different size.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D5250-06, Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.
ASTM D 5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves.
ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

8. Substantially Equivalent Comparison Conclusion

Table 1 General Comparison

ITEM	Proposed Device Vinyl patient examination glove, Powder Free	Predicated Device BLUE VINYL GLOVES POWDER FREE K150224	Remark
Product Code	LYZ	LYZ	SE
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SE
Class	I	I	SE

Intended Use	The Vinyl patient examination glove, Powder Free, is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	The BLUE VINYL GLOVES POWDER FREE is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.	SE
Powdered or Powered free	Powdered free	Powdered free	SE
Design Feature	ambidextrous, smooth	ambidextrous, smooth	SE

Table 2 Device Dimensions Comparison

Proposed Device Vinyl patient examination glove, Powder Free	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	230	230	230	230	min
	Width, mm	85	95	105	115	±5
	Thickness, mm:					
	Finger	≥ 0.05				min
	Palm	0.08				min
Predicate Device (k150224) BLUE VINYL GLOVES POWDER FREE	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	240	240	240	240	min
	Width, mm	85	95	105	115	±5
	Thickness, mm:					
	Finger	0.10				min
	Palm	0.08				min
Remark	Analysis 1					

Analysis 1:

Although the proposed device has different with the predicated device in thickness of finger and palm, but the specifications of proposed device meet the requirements of ASTM D5250.

So we consider this as the proposed device is SE with the predicate device.

Table 3 Performance Comparison

ITEM			Proposed Device Vinyl patient examination glove, Powder Free	Predicated Device BLUE VINYL GLOVES POWDER FREE K150224	Remark
Colorant			N/A	Blue	Analysis 2
Physical Properties	Before Aging	Tensile Strength	11 MPa, min	13 MPa, min	Analysis 3
		Ultimate Elongation	300 % min	400 % min	
	After Aging	Tensile Strength	11 MPa, min	13 MPa, min	
		Ultimate Elongation	300 % min	400 % min	
	Comply with ASTM D5250			Comply with ASTM D5250	SE
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	SE
Powder Content			0.50 mg per glove	Meet the requirements of ASTM 5250	SE

Analysis 2:

The proposed device has no color rather than blue of the predicate device, this different may causes potential biocompatibility, for this risk we conducted the biocompatibility test according to the ISO 10993-10, the test results showed that the proposed devices did not induce skin irritation and showed no significant evidence of causing skin sensitization.

So we consider this as the proposed device is SE with the predicate device.

Analysis 3:

Although the proposed device has different with the predicated device in physical properties, but the specifications of proposed device meet the requirements of ASTM D5250.

So we consider this as the proposed device is SE with the predicate device.

Table 4 Safety Comparison

ITEM		Proposed Device Vinyl patient examination glove, Powder Free	Predicated Device BLUE VINYL GLOVES POWDER FREE K150224	Remark
Material		Vinyl	Vinyl	SE
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
	Sensitization	Under conditions of the study, not a sensitizer.		
Label and Labeling		Single-use indication, powder free, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single-use indication, powder free, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	SE

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.