December 9, 2021

Anhui Xinyisheng Medical Technology Co.,Ltd
% Dave Yungvirt, CEO
Official Correspondent
THIRD PARTY REVIEW GROUP, LLC
25 Independence Blvd
Warren, NJ 07059

Re: K213371
Trade/Device Name: Disposable Medical Nitrile Examination Gloves (Model:XYS-001)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 29, 2021
Received: December 2, 2021

Dear Dave Yungvirt :

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, 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)*
K213371

Device Name
Disposable Medical Nitrile Examination Gloves(Model:XYS-001)

Indications for Use *(Describe)*
The Disposable Medical Nitrile Examination Gloves is disposable device intended for medical purpose that is worn on the examiner's hand 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K213371

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: Oct.11, 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Anhui Xinyisheng Medical Technology Co.,Ltd
Address:	No.999 North of the intersection of Tonghe Road and G343 Road Si County Suzhou City, Anhui Province, China
Contact person:	Shyla Tang
Title:	Manager
E-mail:	shyla@xinlingroup.com
Tel:	86-18012883846

2. Device Identification

510(K) number:	K213371
Trade/Device Name:	Disposable Medical Nitrile Examination Gloves
Size of glove	Large
Models:	XYS-001
Common name:	Polymer Patient Examination Glove
Regulation Number:	880.6250
Regulation Name:	Non-powdered patient examination glove
Regulation Class:	Class I
Panel:	General Hospital
Product Code:	LZA

3. Predicate Device

510(K) number:	K192333
Device Name:	Blue Nitrile Examination Gloves Powder Free
Manufacturer:	JR Engineering & Medical Technologies (M) SDN.BHD
Common name	Polymer Patient Examination Glove
Regulation Number:	880.6250
Regulation Name:	Non-powdered patient examination glove
Regulation Class:	Class I
Panel:	General Hospital
Product Code:	LZA

4. Device Description

Disposable Medical Nitrile Examination Gloves (Model: XYS-001, Size Large) is a patient examination glove and it is made from nitrile compound. It is a single-use, powder-free and non-sterile product. The glove is worn on the examiner's hand to prevent contamination between patient and examiner, and this device meets all the requirement specifications in the ASTM D6319-19 Standard.

5. Indication for use

The Disposable Medical Nitrile Examination Gloves is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

6. Summary of the technological characteristics of the device compared to the Predicate Device

Compared to the predicate device, the subject device has the same intended use, similar product design, and similar performance as the predicate device, the summarized comparison information is listed in the following table:

SE Comparisons		**Subject Device**	**Predicate Device K192333**	**Remarks**
Name		Disposable Medical Nitrile Examination Gloves	Blue Nitrile Examination Gloves Powder Free	/
Model		XYS-001	/	/
Size		Large	Extra Small, Small, Medium, Large, Extra Large	See Note1
Classification		Class I	Class I	Same
Intended use		The Disposable Medical Nitrile Examination Gloves is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	JR MEDIC Blue Nitrile Examination Gloves Powder Free is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Dimensions	ASTM D6319-19	Length Min:230mm Width Min:110±10mm (for Large size)	Length Min 230 mm Width Min 95±10mm (for medium size)	Note1
Physical Properties	ASTM D6319-19	<u>Before Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	<u>Before Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	Same

Thickness	ASTM D6319-19	Palm Min 0.05 mm Finger Min 0.05 mm	Palm Min 0.05 mm Finger Min 0.05 mm	Same
Powder Free	ASTM D6319-19	≤2 mg/glove	≤2 mg/glove	Same
Biocompatibility	ISO 10993-10:2010	/	Under the condition of study not an irritant	Note 2
	ISO 10993-10:2010	Under the conditions of the study, the result shows no Intracutaneous Reactivity	/	
	ISO 10993-10:2010	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
	ISO 10993-5:2009	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern	Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern	Same Note 3
	ISO 10993-11:2017	Under the condition of study the device extracts do not pose a systemic toxicity concern	Under the condition of study the device extracts do not pose a systemic toxicity concern	Same Note 3
	ISO 10993-11:2017	/	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	Note 4
Power free		Yes	Yes	Same
Single Use		Yes	Yes	Same
Non-Sterile		Yes	Yes	Same
Color		Blue	Blue	Same
Intended use population		Adult	Adult	Same
Wear		ambidextrous	ambidextrous	Same
EXPIRE DATE		Not claim	Included	See Note 5

Note 1:

In this submission, only one size “L” of glove was submitted for clearance and this size “L” of glove has been performed the testing according to the ASTM D6319-19,

Note 2:

According to the ISO 10993-10:2010, we conducted Intracutaneous reactivity test,

Note 3:

We evaluated the In vitro cytotoxicity in accordance with ISO 10993-5:2009s. Additionally we evaluated acute systemic toxicity in accordance with ISO 10993-11:2017.

Note 4:

We do not claim “non-pyrogenic” and we evaluated the biocompatibility per ISO 10993-1, the material mediated pyrogenicity testing is unnecessary.

Note 5:According to FDA guidance, claiming shelf life is non-mandatory.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The following bench testing was conducted to demonstrate that the subject device met the performance specification or the acceptance criteria in the standard or the test methodology provided below in the table. The results demonstrate that the subject device met the performance specification and the acceptance criteria for the respected standard and test method below.:

Performance:

1. ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.
2. Freedom from Holes- Testing for freedom from holes were conducted in accordance with Test Method ASTM D5151.
3. Physical Dimension test -Determine the dimension as directed in Table 2 of ASTM D6319-19.
4. Physical Requirement Test-Before and accelerated aging, the physical requirement specified in Table 3 of ASTM D6319-19, tests were conducted in accordance with test method ASTM D412 and accelerated aging test were conducted in accordance with Test Method ASTM D573.
5. Powder Free Gloves-Determine the powder residue in accordance with Test Method ASTM D6124.

