November 23, 2022

Jiangxi Zhonghong Pulin Medical Products Co.,Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608,No.738,Shangcheng Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K222534
Trade/Device Name: Nitrile Patient Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 25, 2022
Received: October 25, 2022

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,

Allan Guan -S

For Bifeng Qian, M.D., 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)*
K222534

Device Name
Nitrile Patient Examination Glove

Indications for Use *(Describe)*
The Nitrile 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.

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."

510(k) Summary
(K222534)

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

1.0 Submitter's Information

Name: Jiangxi Zhonghong Pulin Medical Products Co.,Ltd.
Address: Yinshawan Park, High-tech Industrial Park, Hukou County, Jiujiang City, Jiangxi Province, China
Phone Number: +86-15247135174
Contact: Zhou Ziyu
Date of Preparation: 2022.11.21

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong,Shanghai 200120 ,China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device Information

Trade name: Nitrile Patient Examination Glove
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): S, M, L, XL

3.0 Classification

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

4.0 Predicate Device Information

Manufacturer: Yingxiang Glove Products Co., Ltd.
Device: Nitrile Patient Examination Gloves
510(k) number: K211914

5.0 Indication for Use

The Nitrile 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.

6.0 Device Description

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

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	**Subject Device** (K222534)	**Predicate Device (**K211914**)**	**Remark**
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Nitrile 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.	The Nitrile Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder Free Blue, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove, Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device (K211914)	Designation		Size				Tolerance
			S	M	L	XL	
	9-inch	Length, mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
	12-inch	Length, mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
	Thickness, mm:						
	9-inch/ 12-inch	Finger	0.05				min
		Palm	0.05				min
Subject Device	12 inch	Designation	Size				Tolerance
			S	M	L	XL	
		Length, mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
		Thickness, mm:					
		Finger	0.05				min
		Palm	0.05				min
Remark		SIMILAR					

Analysis: The physical dimensions of subject device are same with the 12inch ones of the predicate device, and they all meet the requirements of ASTM D6319-19.

Table3 Performance Comparison

Item			Subject device (K222534)	Predicate device (K211914)	Remark
Colorant			Blue	Blue	Same
Physical Properties	Before Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		Ultimate Elongation	500% min	500% min	Same
	After Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		Ultimate Elongation	400%min	400%min	Same
	Comply with ASTM D6319			Comply with ASTM D6319	Same
Freedom from Holes			Be free from holes when tested in accordance with ASTMD5151 AQL=2.5	Be free from holes when tested in accordance with ASTMD5151 AQL=2.5	Same

Powder Content	<0.25 mg/glove	Meet the requirements of ASTM D6124	Similar

Table4 Safety Comparison

Item		Subject device (K222534)	Predicate device (K211914)	Remark
Material		Nitrile	Nitrile	Same
Biocompatibility	Irritation (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)	Under the conditions of the study, not an irritant	Comply with ISO10993-10	Same
	Sensitization (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)	Under conditions of the study, not a sensitizer.		
	Cytotoxicity (ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity)	Under conditions of the study, device extract is not cytotoxic	Comply with ISO10993-5	Similar
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Discussion of Non-clinical and Performance 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

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
1	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	All grades are 0. All animals were survived and no abnormal signs were observed during the study.
2			Skin Irritation Test: If the primary irritation index is 0-0,4, the response category is Negligible. 0,5-1,9 means slight 2-4,9 means moderate 5-8 means severe	The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition
3	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	The viab.% of the 100% extract of the test article is the final result, and if viability is reduced to <70% of the blank, it has cytotoxic potential.	Viab.% of 100% test article extract is 70.9% It means the proposed device have no potential toxicity to L-929 in the MTT method

4	ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount ofresidual powder (or filter-retained mass) found on medical gloves	powder residue limit of 2.0 mg	<0.25 mg
5	ASTM D5151-06(Reapproved2 015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 125 gloves AQL: 2.5 (ISO 2859) Criterion ≤ 7 gloves for water leakage	no glove water leakage found
6	ASTM D6319-10(Reapproved 2015),Standard Specification For Nitrile Examination Gloves For Medical Application.	This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.	Sterility: no need Freedom from holes: pl. Refer to No. 5 in table 5 Dimensions: S: width 80±10mm Length ≥220 mm M: width 95±10mm Length ≥230 mm L: width 110±10mm Length ≥230 mm XL: width 120±10mm Length ≥230 mm Thickness: Finger ≥0.05 mm Palm ≥0.05 mm Physical properties: Before aging Tensile strength ≥ 14MPa Ultimate Elongation ≥ 500% After Accelerated Aging Tensile strength ≥ 14MPa Ultimate Elongation ≥ 400%	N.A. Dimensions: S: width: 84-87 mm Length 297-302 mm M: width 94-97 mm Length 296-302 mm L: width 104-108mm Length 296-302 mm XL: width 113-117 mm Length 297-302 mm Thickness: Finger 0.152-0.184 mm Palm 0.112-0.131 mm Physical properties: Before aging Tensile strength 14.2-29.0 MPa Ultimate Elongation 537.700% - 552.733% After Accelerated Aging Tensile strength 14.1-26.8 MPa Ultimate Elongation 421.422% - 552.633% Powder-free Residue: pl. Refer to No. 4 in table 5

			Powder-free Residue: pl. Refer to No. 4 in table 5	

9.0 Discussion of Clinical and Performance Testing

Clinical testing is not needed for this device.

10.0 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 predicate device.