November 16, 2021

Taizhou Kangjian Medical Equipments Co., Ltd.
% Helen Nan
General Manager
Cytech (Shenzhen) Enterprise Management Consulting Co.,Ltd.
Room302, Building3, Hangqian Mansion, Hangqian Street,
Lucheng District
Wenzhou, Zhejiang 325000
China

Re: K212029
Trade/Device Name: Disposable Medical Nitrile Examination Gloves (non-sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 13, 2021
Received: October 13, 2021

Dear Helen Nan:

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)*
K212029

Device Name
Disposable Medical Nitrile Examination Gloves (non-sterile)

Indications for Use *(Describe)*
The Disposable Medical Nitrile Examination Glove is intended for medical purposes that is worn on 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Taizhou Kangjian Medical Equipments Co., Ltd.
The Machine Electricity Zone (Hang Ni Kan) of Yuhuan County, Zhejiang, 317600, CHINA.

510(k) Summary K212029

1.0 Submitter Information

Company:	Taizhou Kangjian Medical Equipments Co., Ltd.
Address:	The Machine Electricity Zone (Hang Ni Kan) of Yuhuan County, Zhejiang, 317600, CHINA.
Phone:	86-576-87299799
Contact Person:	Hua Cong
Title:	Management Representative
E-mail:	webmaster@kangjiancn.com
Date of Preparation:	November 04, 2021

2.0 Device Information

Trade/Device Name:	Disposable Medical Nitrile Examination Gloves (non-sterile)
Regulation Description:	Non-powdered patient examination glove.
Device:	Polymer Patient Examination Glove
Review Panel:	General Hospital
Product Code:	LZA
Regulation Number:	21 CFR 880.6250
Device Class:	Class I

3.0 Predicate Device Information

Trade/Device Name:	Nitrile Glove Powder Free Blue
510k Number:	K210145
Submitter:	Changzhou Universal Medical Equipment Co.Ltd.

4.0 Device Description

The subject device is powder free nitrile examination gloves. The subject device is blue. The subject device is non-sterile.

5.0 Indications for Use

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

6.0 Technological Characteristics

Table 1 - General Comparison

Item	Predicate Device	Proposed Device	Comparison
Manufacturer	Changzhou Universal Medical Equipment CO. LTD.	Taizhou Kangjian Medical Equipments Co., Ltd.	N/A
510K Number	K210145	K212029	N/A
Trade/Device Name	Nitrile Glove Powder Free Blue	Disposable Medical Nitrile Examination Gloves (non sterile)	N/A
Product Code	LZA		Same
Classification	Class I (21 CFR 880.6250)		Same
Intended Use	The Nitrile Glove Powder Free Blue is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Disposable Medical Nitrile Examination Gloves is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non sterile	Non sterile	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder-Free, Non Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder-Free, Non Sterile	Same

Table 2 - Device Dimensions Comparison

Item	Predicate Device	Subject Device	Comparison
Length:	⩾230 mm	⩾220 mm	Same
Width:	110 ± 10 mm	110±10 mm	Same
Finger and Palm Thickness:	≥0.05 mm	≥0.05 mm	Same
Size Statement	M	L	Different

Table 3 - Performance Comparison

Device			Predicate Device	Proposed Device	Comparison
Physical Properties	Before Aging	Tensile Strength	Not publicly available	⩾14 MPa, min	-
		Ultimate Elongation	Not publicly available	⩾500% min	-
	After Aging	Tensile Strength	⩾14 MPa, min	⩾14 MPa, min	Same
		Ultimate Elongation	⩾400% min	⩾400% min	Same
Freedom from Holes			Be free from holes	Be free from holes	Same
Powder Content			Powered free	Powered free	Same

Table 4 - Safety Comparison

Device		Predicate Device	Proposed Device	Comparison
Colorant		Blue	Blue	Same
Material		Nitrile	Nitrile	Same
Biocompatibility	ISO 10993-5 Cytotoxicity	Non-cytotoxic	Non-cytotoxic	Same
	ISO 10993-10 Irritation	Non-irritant	Non-irritant	Same
	ISO 10993-10 Sensitization	Does not cause skin sensitization	Does not cause skin sensitization	Same
	ISO 10993-11 Systemic Toxicity	Does not cause systemic toxicity	Does not cause systemic toxicity	Same

7.0 Non-clinical Tests Performed on the Proposed Device

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 10993-5**: Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
- **ISO 10993-10**: Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- **ISO 10993-11**: Biological Evaluation of Medical Devices - Part 11: Tests For Tests for Systemic Toxicity.
- **ASTM D5151**: Standard Test Method for Detection of Holes in Medical Gloves.

- **ASTM D6319**: Standard Specification for Nitrile Examination Gloves for Medical Application.

Table 5 Relevant Standards and Test Results

	Purpose	Acceptance Criteria	Results
ISO 10993-5 Biological evaluation of medical devices Test for in vitro cytotoxicity	To determine the potential cytotoxicity.	Non-cytotoxic	Pass
ISO 10993-11 Biological evaluation of medical devices Part 11: Tests for Systemic Toxicity	To determine the potential systemic toxicity.	Does not cause systemic toxicity.	Pass
ISO 10993-10 Biological evaluation on medical device Part 10: Test for Irritation and Skin Irritation	To determine the potential for irritation and skin irritation.	Non-irritant, and Non skin irritant.	Pass
ISO 10993-10 Biological evaluation on medical device Part 10: Test Skin Sensitization	To determine the potential skin sensitization.	Does not cause skin sensitization.	Pass
ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application	To test for: (1) freedom from holes (2) physical dimensions (3) Aging	(1) Shall not leak (2) For size L (mm): Width: 110 ± 10 Length: ≥ 230 Finger and palm thickness: median value ≥ 0.05 (3) After Aging: Tensile Strength: ≥14 MPa Ultimate elongation: ≥400%	Pass

8.0 Clinical Tests Performed on the Proposed Device

Clinical testing was not required to support this device.

9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.