Stand ard	Test item	Test method	Criteria	Result	Conclusion
ASTM D6319 -19	freedom from holes	ASTM D5151	Any glove that shows a droplet, stream, or other type of water leakage shall be considered to have failed the test.	Did not show a droplet, stream, or other type of water leakage	200 samples tested 0 failures Pass
	Physical Dimension test	ASTM D412 ASTM D3767	L size Width:95±10mm Length:230min Thickness: Finger 0.05min Palm 0.05min	Width: 110mm Length: 237mm Thickness: Finger 0.142mm Palm 0.082mm	13 samples tested/size 0 failure Pass
	Physical Requiremen t Test	ASTM D412 ASTM D573	Tensile Strength: Before Aging 14 Mpa, min.	Tensile Strength: Before Aging 19.1 Mpa,	13 samples tested/L size

			After Aging 14 Mpa, min. Elongation: Before Aging 500% min. After Aging 400% min.	After Aging 25.4 Mpa, Elongation: Before Aging 508% After Aging 517%	0 failure Pass
	Powder Free Gloves	ASTM D6124	Max. 2.0mg	sample quantity: 5pcs Average: 0.5mg	Pass

Biocompatibility:

1. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
2. ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
3. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5 Tests for In vitro cytotoxicity

Standard	Test item	Test method	Criteria	Results
ISO 10993-5: 2009	In Vitro Cytotoxicity	In this study, mammalian L- 929 cells were cultured in vitro according to ISO 10993- 5:2009 to test the potential cytotoxicity of the test article. The test articles and the control material were separately placed in MEM medium containing 10% fetal bovine serum, and extracted in a 37℃ incubator for 24 hours. After the end of the extraction, the cell culture medium in the 96-well plate (10^4 cells/well) cultured for 24 hours was removed and replaced with the corresponding extract, cultured in 37℃, 5% CO_2, >90% humidity for 24 hours. After the culture，the morphology and cell lysis of the cells were observed under the microscope, and the cytotoxicity of the test samples was determined by MTT assay.	The 50% extract of the test article should have at least the same or a higher viability than the 100% extract. Otherwise the test should be repeated. The lower the Viab. % value, the higher the cytotoxic potential of the test article is. If viability is reduced to <70% of the blank, it has a cytotoxic potential. The Viab.% of the 100% extract of the test article is the final result.	Under the condition of the test, the test article was found to be cytotoxic
ISO 10993 -10: 2010	Skin Sensitization	we took guinea pigs to observe the skin sensitization of the test article according to ISO 10993-10: 2010. The test article were extracted in Constant Temperature Vibrator at	Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.	Under the condition of the test, the test article was found to be non-

		50℃, 60 rpm for 72 h by 0.9 % Sodium Chloride Injection and Sesame Oil. Mix 50:50 (by volume) stable emulsion of Freund's complete adjuvant with selected solvent. Intradermal induction and topical induction were operated in the clipped intrascapular region of each animal. After the topical induction phase was completed on day 14, all test and control animals were challenged with the test sample. The erythema and edema of the challenge site were observed to test the sensitization response of the test article. According to the Magnusson and Kligman scales, the response to erythema and edema at each application site of the skin was described and scored 24 hours and 48 hours after the challenge phase.	If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.	sensitizin g
	Intracutaneous reactivity	Within a 4 h to 18 h period before testing, closely clip the fur on the back of the animals, allowing. a sufficient distance on both sides of the spine for injection of the extracts. Use the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Inject intracutaneously 0.2 mL of the extracts obtained with polar solvent at five sites and with non-polar solvent control at another five posterior sites on one side of each rabbit. Similarly, inject 0.2 mL of polar solvent control at five sites and non-polar solvent control at another five posterior sites on the contralateral side of each rabbit.	The requirements of the test are met if the final test article score is 1.0 or less.	the result showed that the polar and non-polar extract of the final test sample score is less 1.0.

ISO 10993 -11: 2017	Acute systemic toxicity	A single dose of test article extract was injected into the designated group of mice intraperitoneally at the dose level of 50 mL/kg bw. The negative control liquid was injected similarly into the separate group of designated control mice. Mice were observed for any adverse clinical reactions immediately after injection, and then the animals were returned to their cages. The animals were observed for signs of systemic reactions at4,24,48 and 72 hours after injection and weighed daily for three days after dosing. Any animal found dead or showed abnormal signs were subjected to gross necropsy.	(1) If during the observation period of an acute systemic toxicity test none of the mice treated with the test article extract exhibited a significantly greater biological reactivity than control mice, the test article met the requirements. If two or more animals died, or if abnormal behavior such as convulsions or prostration occurs in two or more animals, or if body weight loss greater than 10 %occurs in three or more animals, the test article did not meet the requirements. (2)If any animals treated with the sample exhibited only slight signs of biological reactivity, and no more than one animal showed gross symptoms of biological reactivity or died, repeat the testing using groups of ten animals. On the repeat test, if all ten animals treated with the test article extract exhibited no scientifically meaningful biological reactivity above the vehicle control animals during the observation period, the test article met the requirements.	Under the condition of the test, the test article was found to be non- systemic toxicity

8. 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.