September 17, 2021

Jiangsu Dihong Industry and Trade Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211904
Trade/Device Name: Vinyl Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: April 19, 2021
Received: June 21, 2021

Dear Boyle 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Liqun Zhao -S

For Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211904

Device Name
Vinyl Glove

Indications for Use *(Describe)*
The Vinyl Glove is 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- K211904

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

1.0 Submitter's Information

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Date of Preparation: 09/09/2021

Designated Submission Correspondent

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2.0 Device Information

Trade name: Vinyl Glove
Common name: Vinyl Patient Examination Glove
Classification name: Non-powdered Patient Examination Glove
Model(s): S, M, L, XL

3.0 Classification

Production code: LYZ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Hebei Hongtai Plastic Products Company Limited
Device: Vinyl Patient Examination Gloves (White, Blue, Yellow)
510(k) number: K163168

5.0 Indication for Use

The Vinyl Glove is disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

6.0 Device Description

The subject device is powder free vinyl patient examination gloves. The subject device is clear. The design of subject device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250. The subject device is non-sterile.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject device	Predicate device	Comparison
510(k) number	K211904	K163168	-
Product Code	LYZ	LYZ	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Vinyl Glove is 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, powder free, device color, device name, glove size and quantity, Vinyl Glove, Non-Sterile	Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Similar

Table2 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
Subject Device	Designation	Size					Tolerance

(K211904)		S	M	L	XL	
	Length, mm	230	230	230	230	min
	Width, mm	85	95	105	115	±5
	Thickness, mm:					
	Finger	0.08				min
	Palm	0.08				min
Remark	Similar					

Analysis: The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D5250,so the differences do not raise any new safety or performance questions.

Table3 Performance Comparison

Item			Subject device (K211904)	Predicate device (K163168)	Comparison
Colorant			Clear	White, Blue, Yellow	Analysis 1
Physical Properties	Before Aging	Tensile Strength	11MPa, min	15MPa, min	Analysis 2
		Ultimate Elongation	300%min	380%min	Analysis 2
	After Aging	Tensile Strength	11MPa, min	15MPa, min	Analysis 2
		Ultimate Elongation	300%min	380%min	Analysis 2
	Comply with ASTM D5250			Comply with ASTM D5250	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Same
Powder Content			＜ 0.04 mg per glove, Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	Similar

Analysis 1: The colorant of the subject device is different with that of the predicate device, the subject device was evaluated according to ISO 10993-1 standards, and there were no risks identified.

Analysis 2: The tensile strength and ultimate elongation are different with that of the predicate, but they all meet the requirements of ASTM D5250,so the differences do not raise any new safety or performance questions.

Table4 Safety Comparison

Item	Subject device	Predicated device	Comparison

Material		Vinyl	Vinyl	Same
Biocompatibility	Irritation	Comply with ISO10993-10. Under the conditions of the study, not an irritant	Comply with ISO10993-10	Same
	Sensitization	Comply with ISO10993-10. Under conditions of the study, not a sensitizer.		
	Cytotoxicity	Comply with ISO10993-10. Under conditions of the study, did not show potential toxicity to L-929 cells.	Not provided	Different
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	Same

8.0 Summary of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards as shown in Table 5 Biocompatibility and Table 6 Non-Clinical Testing below:

Table 5 Biocompatibility Testing

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 Tests For Irritation And Skin Sensitization	To determine if device is a skin irritant	The device must be a non-irritant	Pass
ISO 10993-10:2010 Tests For Irritation And Skin Sensitization	To determine if device is a skin sensitizer	The device must be a non- sensitizer	Pass
ISO 10993-5:2009 Tests For In Vitro Cytotoxicity	To determine if the device is potential toxicity to L-929 cells.	The device must be a non toxicity.	Pass

Table 6 Non-Clinical Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6124-06 (Reapproved 2017) Standard Test Method	To determine residual powder	≤ 2 mg/glove	Pass

for Residual Powder on Medical Gloves			
ASTMD5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine water tightness	Meet the requirements of ASTM D5151 AQL 2.5	0/125 leaks Pass
ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application	To determine physical dimensions	Length(mm):≥230. Width(mm): S: 85±5; M: 95±5; L: 105±5; XL: 115±5;	Length(mm):＞230 Width(mm): S: 84-86 M: 95-97 L: 105-107 XL: 115-117 Pass
		Thickness (mm): Finger: ≥0.08 Palm: ≥0.08	Finger: 0.09-0.11 Palm: 0.08-0.11 Pass
ASTM D412-06a-2013 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension	To determine physical properties	Before Aging: Tensile Strength≥11MPa Ultimate Elongation≥300% After Aging: Tensile Strength≥11MPa Ultimate Elongation≥300%	Before Aging: Tensile Strength：15.1 ~17.4 MPa Ultimate Elongation：552%~560% After Aging: Tensile Strength: 15.7~17.4 MPa Ultimate Elongation: 527%~550% Pass

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K211904, Vinyl Glove, is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K163168.