November 15, 2021

Dong Tai City Huayi Gloves Co.,Ltd.
Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161 East Lujiazui East Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211727
Trade/Device Name: Powder Free Blue 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: October 11, 2021
Received: October 18, 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 *(if known)*
K211727

Device Name
Powder Free Blue Nitrile Examination Gloves,Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
These gloves were tested for use with chemotherapy drugs, as per ASTM D6978-05 (Reapproved 2019) 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)	35.0 Minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 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
Methotrexate	25 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)	35.5

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.0 Minutes
ThioTepa 10.0 mg/ml 35.5 Minutes

WARNING: Do not use with Carmustine and Thio-Tepa.

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

(K211727)

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

1.0 Submitter's Information

Name: Dong Tai City Huayi Gloves Co.,Ltd.
Address: No.36 Nanzhuang Road, Dongtai High-tech Industrial Development Zone,Jiangsu Province, 224249 P.R.China.
Contact: Wang Huamei
Tel: +86-13705111918

Designated Submission Correspondent

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

Date of Preparation: Nov.9,2021

2.0 Device Information

Trade name: Powder Free Blue 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
Production code: LZA,LZC
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

3.0 Predicate Device Information

Manufacturer: Medline Industries, Inc.
Device: Medline Powder-Free Light Blue Nitrile Exam Glove

(Tested for Use with Chemotherapy Drugs)
510(k) number: K201390

4.0 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 five sizes: extra-small, small, medium, large, and extra-large.

5.0 Indication for Use

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.
These gloves were tested for use with chemotherapy drugs, per ASTM D6978-05 *Standard Practice for Assessment of Resistance 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)	35.0
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 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
Methotrexate	25 mg/ml(25,000 ppm)	＞ 240
Paclitaxel	6.0 mg/ml(6,000 ppm)	＞ 240
ThioTepa	10.0 mg/ml(10,000 ppm)	35.5

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 35.0 Minutes
ThioTepa 10.0 mg/ml 35.5 Minutes

WARNING: Do not use with Carmustine and ThioTepa.

6.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device	Predicate Device	Remark

	(K211727)	(K201390)	
Product Code	LZA, LZC	LZA, LZC	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs as per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance 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

Table2 Device Dimensions Comparison

Predicate Device(K201390)	Designation	Size				Tolerance
		S	M	L	XL	
	Length, mm	240	240	240	240	min
	Width, mm	85	95	105	115	±10
	Thickness, mm:					
	Finger	0.16				min
	Palm	0.14				min

Subject Device (K211727)	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 (K211727)	Predicated device (K201390)	Remark
Colorant			Blue	Light Blue	Different
Physical Properties	Before Aging	Tensile Strength	14MPa, min	17MPa, min	Different
		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		0.09 mg per glove, Meet the requirements of ASTM D6124		Meet the requirements of ASTM D6124	Same
		Carboplatin 10.0 mg/ml: ＞ 240 Minutes		Carboplatin 10.0 mg/ml: Not detected	Different
		Carmustine (BCNU) 3.3 mg/ml: 35.0 Minutes		Carmustine (BCNU) 3.3 mg/ml: 25.3 Minutes	Different
		Cisplatin 1.0 mg/ml: Not detected		Cisplatin 1.0 mg/ml: ≥240 Minutes	Same
		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ＞ 240 Minutes		Cyclophosphamide (Cytoxan) 20.0 mg/ml: ≥240 Minutes	Same

Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978	Dacarbazine (DTIC) 10.0 mg/ml: Not detected	Dacarbazine (DTIC) 10.0 mg/ml: ≥240 Minutes	Different
	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
	Methotrexate 25 mg/ml: ＞240 Minutes	Methotrexate 25 mg/ml: ≥240 Minutes	Same
	Mitomycin C 0.5 mg/ml: Not detected	Mitomycin C 0.5 mg/ml: ≥ 240 Minutes	Different
	Paclitaxel 6.0 mg/ml: ＞ 240 Minutes	Paclitaxel (Taxol) 6.0 mg/ml: ≥240 Minutes	Same
	Thio Tepa 10.0 mg/ml: 35.5 Minutes	Thio-Tepa 10.0 mg/ml: 43.7 Minutes	Different
	Vincristine Sulfate 1.0 mg/ml: Not detected	Vincristine Sulfate (Oncovin) 1.0 mg/ml: ≥240 Minutes	Different

Analysis 1：The color of the subject device is different with that of the predicate. The subject device was evaluated according to ISO 10993-1 standards, and there were no risks identified.

Analysis 2: Tensile Strength before Aging of the subject device is different with that of the predicate. But both of the devices meet the requirement of ASTM D6319, so the differences do not raise any new safety or performance questions.

Analysis 3: Breakthrough detection time of Carboplatin is not detected on the predicate device, Breakthrough detection times of Cisplatin, Dacarbazine (DTIC), Mitomycin C and Vincristine Sulfate are not detected on the subject device.And Breakthrough detection times of Carmustine (BCNU) and Thio Tepa are different with those of the predicate. The Chemotherapy Labeling Claims has clearly defined on the labeling. So it does not raise any new safety or performance questions.

Table4 Safety Comparison

Item		Subject device (K211727)	Predicate device (K201390)	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	Under conditions of the study, device extract is not cytotoxic	Same

7.0 Summary of Non-Clinical Testing

The biocompatibility evaluation for Powder Free Blue 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

Table 5 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.

Table 6 Non-Clinical Testing

Test Method	Purpose	Acceptance Criteria	Results
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine residual powder	≤ 2 mg/glove	0.09 mg/glove 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	0/125 leaks Pass
ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application	To determine physical dimensions	Length(mm): XS/S ≥220; M/L/XL≥230. Width(mm): XS:70±10; S: 80±10; M: 95±10; L: 110±10; XL: 120±10.	Length(mm):＞230 Width(mm): XS:77-79 S: 87-88 M: 96-98 L: 110-111 XL: 115-117 Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05	Finger: 0.09-0.18 Palm: 0.08-0.13 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：27.45 ~40.30 MPa Ultimate Elongation：983%~1162% After Aging: Tensile Strength: 27.92~38.75 MPa Ultimate Elongation: 800%~1127% Pass

8.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Powder Free Blue 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 K201390.