November 26, 2021

Shandong Hongxin Chemicals Co.,Ltd.

% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212488
Trade/Device Name: Synthetic Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: October 18, 2021
Received: October 29, 2021

Dear Mr. 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 and Part 809); 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)*
K212488

Device Name
Synthetic Nitrile Examination Gloves

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

(K212448)

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

1.0 Submitter's Information

Name: Shandong Hongxin Chemicals Co.,Ltd.
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Contact: Ping Wang

Designated Submission Correspondent

Name: Shanghai Truthful Information Technology Co., Ltd.
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Tel: +86-21-50313932
Contact: Mr. Boyle Wang
Email: Info@truthful.com.cn

Date of Preparation: Oct.18th,2021

2.0 Device Information

Trade name: Synthetic Nitrile Examination Gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): S, M, L, XL
Production code: LYZ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

3.0 Predicate Device Information

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

4.0 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.

5.0 Device Description

The subject device is powder free vinyl examination gloves, adding 1%-3% nitrile to improve the tensile strength and ultimate elongation. The subject device is blue color. It can be available in four specifications: S,M,L and XL.
The subject device is non-sterile.

6.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device (K212448)	Predicate Device (K153028)
Product Code	LZA	LZA
Regulation No.	21CFR880.6250	21CFR880.6250
Class	I	I
Intended 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 to prevent contamination between patient and examiner.
Material	Poly Vinyl Chloride Polyurethane Nitrile Di-(2-ethylhexyl) Terephthalate(DOTP)	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)
Powdered or Powered free	Powdered free	Powdered free
Design Feature	Ambidextrous	Ambidextrous
Colorant	Blue	Blue
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile
Dimensions(mm)	Length: ≥230； Width:	Length: Average over 234 on M size； Width:

		S: 85±5; M: 95±5; L: 105±5; XL: 115±5		Average over 96 on M size	
Thickness(mm)		Finger: ⩾0.08; Palm: ⩾0.08		Finger: Average 0.98; Palm: Average 0.096	
Physical Properties	Before Aging	Tensile Strength	11MPa, min	Tensile Strength	Average 16.9MPa
		Ultimate Elongation	300% min	Ultimate Elongation	Average 550%
	After Aging	Tensile Strength	11MPa, min	Tensile Strength	Average 14.4MPa
		Ultimate Elongation	300%min	Ultimate Elongation	Average 500%
Freedom from Holes		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5		Be free from holes when tested in accordance with ASTMD5151 AQL=2.5	
Powder Content		Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124	
Biocompatibility		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer	
		ISO 10993-11; Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.		/	
		ISO 10993-5 Under conditions of the study, device extract is cytotoxic		/	

7.0 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:

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.

ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

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

Table 2 - Summary of non-clinical performance testing

Test Method	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: ＞240/Pass; Width: S: 87-88 /Pass M: 96-98/ Pass L: 105-107/ Pass XL:116/ Pass
		Thickness (mm): Finger: ≥0.08 Palm: ≥0.08			Finger: 0.12-0.13/Pass Palm: 0.08-0.09/Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			0/125/Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			0.14mg/Pass;
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥11MPa	14 -22/Pass;
			Ultimate Elongation	≥300%	424-509/Pass;
		After Aging	Tensile Strength	≥11MPa	13.4-19/Pass;
			Ultimate Elongation	≥300%	357-493/Pass;
ISO 10993-11	Cytotoxicity	Non- acute systemic toxicity			Under conditions of` the study, did not

			show acute systemic toxicity in vivo / 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

8.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device Synthetic Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicated device.