February 12, 2018

Yurun Glove Co., Ltd.
% Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
5-402, Building #27, No. 56, LiangXiang East Rd.,
FangShan District
Beijing, 102401 Cn

Re: K173561
Trade/Device Name: Vinyl Patient Examination Glove (Yellow)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LYZ
Dated: November 15, 2017
Received: November 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.

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.

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,

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)*

K173561

Device Name
Vinyl Patient Examination Glove (Yellow)

Indications for Use *(Describe)*
The Vinyl Patient Examination Glove (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

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

The assigned 510(k) Number: K173561

1. Date of Preparation:2018/01/26

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Vinyl Patient Examination Glove (Yellow)
Common Name: Vinyl Patient Examination Gloves (Powder Free)
Model(s): S M L XL

Regulatory Information
Classification Name: Vinyl Patient Examination Gloves (Powder Free)
Classification: I
Product Code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication for use Statement:
The Vinyl Patient Examination Glove (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 yellow. The design of proposed device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250. The proposed device is non-sterile.

6. Identification of Predicate Device(s)

Predicate Device
K163168
Vinyl Examination Gloves (White, Blue or Yellow)
Hebei Hongtai Plastic Products Company Limited

7. Technological Comparison Table

Table 1 General Comparison

ITEM	Proposed Device (K173561)	Predicate Device (K163168)	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 Patient Examination Glove (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 Vinyl Examination Glove (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.	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

Predicate 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
Proposed Device (K173561)	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
Remark	Analysis 1						

Analysis 1:

The proposed device has different size specification to the predicate device, but all proposed device meets the specifications of ASTM D 5250.

Table 3 Performance Comparison

ITEM			Proposed Device (K173561)	Predicate Device (K163168)	Remark
Colorant			Yellow	White, Blue, Yellow	SAME
Physical Properties	Before Aging	Tensile Strength	12 MPa, min	15 MPa, min	Analysis 2
		Ultimate Elongation	300 % min	380 % min	
	After Aging	Tensile Strength	12 MPa, min	15 MPa, min	
		Ultimate Elongation	300 % min	380 % min	
	Comply with ASTM D5250			Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 Level=G-I, AQL=1.5	Be free from holes when tested in accordance with ASTM D5151 AQL=1.5	SAME
Powder Content			1.7 mg	Meet the requirements of ASTM 5250	SAME

Table 4 Safety Comparison

ITEM		Proposed Device (K173561)	Predicate Device (K163168)	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.		
	Cytotoxicity	Under conditions of the study, did not show potential toxicity to L-929 cells.	N/A	
Label and Labeling		Meet FDA's Requirements of 21 CFR 801	Meet FDA's Requirements of 21 CFR 801	SAME

Analysis 2:
The proposed device has different Ultimate Elongation after aging specification to the predicate device, but all proposed device meets the specification requirements of ASTM D 5250.

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all 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 (Reaffirmation 2011), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D 5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D5250-06 (Reapproved 2015), 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.

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Comparison 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.