October 19, 2021

Niujian Technology Co., Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd.,
Pudong, Shanghai, 200120 CHN

Re: K210706
Trade/Device Name: Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 6, 2021
Received: September 14, 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, 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)*
K210706

Device Name
Nitrile Examination Gloves

Indications for Use *(Describe)*

The Nitrile Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands 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.

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

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510(k) Summary

(K210706)

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

Date Prepared: October 5, 2021

1.0 Submission Sponsor

Manufacturer Name	Niujian Technology Co., Ltd.
Address	Room 401 Building 1, Anfangcheng No. 919, East Qunxian Road, Yuecheng District, Shaoxing, Zhejiang
Tel	86-18210518920
Email	385206015@qq.com
Contact Person	Xiuqiang Zhou

Designated Submission Correspondent

Company Name	Shanghai Truthful Information Technology Co., Ltd.
Address	Room 1801, No. 161 East Lujiazui Rd., Pudong, Shanghai 200120, China
Tel	+86-21-50313932
Email	Info@truthful.com.cn
Contact Person:	Mr. Boyle Wang

2.0 Device Identification

Classification Name	Polymer Patient Examination
Glove Trade Name	Nitrile Examination Gloves
Device Classification	Class I
Regulation Number	21 CFR 880.6250
Panel	General Hospital
Product Code	LZA
Previous Submissions	**None**

3.0 Classification

Production code: LZA
Regulation number: 21CFR880.6250
Classification: Class I

Panel: General Hospital

4.0 Predicate Device Information

Sponsor: Ever Growth (Vietnam) Co., Ltd.
Device: Disposable Powder Free Nitrile Examination Glove, Pink Color
Disposable Powder Free Nitrile Examination Glove, Black Color
510(k) number: K190942

5.0 Indication for Use

The Nitrile Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands or finger to prevent contamination between patient and examiner.

6.0 Device Description

Nitrile Examination Gloves are patient examination gloves made from nitrile compound, non-sterile (as per 21 CFR 880.6250, Class I). The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirements specifications for barrier protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.
The subject device is powder free nitrile examination gloves. The subject device is in blue color.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	**Subject Device** (K210706)	**Predicate Device** (K190942)
Product Code	LZA	LZA
Regulation No.	21CFR880.6250	21CFR880.6250
Class	I	I
Intended Use	The Nitrile Examination Gloves are non-sterile disposable device intended for medical purposes that are worn on the examiner's hands or finger to prevent contamination between patient and examiner.	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.

Material		Nitrile		Nitrile	
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)		Complies with ASTM D6319-19: Length:≥230； Width: S: 80±10; M: 95±10; L: 110±10; XL: 120±10		Complies with ASTM D6319-19: Length:≥230； Width: XS:70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10	
Thickness(mm)		Complies with ASTM D6319-19: Finger: ≥0.05; Palm: ≥0.05		Complies with ASTM D6319-19: Finger: ≥0.05; Palm: ≥0.05	
Physical Properties	Before Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min
		Ultimate Elongation	500% min	Ultimate Elongation	500% min
	After Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min
		Ultimate Elongation	400%min	Ultimate Elongation	400%min
Freedom from Holes		In accordance with ASTM D6319-19 and ASTM D5151-19, G-1, AQL 2.5		In accordance with ASTM D6319-19 and ASTM D5151-19, G-1, AQL 2.5	
Powder Content		Complies with ASTM D6319-19:< 2mg per glove		Complies with ASTM D6319-19: < 2mg per glove	
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	ISO 10993-5 Under conditions of the study, device extract is cytotoxic

8.0 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 10993-5:2009 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

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

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

Table 5 Summary of non-clinical performance testing

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm):≥230; Width(mm): S: 80±10; M: 95±10; L: 110±10; XL: 120±10;	Length: ≥230; Width: S: 80-84 M: 95-99 L: 108-111 XL: 117-121 Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05	Finger: 0.08-0.10 Palm: 0.06-0.08 Pass
ASTM D5151	Watertightness Test for Detection of	Meet the requirements of ASTM D5151 AQL 2.5	0/125 leaks Pass

	Holes				
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			0.02 mg Pass
ASTM D6319 ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	26-35 Pass
			Ultimate Elongation	≥500%	509-545 Pass
		After Aging	Tensile Strength	≥14MPa	19-36 Pass
			Ultimate Elongation	≥400%	447-510 Pass
ISO 10993-5	Cytotoxicity	cytotoxic			Under conditions of the study, show slight potential toxicity to L-929 cells.
ISO 10993-11	Acute systemic toxicity test	Non- toxicity			Under the condition of acute systemic toxicity test, the test article 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

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device in K190942.