December 1, 2021

5R MED Instruments (CHENGDU) Co., Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161 Lujiazui East Rd., Pudong
Shanghai, 200120
China

Re: K212789
Trade/Device Name: Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: August 27, 2021
Received: September 1, 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
K212789

Device Name
Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

Indications for Use *(Describe)*
A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	15.1(15.1, 16.4, 16.6) Minutes
Cisplatin	1.0 mg/ml(1,000 ppm)	＞240 Minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	＞240 Minutes
Carboplatin	10.0 mg/ml(10,000 ppm)	＞240 Minutes
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	＞240 Minutes
Etoposide	20.0 mg/ml(20,000 ppm)	＞240 Minutes
Fluorouracil	50.0 mg/ml(50,000 ppm)	＞240 Minutes
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞240 Minutes
Thio Tepa	10.0 mg/ml(10,000 ppm)	32.8 (48.6，32.8，46.1) Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 15.1 Minutes (min.);
Thio Tepa 10.0 mg/ml 32.8 Minutes (min.).

Warning: Please do not use with Carmustine (BCNU) and Thiotepa.

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.

510(k) Summary

K212789

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

1.0 Submitter's Information

Name: 5R MED Instruments (CHENGDU) Co., Ltd.
Address: Building 9, Section 1, No.618 of West Kelin Road, Chengdu Cross-Straits Technology Industry Development Zone, Wenjiang District, Chengdu, Sichuan Province, 611130, China
Contact: Mr. Pan Yuzhang
Date of Preparation: 2021.08.12

Designated Submission Correspondent

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

2.0 Device Information

Trade name: Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): XS, S, M, L, XL

3.0 Classification

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

4.0 Predicate Device Information

Manufacturer: Ever Growth (Vietnam) Co., Ltd.
Device: Disposable Powder Free Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, Disposable Powder Free

Nitrile Examination Glove, Tested For Use With Chemotherapy Drugs, Orange Color

510(k) number: K190860

5.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands to prevent contamination between patient and examiner. The gloves are powder-free, ambidextrous with beaded cuff, blue colored, nitrile, and tested for use with chemotherapy drugs. The gloves are offered in four sizes: extra-small, small, medium, large, and extra-large.

6.0 Indication for Use

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 *Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs*

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	15.1 (15.1,16.4,16.6）
Carboplatin	10.0 mg/ml(10,000 ppm)	＞ 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	＞ 240
Cisplatin	1.0 mg/ml(1,000 ppm)	＞ 240
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	＞ 240
Etoposide	20.0 mg/ml(20,000 ppm)	＞ 240
Fluorouracil	50.0 mg/ml(50,000 ppm)	＞ 240
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240
Thio Tepa	10.0 mg/ml(10,000 ppm)	32.8 （48.6，32.8，46.1）

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 15.1 Minutes (min.);
Thio Tepa 10.0 mg/ml 32.8 Minutes (min.).

Warning: Please do not use with Carmustine (BCNU) and Thiotepa.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K212789	Predicate Device (K190860)	Remark
Product Code	LZA,LZC	LZA,LZC	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	Same
Powdered or Powered free	Powdered free	Powdered free	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,Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 compliance and a summary of the testing results.	Similar

Table2 Device Dimensions Comparison

	Designation	Size					Tolerance
		XS	S	M	L	XL	
Predicate Device(K190860)	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						

	Finger	0.05					min
	Palm	0.05					min
Subject Device	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	220	220	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Remark	Different						

Analysis: The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D6319-19,so the differences do not raise any new safety or performance questions.

