December 18, 2021

Yunnan Huazhiyuan Medical Technology Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161 Lujiazui East Rd.,Pudong
Shanghai, 200120
China

Re: K213051
Trade/Device Name: Nitrile Patient 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: September 16, 2021
Received: September 22, 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,

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)*

K213051

Device Name
Nitrile Patient 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
Carboplatin	10.0 mg/ml(10,000 ppm)	> 240 Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	35.2 Minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	> 240 Minutes
Doxorubicin	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
Methotrexate	25.0 mg/ml(25,000 ppm)	> 240 Minutes
Paclitaxel	6.0 mg/ml(6,000 ppm)	> 240 Minutes
ThioTepa	10.0 mg/ml(10,000 ppm)	76.3 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.2 Minutes
ThioTepa 10.0 mg/ml 76.3 Minutes

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.

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."

K213051

510(k) Summary

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

1.0 Submitter's Information

Name: Yunnan Huazhiyuan Medical Technology Co., Ltd.
Address: Yangjie Industrial Park,Jianshui County,Honghe Hani and Yi Autonomous Prefecture, Yunnan Province,China
Contact: Yun Gao
Date of Preparation: Sept 16, 2021

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 Patient 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, XXL

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 six sizes: XS, S, M, L, XL, XXL.
The subject device is non-sterile.

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
Carboplatin	10.0 mg/ml(10,000 ppm)	＞ 240
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	35.2
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	＞ 240
Doxorubicin	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
Methotrexate	25.0 mg/ml(25,000 ppm)	＞ 240
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240
ThioTepa	10.0 mg/ml(10,000 ppm)	76.3

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.2 Minutes;
Thio Tepa 10.0 mg/ml 76.3 Minutes.

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

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device	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.	Same
Dimensions(mm)	Length: XS/S:≥220; M/L/XL/XXL: ≥230; Width: XS: 70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10; XXL: 130±10	Length: XS/S/M/L/XL: ≥230; Width: XS:70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10	Similar
Thickness(mm)	Finger: ≥0.05;	Finger: ≥0.05;	Same

		Palm: ≥0.05		Palm: ≥0.05		
Colorant		Blue		White, Orange		Different
Physical Properties	Before Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	500% min	Ultimate Elongation	500% min	Same
	After Aging	Tensile Strength	14MPa, min	Tensile Strength	14MPa, min	Same
		Ultimate Elongation	400%min	Ultimate Elongation	400%min	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		0.02 mg per glove, Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124		Similar
Biocompatibility		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer		ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer		Same
		ISO 10993-5 Under conditions of the study, device extract is not cytotoxic		ISO 10993-5 Under conditions of the study, device extract is not cytotoxic		Same
		Carboplatin 10.0 mg/ml: ＞240 Minutes		/		Different
		Carmustine (BCNU) 3.3 mg/ml: 35.2 Minutes		Carmustine (BCNU) 3.3 mg/ml: White:11.8 Minutes; Orange:31.6Minutes		Similar
		/		Cisplatin 1.0 mg/ml: ＞240 Minutes		Different
		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞240 Minutes		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞240 Minutes		Same
		/		Dacarbazine (DTIC) 10.0 mg/ml:		Different

Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978		＞240 Minutes	
	Doxorubicin 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
	Methotrexate 25.0 mg/ml(25,000 ppm): ＞240 Minutes	/	Different
	Paclitaxel 6.0 mg/ml: ＞240 Minutes	Paclitaxel (Taxol) 6.0 mg/ml: ＞240 Minutes	Same
	ThioTepa 10.0 mg/ml: 76.3 Minutes	Thio-Tepa 10.0 mg/ml: White:16.9 Minutes; Orange: 72.5 Minutes	Similar

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Patient 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.*

Table 2 - Summary of non-clinical performance testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6319	Physical Dimensions Test	Length(mm): XS:⩾220; S/M/L/XL/XXL: ⩾230; Width(mm): XS: 70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10; XXL: 130±10	Length(mm): ＞240/Pass; Width(mm): XS: 67-72/Pass S: 76-83/Pass M: 91-99/ Pass L: 106-112/ Pass XL:116-124/ Pass XXL: 127-134/ Pass
		Finger: ⩾0.05; Palm: ⩾0.05	Thickness (mm): Finger: 0.06-0.10/Pass Palm: 0.07-0.10/Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5	0/125/Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg	0.02mg/Pass;

ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	16.4-17.8MPa/Pass;
			Ultimate Elongation	≥500%	533-551%/Pass;
		After Aging	Tensile Strength	≥14MPa	15.8-16.8MPa/Pass;
			Ultimate Elongation	≥400%	520-554%/Pass;
ISO 10993-5	Cytotoxicity	Non- In Vitro Cytotoxicity			Under conditions of the study, device extract is not cytotoxic. /Pass
ISO 10993-10	Irritation	Non-irritating			Under the conditions of the study, not an irritant. / Pass
ISO 10993-10	Sensitization	Non-sensitizing			Under conditions of the study, not a sensitizer. / Pass

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 Patient 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.