July 24, 2021

Tangshan Hongyun Healthcare Products Co., Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211262
Trade/Device Name: Disposable Vinyl Nitrile Synthetic Gloves Powder Free
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: April 26, 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,

For Clarence W. Murray, III, Ph.D.
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)*
K211262

Device Name
Disposable Vinyl Nitrile Synthetic Gloves Powder Free

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon 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

K211262

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

1.0 Submitter's Information

Name: Tangshan Hongyun Healthcare Products Co.,Ltd.
Address: South Shenggezhuang Village,Pachigang Town, Luannan,Tangshan, Hebei 063500, China.
Phone Number: +86-13933365259
Contact: Suying Le
Date of Preparation: 07/23/2021

Designated Submission Correspondent

Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Disposable Vinyl Nitrile Synthetic Gloves Powder Free
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: Zibo Huiying Medical Products, Co. Ltd.
Device: Synmax Synthetic Patient Examination Vinyl Gloves,Powder Free,Blue
510(k) number: K153028

5.0 Indication for Use

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands to prevent contamination between patient and examiner.

6.0 Device Description

The subject device is powder free vinyl synthetic patient examination gloves. The subject device is blue. 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	Predicated device	Comparison
510(k) number	K211262	K153028	I
Product Code	LYZ	LYZ	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use/ Indications foru Use	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands to prevent contamination between patient and examiner.	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers 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, product name, Non-Sterile	Single use, powder free, device color, device name, glove size and quantity, product name, Non-Sterile	Similar

Table2 Device Dimensions Comparison

Predicate Device(K153028)	Designation	Size	Tolerance
	Length, mm	Average over 234 on M size	-
	Width, mm	Average over 96 on M size	-
	Thickness, mm:		

	Finger	Average 0.98				-
	Palm	Average 0.096				-
Subject Device	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	0.05				min
Remark	Similar					

Analysis: The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D5250.

Table3 Performance Comparison

Item			Subject device	Predicated device	Comparison
Colorant			Blue	Blue	Same
Physical Properties	Before Aging	Tensile Strength	11MPa, min	Average 16.9MPa	Analysis
		Ultimate Elongation	300%min	Average 550%	Analysis
	After Aging	Tensile Strength	11MPa, min	Average 14.4MPa, min	Analysis
		Ultimate Elongation	300%min	Average 500%	Analysis
	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			0.07 mg per glove. Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	Similar

Analysis: The tensile strength and ultimate elongation are different with that of the predicate, but they all meet the requirements of ASTM D5250

Table4 Safety Comparison

Item	Subject device	Predicated device	Comparison
Material	Poly Vinyl Chloride Polyurethane	Poly Vinyl Chloride Polyurethane	Similar

		Nitrile Di-(2-ethylhexyl) Terephthalate(DOTP)	Diisononyl Phthalate (DINP)	
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO10993-10	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.	/	Different
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

Analysis: The materials of the subject device are little different with that of the predicate, but they all meet the performance requirements of ASTM D5250,also biocompatibility test has been performed on subject device and the test result can meet the requirements of ISO 10993 standards.

8.0 Discussion of Non-clinical and Clinical Test Performed

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:

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 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

ASTMD5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D5250-19, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D5250	Physical Dimensions Test	Length(mm):≥230； Width(mm): S: 85±5; M: 95±5; L: 105±5; XL: 115±5;	Length:＞230 Width: S: 84-89 M: 93-97 L: 105-107 XL: 115-116 Pass

		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Finger: 0.08-0.2 Palm: 0.07-0.08 Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			0/125 leaks Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			0.07 mg; Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥11MPa	11.6-16.2 Pass
			Ultimate Elongation	≥300%	308-391 Pass
		After Aging	Tensile Strength	≥11MPa	11.0-14.0 Pass
			Ultimate Elongation	≥300%	323-337 Pass
ISO 10993-5	Cytotoxicity	Non-cytotoxic			Under conditions of the study, did not show potential toxicity to L-929 cells. Pass
ISO 10993-10	Irritation	Non-irritating			Under the conditions of the study, not an irritant. Pass
ISO 10993-10	Sensitization	Non-sensitizing			Under conditions of the study, not a sensitizer. Pass

9.0 Clinical Test Conclusion

Clinical testing is not needed for this device.

10.0 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 predicated device in K153028.