October 13, 2021

Jiangxi Ronglai Medical Technology Co., Ltd.
Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O.box 120-119
Shanghai, 200120
China

Re: K212014
Trade/Device Name: Medical 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: July 9, 2021
Received: September 14, 2021

Dear Diana Hong:

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, Ph.D.
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)*

K212014

Device Name
Medical Nitrile Examination Gloves

Indications for Use *(Describe)*
Medical Nitrile Examination Gloves 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.

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

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212014

1. Date of Preparation: 10/13/2021

2. Sponsor Identification

Jiangxi Ronglai Medical Technology Co., Ltd.
NO.666 Baixu Street, Baixu town, Jinxian County, Nanchang City, Jiangxi Province, China

Establishment Registration Number: 3016681386

Contact Person: Hailin Shu
Position: Manager
Tel: +86-13870683591
Email: 910604423@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-2281-5850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Medical Nitrile Examination Gloves
Common Name: POWDER FREE NITRILE EXAMINATION GLOVES

Regulatory Information

Classification Name: polymer patient examination glove
Classification: I;
Product Code: LZA;
Regulation Number: 21CFR 880.6250
Review Panel: General Hospital;

Indication for Use:
Medical Nitrile Examination Gloves 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.

Device Description
The proposed device is a powder free medical glove. The device is blue in color. The device meets the requirements of *ASTM D6319-19: Standard specification for Nitrile Examination Gloves for Medical Application*. The proposed gloves are available in six sizes, which are XS, S, M, L, XL, XXL, it could be selected by the user depended on size of hand. The different between each size is just in the dimension. The proposed device is provided in non-sterile.

5. Identification of Predicate Device

510(k) Number: K172015
Product Name: Powder Free Nitrile Examination Gloves, Blue (colored)

6. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K172015	Remark
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indication for use	Medical Nitrile Examination Gloves 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.	A patient examination glove 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.	Same

Material	Nitrile		Nitrile		Same
Color	Blue		Blue		Same
Sterility	Non-sterile		Non-sterile		Same
Single-use	Yes		Yes		Same
Size	XS, S, M, L, XL, XXL		XS, S, M, L, XL		Different
Dimensions (ASTM D6319-19)	Width				
	XS	75±5mm	XS	70±10mm	
	S	85±5mm	S	80±10mm	
	M	95±5mm	M	95±10mm	
	L	115±5mm	L	110±10mm	
	XL	125±5mm	XL	120±10mm	
	XXL	135±5mm	/	/	
	Length				
	XS	＞220mm	XS	220mm min	
	S	＞230mm	S	220mm min	
	M	≥240mm	M	230mm min	
	L	≥250mm	L	230mm min	
	XL	＞250mm	XL	230mm min	
	XXL	≥260mm	/	/	
	Thickness				
	Palm	＞0.05mm	Palm	0.05mm min	
	Finger	＞0.05mm	Finger	0.05mm min	
Physical Properties (ASTM D6319-19 and ASTM D412-16)	Before Aging				Same
	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	
Powder free residue (ASTM D6319-19 and ASTM D6124-06)	Less than 2mg per glove		Less than 2mg per glove		Same
Freedom from Holes (ASTM D5151-19)	Meet AQL 2.5		Before aging: Meet AQL 1.5 After aging: Meet AQL 2.5		Different
Biocompatibility					
Skin Irritation	ISO 10993-10, Under the condition of study, not an irritant.		No Irritation		Different
Sensitization	ISO 10993-10, Under the condition of study, not a sensitizer		No Sensitization		
System Toxicity	ISO 10993-11, Under the condition of the study, the device extract does		/		

	not pose a systemic toxicity concern.		

Different- Size& Dimensions

The size and dimension of the proposed device is not exactly same as the predicate device. However, the size and dimension of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user's hand. In addition, its dimension has been tested and meet the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different-Freedom from holes

The adopted AQL for the proposed device is different from predicate device. However, the adopted AQL was same as the requirement of ASTM D6319 standard. Therefore, this AQL is acceptable and it can be considered that this the difference will not affect the safety and effectiveness of the proposed device.

Different- Biocompatibility

The biocompatibility test item of the proposed device is different from the predicate device. However, more biocompatibility tests have been performed on the proposed device than the predicate device and the all test results show the material of the proposed device has no toxicity. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

7. Non-Clinical Test Conclusion

The test results demonstrated that the proposed device complies with the following standards:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D3767-03 (2020) Standard Practice for Rubber-Measurement of Dimensions
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;
- ISO 10993-11:2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity;

Test Method	Purpose	Acceptance Criteria	Results
Freedom from Holes-ASTM D5151	Detection the holes that allow water leakage	Do not show droplet, stream or other type of water leakage	No leakage
Physical	Evaluate the glove	Length: >220 mm (XS	Length

dimension-ASTM D6319	physical dimension	and S sizes) Length: > 230 mm (M, L, XL and XXL sizes) Width (±10mm) XS = 70mm S = 80mm M = 95mm L = 110mm XL = 120mm XXL=130mm Thickness at Finger (mm) All Sizes ⩾ 0.05 mm Thickness at Palm All Sizes ⩾ 0.05 mm	Larger than 220mm for XS and S size Larger than 230mm for M, L, XL and XXL sizes Width XS: within 75±5mm S: within 85±5mm M: within 95±5mm L: within 115±5mm XL: within 125±5mm XXL: within 135±5mm Thickness Larger than 0.05mm
Physical requirement-ASTM D412	Evaluate the physical requirement	Before Aging (Min) Tensile strength: 14Mpa Ultimate elongation: 500% After Aging (Min) Tensile strength: 14Mpa Ultimate elongation: 400%	Before aging Larger than 14Mpa and 500% After aging Larger than 14Mpa and 400%
Powder residue-ASTM D6214	Evaluate the residue powder	Less than 2.0mg	Less than 2.0mg
Skin sensitization-ISO 10993-10	Evaluated for the potential to cause delayed dermal contact sensitization	Non-sensitizing	No skin sensitization
Skin irritation-ISO 10993-10	Evaluated for the potential to cause skin irritation	Non-irritating	No skin irritation
Acute toxicity-ISO 10993-11	Evaluated for acute systemic toxicity	Non-acute systemic toxic	No acute toxicity

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device K172015.