Table3 Performance Comparison

Item			Subject device	Predicate device (K190860)	Remark
Colorant			Blue	White, Orange	Different 1
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		0.1mg per glove, Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124	Same
Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978		Carmustine (BCNU) 3.3 mg/ml: 15.1 Minutes (min.)		Carmustine (BCNU) 3.3 mg/ml: White:11.8 Minutes; Orange:31.6Minutes	Similar
		Cisplatin 1.0 mg/ml: ＞ 240 Minutes		Cisplatin 1.0 mg/ml: ＞240 Minutes	Same
		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞ 240 Minutes		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞ 240	Same

		Minutes	
	Carboplatin 10.0 mg/ml:＞ 240 Minutes	Dacarbazine (DTIC) 10.0 mg/ml: ＞240 Minutes	Different 2
	Doxorubicin HCl 2.0 mg/ml: ＞ 240 Minutes	Doxorubicin Hydrochloride 2.0 mg/ml: ＞240 Minutes	Same
	Etoposide 20.0 mg/ml: ＞ 240 Minutes	Etoposide (Toposar) 20.0 mg/ml: ＞240 Minutes	Same
	Fluorouracil 50.0 mg/ml: ＞ 240 Minutes	Fluorouracil 50.0 mg/ml: ＞240 Minutes	Same
	Paclitaxel 6.0 mg/ml: ＞240 Minutes	Paclitaxel (Taxol) 6.0 mg/ml: ＞240 Minutes	Same
	Thio Tepa 10.0 mg/ml: 32.8 Minutes (min.)	Thio-Tepa 10.0 mg/ml: White:16.9 Minutes; Orange: 72.5 Minutes	Similar

Analysis:

Different 1: The color of the subject device is different of that of the predicate. Biocompatibility testing was successfully completed for the subject device, demonstrating that any color differences do not affect the safety of the proposed device.

Different 2: The chemotherapy drug is different with that of the predicate, but they all meet the requirements of ASTM D6978-05(2019),so the differences do not raise any new safety or performance questions.

Table4 Safety Comparison

Item		Subject device	Predicated device (K190860)	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	Under conditions of		

	Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)	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	Under conditions of the study, device extract is not cytotoxic	Same

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) was conducted in accordance 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*

Performance Testing (Bench)

Physical performance qualities of the proposed device were evaluated per ASTM D6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

Permeation testing was conducted to support the addition of the labeling claim: *Tested for use with chemotherapy drugs*. In addition, the proposed device was tested according to ASTM D6978-05 (Reapproved 2019), *Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs*, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

In summary, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

- 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.*
- ASTM D6978-05 (Reapproved 2019) ,*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

Test Methodology / Standard	Purpose	Acceptance Criteria	Results
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.
		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
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 86.5% It means the proposed device have no potential toxicity to L-929 in the MTT method
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	powder residue limit of 2.0 mg	0.1 mg /glove

	on medical gloves		
ASTM D5151-19 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
ASTM D6319-19 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 table 3 Dimensions: XS: width 70±10mm Length ≥220 mm 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% Powder-free Residue: pl. Refer to table 3	N.A. Dimensions: XS: width: 75-76 mm Length 234-243 mm Thickness: Finger 0.091-0.100 mm Palm 0.071-0.079 mm S: width: 86-87 mm Length 240-248 mm Thickness: Finger 0.098-0.114 mm Palm 0.084-0.094mm M: width 98-99 mm Length 246-256 mm Thickness: Finger 0.106-0.124 mm Palm 0.077-0.093 mm L: width 109-111 mm Length 250-258 mm Thickness: Finger 0.111-0.127 mm Palm 0.080-0.088 mm XL: width 115-118mm Length 258-255mm Thickness: Finger 0.112-0.124 mm

			Palm 0.081-0.093 mm Physical properties: Before aging Tensile strength 21.6-29.5 MPa Ultimate Elongation 536% - 571% After Accelerated Aging Tensile strength 24.1-31.0 MPa Ultimate Elongation 479% - 519% Powder-free Residue: pl. Refer to table 3
ASTM D 6978	Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time	Carmustine (BCNU) 3.3 mg/ml: 15.1 Minutes (min.)	
		Cisplatin 1.0 mg/ml: ＞ 240 Minutes	
		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞ 240 Minutes	
		Carboplatin 10.0 mg/ml:＞ 240 Minutes	
		Doxorubicin HCl 2.0 mg/ml: ＞ 240 Minutes	
		Etoposide 20.0 mg/ml: ＞ 240 Minutes	
		Fluorouracil 50.0 mg/ml: ＞240 Minutes	
		Paclitaxel 6.0 mg/ml: ＞240 Minutes	
		Thio Tepa 10.0 mg/ml: 32.8 Minutes (min.)	

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, Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K190860.