January 11, 2022

Shandong Huiwosheng Health Technology Co.,Ltd
Haitao Wu
QA Director
50m East Of Chaoyang Road, Zhanqian Street, Linyi Chemical
Industrial Park, Linzi Town
Dezhou, Shandong 250000
China

Re: K213168
Trade/Device Name: Medical Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 18, 2021
Received: September 28, 2021

Dear Haitao Wu:

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,

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)*

K213168

Device Name
Medical Examination Gloves

Indications for Use *(Describe)*
A medical glove is a disposable device intended for medical purposes that is worn on hand of the examiner's hand to prevent contamination between the patient and the 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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K213168

1. Date of Preparation: 01/11/2022

2. Sponsor Identification

Shandong Huiwosheng Health Technology Co.,Ltd
50m east of Chaoyang Road, Zhanqian street, Linyi Chemical Industrial Park, Linzi Town, Linyi County, Dezhou City, Shandong Province, China

Establishment Registration Number: Not yet registered

Contact Person: Haitao Wu
QA Director
Tel: +86-18865233273
Email: haitao@kbt-cn.com

3. Identification of Proposed Device

Trade Name: Medical Examination Gloves
Common Name: POWDER FREE EXAMINATION GLOVES

Regulatory Information

Classification Name: polymer patient examination glove
Classification: I;
Product Code: LZA;
Regulation Number: 21CFR 880.6250
Review Panel: General Hospital;

Indication for Use:
A medical glove is a disposable device intended for medical purposes that is worn on hand of the examiner's hand to prevent contamination between the patient and the examiner.

Device Description
The proposed device is a powder free medical glove. The device is blue in color. The device meets the requirements of *ASTM D6319-19: Standard specification for Nitrile Examination Gloves for Medical Application*. The proposed gloves are available in five sizes, which are XS, S, M, L, XL, it could be

selected by the user depended on size of hand. The difference between each size is just in the dimension. The proposed device is provided non-sterile.

4. Identification of Predicate Device

510(k) Number: K031384
Product Name: MULTIPLE PRIVATE LABELED, NON-STERILE, POWDER-FREE, POLYURETHANE WHITE COLOR, EXAMINATION GLOVES

5. Technological Characteristics Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device K213168		Predicate Device K031384		Remark
Product Code	LZA		LZA		Same
Regulation Number	21 CFR 880.6250		21 CFR 880.6250		Same
Class	I		I		Same
Indication for use	A medical glove is a disposable device intended for medical purposes that is worn on hand of the examiner's hand to prevent contamination between the patient and the examiner.		This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.		Same
Material	Polyurethane		Polyurethane		Same
Color	Blue		White		Analysis 1
Sterility	Non-sterile		Non-sterile		Same
Single-use	Yes		Yes		Same
Size	XS, S, M, L, XL		XS, S, M, L, XL		Same
Dimensions (ASTM D6319-19)	Width				Analysis 2
	XS	70±10mm	XS	73 – 78 mm	
	S	80±10mm	S	83 – 88 mm	
	M	95±10mm	M	93 – 98 mm	
	L	110±10mm	L	103 – 107 mm	
	XL	120±10mm	XL	—	
	Length				
	XS	220mm min	XS	240mm minimum for	
	S	220mm min	S		
	M	230mm min	M		

	L	230mm min	L	all sizes	
	XL	230mm min	XL		
	Thickness				
	Palm	0.05mm min	Palm	Min 0.13mm	
	Finger	0.05mm min	Finger	Min 0.11mm	
Physical Properties (ASTM D6319-19 And ASTM D412-16)	Before Aging				Analysis 3
	Tensile Strength	16.2 – 19.7MPa	Tensile Strength	16 – 23MPa	
	Ultimate Elongation	642% – 754%	Ultimate Elongation	600% – 800%	
	After Aging				
	Tensile Strength	15.2 – 19.1MPa	Tensile Strength	20 – 23MPa	
	Ultimate Elongation	552% – 662%	Ultimate Elongation	600% – 720%	
Powder free residue (ASTM D6319-19 And ASTM D6124-06)	Less than 2mg per glove		Below 2mg/glove		Same
Freedom from Holes (ASTM D5151-19)	Meet AQL 2.5		Pass GI AQL=2.5		Same
Biocompatibility					
Skin Irritation	No Irritation		No Irritation		Analysis 4
Sensitization	No Sensitization		No Sensitization		
System Toxicity	No Toxicity		/		

Analysis 1- Color

The color of the proposed device is different from the predicate device.

Analysis 2- Dimensions

The dimension of the proposed device is not exactly same as the predicate device. The user can select appropriate model depended on size of user's hand.

Analysis 3- Physical Properties (ASTM D6319-19 and ASTM D412-16)

The physical properties of the proposed device are not exactly same as the predicate device.

Analysis 4- Biocompatibility

The biocompatibility test item of the proposed device is different from the predicate device.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and

acceptance criteria in the test methodology and the standards. The test results demonstrated that the proposed device complies with the following standards and test methodology:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D3767-03 (2020) Standard Practice for Rubber-Measurement of Dimensions
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity;

Table 2 Summary of non-clinical performance testing

Test Methodology	**Purpose**	**Acceptance Criteria**			**Results (Pass/Fail)**
ASTM D6319-19, ASTM D3767-03 (2020)	Physical Dimensions	Width	XS	70±10mm	Pass
			S	80±10mm	
			M	95±10mm	
			L	110±10mm	
			XL	120±10mm	
		Length	XS	220mm min	
			S	220mm min	
			M	230mm min	
			L	230mm min	
			XL	230mm min	
		Thickness	Palm	0.05mm min	
			Finger	0.05mm min	
ASTM D6319-19, ASTM D412-16	Physical Properties	Before Aging	Tensile Strength	14MPa min	Pass
			Ultimate Elongation	500% min	
		After Aging	Tensile Strength	14MPa min	
			Ultimate Elongation	400% min	
ASTM D5151-19	Freedom from Holes	Be free from holes when tested in accordance with ASTM D5151			Pass
ASTM D6124-06	Powder free residue	Less than 2mg per glove			Pass

ISO 10993-10:2010	Irritation	Non-Irritating	Pass
ISO 10993-10:2010	Sensitization	Non-Sensitizing	Pass
ISO 10993-11:2009	System toxicity	Non-toxicity	Pass

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K031384.