August 4, 2021

Hengchang (Dongying) 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: K211714
Trade/Device Name: Nitrile Exam Gloves, Powder Free,Blue (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: May 25, 2021
Received: June 3, 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 and Part 809); 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 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)*
k211714

Device Name
Nitrile Exam Gloves, Powder Free,Blue (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
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	23.6 Minutes
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240 Minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	> 240 Minutes
Dacarbazine (DTIC)	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
Methotrexate	25 mg/ml(25,000 ppm)	>240 Minutes
Mitomycin C	0.5 mg/ml(500 ppm)	> 240 Minutes
Paclitaxel	6.0 mg/ml(6,000 ppm)	>240 Minutes
Thio Tepa	10.0 mg/ml(10,000 ppm)	57.4 Minutes
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	> 240 Minutes

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 23.6 Minutes
Thio-Tepa 10.0 mg/ml 57.4 Minutes

Caution: Testing showed an average breakthrough time of 57.4 minutes with Thio-Tepa
WARNING: Do not use with Carmustine

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

(K211714)

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

1.0 Submitter's Information

Name: Hengchang (Dongying) Medical Technology Co.,Ltd.
Address: Room 101,Building 2,No.26 Xinghe Road,Niuzhuang Town,Dongying District,Dongying City,China.
Phone Number: +86-18653343268
Contact: Li Jing
Date of Preparation: Aug.4,2021

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 Exam Gloves, Powder Free,Blue (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: Medline Industries, Inc.
Device: Medline Powder-Free Light Blue Nitrile Exam Glove (Tested for Use with Chemotherapy Drugs)

510(k) number: K201390

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: small, medium, large, and extra-large.

6.0 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
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	23.6
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml(20,000 ppm)	> 240
Dacarbazine (DTIC)	10.0 mg/ml(10,000 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
Mitomycin C	0.5 mg/ml(500 ppm)	> 240
Paclitaxel	6.0 mg/ml(6,000 ppm)	> 240
Thio Tepa	10.0 mg/ml(10,000 ppm)	57.4
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	> 240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 23.6 Minutes;
Thio Tepa 10.0 mg/ml 57.4Minutes.

Caution: Testing showed an average breakthrough time of 57.4 minutes with Thio-Tepa
WARNING: Do not use with Carmustine

7.0 Technological Characteristic Comparison Table

Item	Subject Device	Predicate Device	Remark
Product Code	LZA,LZC	LZA,LZC	Same
510(k) Reference	K211714	K201390	
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 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.	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 usewith 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
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Color	Blue	Light Blue	Different
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 D6319-19: S: ≥220 mm; M/L/XL: ≥230 mm.	Complies with ASTM D6319-19: ≥240 mm.	Similar
Dimensions - Width	Complies with ASTM D6319-19: S:80±10mm; M:95±10mm; L: 110±10mm;	Complies with ASTM D6319-19: S:85±10mm; M:95±10mm; L: 105±10mm;	Similar

	XL: 120±10mm;	XL: 115±10mm;	
Dimensions - Thickness	Complies with ASTM D6319-19 Palm:≥0.05mm Finger: ≥0.05mm	Complies with ASTM D6319-19 Palm:≥0.16mm Finger: ≥0.14mm	Similar
Physical Properties - Tensile Strength	Complies with ASTM D6319-19: Before Aging: ≥14MPa After Aging: ≥500%	Complies with ASTM D6319-19: Before Aging: ≥17MPa After Aging: ≥500%	Similar
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	
Carmustine (BCNU), 3.3 mg/ml	23.6	25.3	Different
Cisplatin 1 mg/ml	> 240	> 240	Same
Cyclophosphamide 20 mg/ml	> 240	> 240	Same
Dacarbazine (DTIC), 10.0 mg/ml	> 240	> 240	Same
Doxorubicin Hydrochloride, 2.0 mg/ml	> 240	> 240	Same
Etoposide (Toposar), 20.0 mg/ml	> 240	> 240	Same
Fluorouracil, 50.0 mg/ml	> 240	> 240	Same
Methotrexate 25 mg/ml	> 240	> 240	Same
Mitomycin C 0.5 mg/ml	> 240	> 240	Same
Paclitaxel, 6.0 mg/ml	> 240	> 240	Same
Thiotepa, 10.0 mg/ml	57.4	43.7	Different
Vincristine Sulfate 1.0 mg/ml	> 240	> 240	Same

Analysis:

1. The physical properties are a little different with that of the predicate, but they all meet the requirements of ASTM D6319-19.

2. 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.

3: Breakthrough detection times of Carmustine (BCNU) and Thio Tepa are different. The IFU Statement has clearly defined on the labeling.

8.0 Summary of Non-Clinical Testing

Test Method	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Length(mm): S: ⩾220 mm； M/L/XL: ⩾230 mm. Width(mm): S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm.			Length:＞230 Width: S: 81-86 M: 93-99 L: 104-109 XL: 113-116 Pass
		Thickness (mm): Finger: ≥0.05 Palm: ≥0.05			Finger: 0.11-0.15 Palm: 0.08-0.15 Pass
ASTM D5151	Watertightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5			0/125 leaks Pass
ASTM D6124	Powder Content	Meet the requirements of ASTM D6124 < 2.0mg			0.08 (mg/glove) Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	14.0-15.4 Pass
			Ultimate Elongation	≥500%	506-664 Pass
		After Aging	Tensile Strength	≥14MPa	14.0-15.0 Pass
			Ultimate Elongation	≥400%	420-511 Pass
ISO 10993-5	Cytotoxicity	Non-cytotoxic			Under conditions of the study, did not show potential toxicity to L-929 cells. 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

The biocompatibility evaluation for Nitrile Exam Gloves, Powder Free,Blue (Tested for Use with Chemotherapy) 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 D 6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

10.0Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Nitrile Exam Gloves, Powder Free,Blue (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.