July 12, 2022

Anhui Fulewei Electronic Technology Co.,Ltd
Beina Gong
Manager
South Of Binheroad, West Of Gangkou Road,
Economic Development Zone,
Fuyang, Anhui 236000
China

Re: K221108
Trade/Device Name: Nitrile Medical Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 1, 2022
Received: April 15, 2022

Dear Beina Gong:

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,

Bifeng Qian, M.D., Ph.D.
Acting 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)*
K221108

Device Name
Nitrile Medical Examination Gloves

Indications for Use *(Describe)*
Nitrile Medical 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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510(K) Summary K221108

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: July 12, 2022

1. Submitter's Information

Name:	ANHUI FULEWEI ELECTRONIC TECHNOLOGY CO., LTD
Address:	SOUTH OF BINHEROAD, WEST OF GANGKOU ROAD, ECONOMIC DEVELOPMENT ZONE, FUYANG CITY, ANHUI, CHINA 236000
Contact person:	Beina Gong
Title:	Manager
E-mail:	19158151@qq.com
Tel:	86-15055553699

2. Device Identification

Trade/Device Name:	Nitrile Medical Examination Gloves
Size of glove	S, M, L, XL
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

Nitrile Medical Examination Gloves 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

Nitrile Medical 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 K221108**	**Predicate Device K192333**	**Remarks**
Name		Nitrile Medical Examination Gloves	Blue Nitrile Examination Gloves Powder Free	/
Size		Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	See Note1
Classification		Class I	Class I	Same
Intended use / indications for use		Nitrile Medical 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: 220mm Width: 80±10mm (for S size) Length Min: 230mm Width: 95±10mm (for M size) Length Min: 230mm Width: 110±10mm (for L size) Length Min: 230mm Width: 120±10mm (for XL 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	<u>Before Aging</u> Tensile Strength Min 14 Mpa	Same

		Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength Min 14 Mpa Ultimate Elongation Min 400%	
Water leak	ASTM D6319-19	AQL 2.5	AQL 2.5	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	Under the condition of study not an irritant	Same
	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 2
	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 2
	ISO 10993-11:2017	/	Under the conditions of the study, the device did not demonstrate a material mediated pyrogenicity response.	Note 3
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 4

Note 1:

In this submission, the sizes “S, M, L and XL” of Nitrile Medical Examination Gloves have been performed the testing according to the ASTM D6319-19, the dimension and performance meet the requirements of ASTM D6319-19, the difference in sizes does not raise different questions of safety and effectiveness.

Note 2:

We evaluated In vitro cytotoxicity in accordance with ISO 10993-5:2009, the result demonstrated toxicity to L929 cells. Additionally, we evaluated acute systemic toxicity in accordance with ISO 10993-11:2017. Under the conditions of the study, there was no evidence of systemic toxicity from the test article extract. Similar to the predicate device, the proposed device met the requirements of the study.

Note 3:

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

Note 4: 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.

1. ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.
2. Freedom from Holes - Testing for freedom from holes was 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.

Standard	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. AQL 2.5	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	Length Min:220mm Width Min:80±10mm (for S size) Length Min:230mm Width Min:95±10mm (for M size) Length Min:230mm Width Min:110±10mm (for L size) Length Min:230mm Width Min:120±10mm (for XL size) Thickness: Finger 0.05min Palm 0.05min	Length: 241~246mm Width: 85~88mm (for S size) Length: 243~252mm Width: 92~94mm (for M size) Length: 287~298mm Width: 109~110mm (for L size) Length: 288~292mm Width: 114~117mm (for XL size) Thickness: Finger 0.08~0.125mm Palm 0.063~0.082mm	13 samples tested/size 0 failure Pass
	Physical Requirement Test	ASTM D412 ASTM D573	Tensile Strength: Before Aging 14 Mpa, min. After Aging 14 Mpa, min. Elongation: Before Aging 500% min. After Aging 400% min.	Tensile Strength: Before Aging 19.6~26.7 Mpa, After Aging 20.9~26.1 Mpa, Elongation: Before Aging 650~700% After Aging 560~620%	13 samples tested/L size 0 failure Pass
	Powder Free Gloves	ASTM D6124	Max. 2.0mg	sample quantity: 5pcs Average: 1.9 mg	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

Test item	Test Standard	Criteria	Results
In Vitro Cytotoxicity	ISO 10993-5: 2009	Under conditions of the study, the test article must not show potential toxicity.	Fail – Under the condition of the test, the test article was found to be cytotoxic
Skin Sensitization	ISO 10993 -10: 2010	Under the conditions of the study, the test article must be found to be non-sensitizing.	Pass – Under the condition of the test, the test article was found to be non-sensitizing
Skin Irritation test	ISO 10993 -10: 2010	Under the conditions of the test, the test article must be found to be non- irritating	Pass – Under the conditions of the test, the test article was found to be non-irritating
Acute systemic toxicity	ISO 10993-11:2017	Under the conditions of the test, the test article must be found to be non- systemic toxicity	Pass – 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 subject device is as safe, as effective, and performs as well as or better than the predicated device(K192333).