October 5, 2021

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

Re: K212036
Trade/Device Name: Nitrile Powder Free 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 25, 2021
Received: August 31, 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, 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)*
K212036

Device Name
Nitrile Powder Free 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)	16.4 Minutes
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240 Minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	> 240 Minutes
Dacarbazine	10.0 mg/ml(10,000 ppm)	> 240 Minutes
Docetaxel	10.0 mg/ml(10,000 ppm)	> 240 Minutes
Doxorubicin HCI	2.0 mg/ml(2,000 ppm)	> 240 Minutes
Epirubicin HCI	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
Gemcitabine	38.0 mg/ml(38,000 ppm)	> 240 Minutes
Ifosfamide	50.0 mg/ml(50,000 ppm)	> 240 Minutes
Irinotecan	20.0 mg/ml(20,000 ppm)	> 240 Minutes
Methotrexate	25.0 mg/ml(25,000 ppm)	> 240 Minutes
Miromycin C	0.5 mg/ml(500 ppm)	> 240 Minutes
Mitoxantrone	2.0 mg/ml(2,000 ppm)	> 240 Minutes
Oxaliplatin	5.0 mg/ml(5,000 ppm)	> 240 Minutes
Paclitaxel	6.0 mg/ml(6,000 ppm)	> 240 Minutes
ThioTepa	10.0 mg/ml(10,000 ppm)	98.6 Minutes
Vincristine Sulface	1.0 mg/ml(1,000 ppm)	> 240 Minutes

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:
Carmustine (BCNU) 3.3 mg/ml 16.4 Minutes
Thio Tepa 10.0 mg/ml 98.6 Minutes
Warning: Please do not use with Carmustine (BCNU).

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

(K212036)

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

1.0 Submitter's Information

Name: Jiangsu Yanfang Medical Technology Co., Ltd.
Address: No.16, Kaiyuan Road, Changjing Town, Jiangyin, Wuxi, Jiangsu, China 214411.
Contact: Kaijian Wei
Date of Preparation: Oct.05,2021

Designated Submission Correspondent

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

2.0 Device Information

Trade name: Nitrile Powder Free Examination Gloves, Tested For Use With Chemotherapy Drugs
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): 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, Blue Color, Tested For Use With Chemotherapy Drugs
510(k) number: K190736

5.0 Device Description

The subject device is single use, disposable gloves intended for medical purposes to be worn on the examiner's hands or fingers 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: 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
Carboplatin	10.0 mg/ml(10,000 ppm)	＞ 240
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	16.4
Cisplatin	1.0 mg/ml(1,000 ppm)	＞ 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	＞ 240
Dacarbazine	10.0 mg/ml(10,000 ppm)	＞ 240
Docetaxel	10.0 mg/ml(10,000 ppm)	＞ 240
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	＞ 240
Epirubicin 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
Gemcitabine	38.0 mg/ml(38,000 ppm)	＞ 240
Ifosfamide	50.0 mg/ml(50,000 ppm)	＞ 240
Irinotecan	20.0 mg/ml(20,000 ppm)	＞ 240
Methotrexate	25.0 mg/ml(25,000 ppm)	＞ 240
Miromycin C	0.5 mg/ml(500 ppm)	＞ 240
Mitoxantrone	2.0 mg/ml(2,000 ppm)	＞ 240
Oxaliplatin	5.0 mg/ml(5,000 ppm)	＞ 240
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240
ThioTepa	10.0 mg/ml(10,000 ppm)	98.6
Vincristine Sulface	1.0 mg/ml(1,000 ppm)	＞ 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU) 3.3 mg/ml 16.4 Minutes
Thio Tepa 10.0 mg/ml 98.6 Minutes
Warning: Please do not use with Carmustine (BCNU).

7.0 Technological Characteristic Comparison Table

Table1- Comparison of Subject and Predicate Devices

Item	Subject Device	Predicate Device	Remark
Product Code	LZA,LZC	LZA,LZC	Same
510(k) Reference	K212036	K190736	
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
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Color	Blue	Blue	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
Dimensions - Length	Complies with ASTM	Complies with ASTM D6319-	Similar

	D6319-19: S: ≥220 mm; M/L/XL: ≥230 mm.	19: ≥230 mm.	
Dimensions - Width	Complies with ASTM D6319-19: S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm;	Complies with ASTM D6319-19: XS: 70±10mm; S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm;	Similar
Dimensions - Thickness	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Same
Physical Properties - Tensile Strength	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Same
Physical Properties - Elongation	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥400%	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥400%	Same
Freedom from Holes	Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5	Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5	Same
Powder Content	Complies with ASTM D6319-19,< 2 mg per glove	Complies with ASTM D6319-19,< 2 mg per glove	Same
Biocompatibility	Complies with ISO 10993-5 (2009) * Under the conditions of the study, the device is not cytotoxic. Complies with ISO 10993-10 (2010) * Under the conditions of the study, the device is a non-irritant and a non-sensitizer.	Comply with ISO10993-10(2010) and ISO 10993-5 (2009)	Same

