Food and Drug Administration
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February 23, 2017

Hebei Hongtai Plastic Products Company Limited
% Ray Wang
Official Correspondent
Beijing Believe Tech.service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd., Liyuan
Tongzhou District
Beijing, 101121 CN

Re: K163168
Trade/Device Name: Vinyl Examination Gloves (White), Vinyl Examination Gloves (Blue), Vinyl Examination Gloves (Yellow)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: January 14, 2017
Received: January 17, 2017

Dear 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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163168

Device Name
Vinyl Examination Gloves (White)
Vinyl Examination Gloves (Blue)
Vinyl Examination Gloves (Yellow)

Indications for Use *(Describe)*
The Vinyl Examination Gloves (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands 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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510(k) Summary

The assigned 510(k) Number: K163168

1. Date of Preparation:2017/02/23

2. Sponsor Identification

Hebei Hongtai Plastic Products Company Limited.
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Vinyl Examination Gloves (White), Vinyl Examination Gloves (Blue), Vinyl Examination Gloves (Yellow);
Common Name: Vinyl Patient Examination Gloves (Powder Free)
Model(s): XS S M L XL

Regulatory Information
Classification Name: Patient Examination Glove
Classification:I
Product Code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for use Statement:
The Vinyl Examination Gloves (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Device Description

The proposed device is Powder Free Vinyl Patient Examination Gloves. The proposed device is available in three different colors: White, Blue, and Yellow. The proposed device was tested according to the following standards: ASTM D 6124-06, ASTM D 5151-06, ASTM D5250-06, ISO 10993-10:2010 and ISO 2859-1:2009.The proposed device is non-sterile.

6. Identification of Predicate Device(s)

Predicate Device
K150224
Blue Vinyl Examination Gloves Powder Free
ZIBO SANYING TRADE CO., LTD

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. 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.
- ASTM D6124-06 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D 5151-06 (Reapproved 2011), Standard Test Method for Detection of Holes in Medical Gloves.

- ASTM D5250-06, Standard Specification for Poly(vinyl chloride) Gloves for Medical Application.
- 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.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device (K163168)	Predicate Device (K150224) Blue Vinyl Examination Gloves Powder Free	Remark
Product Code	LYZ	LYZ	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Intended Use	The Vinyl Examination Gloves (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Blue Vinyl Examination 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.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Same

Table 2 Device Dimensions Comparison

Proposed Device (K163168)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	235	245	245	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.08					min
Predicate Device (K150224) Blue Vinyl Examination 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:

The proposed device has different size specifications as compared to the predicate device, but the proposed device meets the specifications of ASTM D5250.

Table 3 Performance Comparison

ITEM			Proposed Device (K163168)	Predicate Device (K150224) Blue Vinyl Examination Gloves Powder Free	Remark
Colorant			White, Blue, Yellow	Blue	Analysis 2
Physical Properties	Before Aging	Tensile Strength	15 MPa, min	13 MPa, min	Analysis 3
		Ultimate Elongation	380 % min	400 % min	
	After Aging	Tensile Strength	15 MPa, min	13 MPa, min	
		Ultimate Elongation	380 % min	400 % min	
	Comply with ASTM D5250			Comply with ASTM D5250 11 MPa min./300% min.	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL 1.5	Be free from holes when tested in accordance with ASTM D5151 under AQL 2.5/Inspection Level G-I	Same
Powder Content			0.50 mg per glove (White) 0.60 mg per glove (Blue) 0.70 mg per glove (Yellow)	Meet the requirements of ASTM D5250 Less than 2mg per glove	Same

Table 4 Safety Comparison

ITEM		Proposed Device (K163168)	Predicate Device (K150224) Blue Vinyl Examination Gloves Powder Free	Remark
Material		Vinyl	Vinyl	Same
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Same
	Sensitization	Under conditions of the study, not a sensitizer.		
Label and Labeling		Meet FDA's Recommendations	Meet FDA's Recommendations	Same

Analysis 2:

The proposed device has different colors as compared to the predicate device. This difference may cause potential biocompatibility risks. To address this concern, we evaluated the biocompatibility testing according to the standard ISO 10993-10. The results showed that the proposed devices (White, Blue, Yellow) did not induce skin irritation and skin sensitization.

Analysis 3:

The proposed device has different Ultimate Elongation after aging as compared to the predicate device, but the proposed device meets the specifications of ASTM D5250.

10. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.