December 2, 2021

Xingyu Medical Tech Co., Ltd.
Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500# Century Ave
Shanghai, Shanghai 200122
China

Re: K212578
Trade/Device Name: Nitrile disposable examination gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 24, 2021
Received: November 3, 2021

Dear Eva Li:

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)*
K212578

Device Name
Nitrile disposable examination gloves

Indications for Use *(Describe)*
Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger 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

The assigned 510(k) number is: K212578

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name : XINGYU MEDICAL TECH CO.,LTD.
Submitter's Address : NO.2189 YAOQIAN ROAD, GAOMI ECONOMIC DEVELOPMENT ZONE, WEIFANG CITY, SHANDONG PROVINCE, CHINA
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Date of Preparation: 2021-11-23

2.0 Name of the Device

Proprietary/Trade name: Nitrile disposable examination gloves

Model(s):

Model	Color	Size
D5000	Blue	S, M, L, XL
D6000	Black	S, M, L, XL
D7000	White	S, M, L, XL
D8000	Purple	S, M, L, XL

Common Name: Exam gloves
Classification Name: Patient examination glove
Device Classification: Class I
Regulation Number: 21 CFR 880.6250
Panel: General Hospital
Product Code: LZA

3.0 Predicate Device

Device Name: Xingyu Powder Free Nitrile Patient Examination Gloves, Blue Color
Company name: Shandong Xingyu Gloves Co.,Ltd.
510(K) Number: K171616

4.0 Device Description:

How the device functions:

Nitrile films form a barrier to prevent contamination between patient and examiner.

Scientific concepts that form the basis for the device:

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

Physical and performance characteristics such as design, materials and physical properties:

The Nitrile glove acts as a barrier to prevent contamination between patient and examiner. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151.

5.0 Device Indication for use:

Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

Features & Description	Predicate Device	Proposed Device	Result of Comparison
Company	Shandong Xingyu Gloves Co.,Ltd	XINGYU MEDICAL TECH CO.,LTD.	_
510(K) Number	K171616	K212578	_
Product name	Xingyu Powder Free Nitrile Patient Examination Gloves, Blue	Nitrile disposable examination gloves	_
Product Code	LZA	LZA	**Same**
Size	Small/ Medium/ Large/X large	Small/Medium/Large/X large	**Same**
Indications for Use	Powder Free Nitrile Patient Examination Gloves, Blue Color is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	**Same**

Device Description and Specifications	Meets ASTM D6319-10 (Reapproved 2015)			Meets ASTM D6319-19			**same**
Dimensions -- Length ILS-2 AQL4.0	232 mm min for all sizes			230 mm min for all size			**Similar*1**
Dimensions -- Width IL S-2 AQL4.0	S: 76-88 mm			S: 83-89 mm			**Similar*1**
	M: 89-102 mm			M: 88-100 mm			
	L: 108-119mm			L: 103-111 mm			
	XL: 115-128 mm			XL: 114-119 mm			
Dimensions -- Thickness IL S-2 AQL4.0	Thickness (mm) min. Finger 0.08 Palm 0.08			Thickness (mm) min. Finger 0.09 Palm 0.05			**Similar*1**
Physical Properties IL S- 2 AQL4.0	Aging	Before	After	Aging	Before	After	**Similar*2**
	Elongation (%)	530-600	460-580	Elongation (%)	≥500%	≥400%	
	Tensile Strength (MPa)	18-25	17-22	Tensile Strength (MPa)	≥14	≥14	
Freedom from Pinholes Inspection Level I AQL2.5	Meets • 21 CFR 800.20 •ASTM D6319-10 (Reapproved 2015) Tested in accordance with ASTM D5151 (Reapproved 2015) with acceptable results			Meets •ASTM D 6319-19 Tested in accordance with ASTM D5151-19 with acceptable results			**same**
Residual Powder	Meets ASTM D 6124-06 (Reaffirmation 2011) Results generated values below 2mg of residual powder			Meets ASTM D 6124-06 (2017) Results generated values below 2mg of residual powder			**same**
Materials used to fabricate the devices	Nitrile			Nitrile			**same**
Shelf life	NA			3 years			**Different*1**
Compare data supporting Device Performance	Meets ASTM D5151-06 (Reapproved 2015) ASTM D6319-10 (Reapproved 2015) ASTM D6124-06 (Reaffirmation 2011)			Meets ASTM D5151-19 ASTM D6319-19 ASTM D6124-06(2017)			**same**
Single Patient Use	Single Patient Use			Single Patient Use			**same**
Biocompatibility	Under the conditions of this study, the test article was a non-irritant or non-sensitizer. Meets ISO 10993-10:2010			Under the conditions of this study, the test article was a non-irritant, non- sensitizer and does not pose acute systemic toxicity. Meets ISO 10993-10:2010. Meets ISO 10993-11:2017			**Similar*3**