Chemotherapy drugs tested	Breakthrough Detection Time in Minutes		/
	Subject Device	Predicate Device	
Bleomycin Sulfate 15.0 mg/ml	Not tested	> 240	Different
Busulfan 6.0 mg/ml	Not tested	> 240	Different
Carboplatin 10.0 mg/ml	> 240	> 240	Same
Carmustine (BCNU), 3.3 mg/ml	16.4	59.4	Same

Chloroquine 50.0 mg/ml	Not tested	> 240	Different
Cisplatin 1 mg/ml	> 240	> 240	Same
Cyclophosphamide 20 mg/ml	> 240	> 240	Same
Cyclosporin A 100.0 mg/ml	Not tested	> 240	Different
Cytarabine 100.0 mg/ml	Not tested	> 240	Different
Dacarbazine (DTIC), 10.0 mg/ml	> 240	> 240	Same
Daunorubicin 5.0 mg/ml	Not tested	> 240	Different
Docetaxel 10.0 mg/ml	> 240	> 240	Same
Doxorubicin Hydrochloride, 2.0 mg/ml	> 240	> 240	Same
Epirubicin 2.0 mg/ml	> 240	> 240	Same
Etoposide (Toposar), 20.0 mg/ml	> 240	> 240	Same
Fludarabine 25.0 mg/ml	Not tested	> 240	Different
Fluorouracil, 50.0 mg/ml	> 240	> 240	Same
Gemcitabine 38.0 mg/ml	> 240	> 240	Same
Idaribicin 1.0 mg/ml	Not tested	> 240	Different
Ifosfamide 50.0 mg/ml	> 240	> 240	Same
Irinotecan 20.0 mg/ml	> 240	> 240	Same
Mechlorethamine HCl 1.0 mg/ml	Not tested	> 240	Different
Melphalan 5 mg/ml	Not tested	> 240	Different
Methotrexate 25 mg/ml	> 240	> 240	Same
Mitomycin C 0.5 mg/ml	> 240	> 240	Same
Mitoxantrone 2.0 mg/ml	> 240	> 240	Same
Oxaliplatin 2.0 mg/ml	> 240	> 240	Same
Paclitaxel (Taxol), 6.0 mg/ml	> 240	> 240	Same
Paraplatin 10 mg/ml	Not tested	> 240	Different
Retrovir 10 mg/ml	Not tested	> 240	Different
Rituximab 10 mg/ml	Not tested	> 240	Different
Thiotepa, 10.0 mg/ml	98.6	118.5	Different
Topotecan HCl 1 mg/ml	Not tested	> 240	Different
Trisonex 1 mg/ml	Not tested	> 240	Different
Velcade (Bortezomib) 1 mg/ml	Not tested	> 240	Different
Vincristine 1.0 mg/ml	> 240	> 240	Same

8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Nitrile Powder Free 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*

Table 2 Biocompatibility Testing

Test Method	Purpose	Acceptance Criteria	Results
ISO 10993-10:2010 Tests For Irritation And Skin Sensitization	To determine if device is a skin irritant	The device must be a non-irritant	Pass
ISO 10993-10:2010 Tests For Irritation And Skin Sensitization	To determine if device is a skin sensitizer	The device must be a non- sensitizer	Pass
ISO 10993-5:2009 Tests For In Vitro Cytotoxicity	To determine if the device is potential toxicity to L-929 cells.	The device must be a non toxicity.	Pass

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 D 6978-05 (Reapproved 2019),*Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.*

Table 3 Non-Clinical Testing

Test Method	Purpose	Acceptance Criteria	Results(2 mg/glove)
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine residual powder	≤ 2 mg/glove	S:0.02 M:0.12 L:0.16 XL:0.14 Pass
ASTMD5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine water tightness	Meet the requirements of ASTM D5151 AQL 2.5	S:0/125 leaks M: 0/125 leaks L: 0/125 leaks XL: 0/125 leaks Pass
ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application	To determine physical dimensions	Length(mm):S:≥220. M/L/XL: ≥230 Width(mm): S: 80±10; M: 95±10; L: 110±10; XL: 120±10;	Length(mm):＞230 Width(mm): S: 88 M: 98-99 L: 110-112 XL: 115-117 Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05	Finger: 0.101-0.128 Palm: 0.067-0.78 Pass
ASTM D412-06a-2013 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension	To determine physical properties	Before Aging: Tensile Strength≥14MPa Ultimate Elongation≥500% After Aging: Tensile Strength≥14MPa Ultimate Elongation≥400%	Before Aging: Tensile Strength：25.4 ~36.3 MPa Ultimate Elongation：508%~563% After Aging: Tensile Strength: 25.8~35.6 MPa Ultimate Elongation: 483%~525% 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 Powder Free 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 K190736.