Similar*1 analysis：

The Dimensions (length, width and fingers thickness) of the proposed deice is not same with the predicate device, however the Dimensions of the subject device all meet the criteria of the ASTM D6319-19. The test results show the differences do not affect compliance with the associated standards for the proposed device.

Similar*2 analysis：

Physical Properties of the proposed deice is not same with the predicate device, however the Physical Properties meet the criteria of the ASTM D6319-19. The test results show the differences do not affect compliance with the associated standards for the proposed device.

Similar*3 analysis：

Compare the predicate device, except the Skin Irritation Test and Skin sensitization test, the proposed device conduct the Acute Systemic Toxicity Test meets ISO 10993-11：2017 additional and show it non-acute systemic toxicity. The biocompatibility test results show the differences do not affect compliance with the associated standards for the proposed device.

Different*1 analysis：

The proposed device determined with a 3 year shelf life. This shelf life determination was conducted under experiment per ASTM D7161-16. The observed differences do not affect compliance with the associated standards for the proposed device.

7.0 Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate conformance with the applicable standards. The non-clinical performance testing completed for the XINGYU MEDICAL TECH CO.,LTD. nitrile disposable examination gloves demonstrated that the subject device met the acceptance criteria or specification for the applicable test methodology or standard as shown below.

- Dimension per ASTM D6319-19
- Tensile strength (Before aging/ After aging) and Elongated rate (Before aging/ After aging) per ASTM D6319-19
- Water leak test on pinhole per ASTM D6319-19/D6124-06 (2017)
- Powder Residual tests per ASTM D6319-19
- Biocompatibility tests per ISO 10993-10: 2010 and ISO 10993-11：2017

Performance of the nitrile disposable examination gloves are tested with the following technological characteristics as compared to ASTM or equivalent standards.

Test methodology	Purpose	Acceptance criteria						Result
ASTM D6319-19	Physical Dimensions			S	M	L	XL	__
		Length（mm）		≥220	≥230			pass
		Width（mm）±10		80±10	95±10	110±10	120±10	pass
		Thickness	Finger	≥0.05 mm				pass
			Palm	≥0.05 mm				pass
	Physical properties	Before Aging		Tensile≥14Mpa; Elongation ≥ 500%				pass
		After Aging		Tensile≥14Mpa; Elongation ≥ 400%				pass

ASTM D6319-19 Test method in accordance with ASTM D5151-19	Watertightness Test for detection of holes	Batch size=35000, sample 125 ≤7	pass
ASTM standard D 6319-19 Test method in accordance with D6124-06(2017)	Powder Residual	≤2（mg/glove）	pass

Purpose	Standard	Acceptance criteria	Result
Biocompatibility	Skin Irritation Test Extraction Method ISO 10993-10: 2010	non-irritation	Passes Under the conditions of the study, the subject device is non-irritation
	Skin sensitization the guinea pig maximization ISO 10993-10: 2010	non- sensitization	Passes Under the conditions of the study, the subject device is non-sensitization
	Acute Systemic Toxicity Test ISO 10993-11：2017	non- acute systemic toxicity	Passes Under the conditions of the study, the subject device is non-acute systemic toxicity

8.0 Assessment of Clinical Performance Data:

Clinical data is not needed to demonstrate the performance or safety of the subject glove as compared to the predicate device or applicable standards.

9.0 Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K212578, the Nitrile disposable examination gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K171616.