February 18, 2022

Zibo Sinocare Plastic Products Co., Ltd
Mila Guo
Operation Manager
Lot 5, No. 21 Qingtian Road
Zibo, Shandong 255414
China

Re: K213306
Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue,Test 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: January 7, 2022
Received: January 27, 2022

Dear Mila Guo:

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)*
K213306

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

Indications for Use *(Describe)*
The Powder Free Nitrile Examination Gloves, Blue,Test For Use With Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	16.9
Cisplatin	1.0 mg/ml(1,000 ppm)	>240
Cyclophosphamide (Cytoxan)	20 mg/ml(20,000 ppm)	>240
Dacarbazine	10 mg/ml(10,000 ppm)	>240
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	>240
Eotoside (Toposar)	20.0 mg/ml(20,000 ppm)	>240
Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
Mechlorethamine	1.0 mg/ml(1,000 ppm)	>240
Methotrexate	25.0 mg/ml(25,000 ppm)	>240
Mitomycin C	0.5 mg/ml(500 ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000 ppm)	>240
Thio Tepa	10.0 mg/ml(10,000 ppm)	22.6
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	>240

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3mg/ml 16.9 Minutes
Thio Tepa 10.0 mg/ml 22.6 Minutes.

Warning: Don't to use with either Carmustine or 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.

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510 (k) SUMMARY

(K213306)

This summary of K213306 is being submitted in accordance with 21 CFR 807.92

1.0 Submitter's Information

Submitter Name: Zibo Sinocare Plastic Products Co., Ltd

Registration Number: 3005060582

Address: Lot 5, No. 21 Qingtian Road, Zibo, Shandong, China 255414

Contact Person & Title: Mila Guo, Operation Manager

Contact: Tel & Fax : +86-533-7859433

Email: sinocare2000@126.com

Summary Preparation Date: Feb 10, 2022

2.0 Name of the Device

Proprietary/Trade name: Powder Free Nitrile Examination Gloves, Blue, Tested For Use With Chemotherapy Drugs

Common Name: Patient Examination Gloves, Nitrile, Powder free

Classification Name: Non-Powdered Patient Examination Glove

Device Classification: Class 1

Regulation Number: 21 CFR 880.6250

Product Code: LZA, LZC

3.0 Predicate device

Primary Device Name: Nitrile Exam Gloves, Powder Free, Blue (Tested for Use with Chemotherapy Drugs)

Company name: Hengchang (Dongying) Medical Technology Co., Ltd.

510(K) Number: K211714

4.0 Device Description:

The powder free Nitrile Examination glove is a disposable Class 1 medical device made of Nitrile rubber, and is intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. The principal operation of the medical device to provide single use barrier protection for the wearer and the device meets

all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-19, Standard specification for Nitrile Examination Gloves for medical Application.

5.0 Indication for use:

The Powder Free Nitrile Examination Gloves, Blue, Tested For Use With Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

No.	Test Chemotherapy Drugs	Concentration	Minimum Breakthrough Detection Time in Minutes
1	Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	16.9
2	Cisplatin	1.0 mg/ml(1,000 ppm)	>240
3	Cyclophosphamide	20 mg/ml(20,000 ppm)	>240
4	Dacarbazine	10 mg/ml(10,000 ppm)	>240
5	Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	>240
6	Eotoside (Toposar)	20.0 mg/ml(20,000 ppm)	>240
7	Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
8	Mechlorethamine	1.0 mg/ml(1,000 ppm)	>240
9	Methotrexate	25.0 mg/ml(25,000 ppm)	>240
10	Mitomycin C	0.5 mg/ml(500 ppm)	>240
11	Paclitaxel (Taxol)	6.0 mg/ml(6,000 ppm)	>240
12	Thio Tepa	10.0 mg/ml(10,000 ppm)	22.6
13	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 16.9 Minutes;

Thio Tepa 10.0 mg/ml 22.6 Minutes.

Warning: Do not use with either Carmustine or Thio Tepa

6.0 Technological Characteristics Comparison Table

Shown below is a technological comparison of the subject device (K213306) with the predicate device (K211714) .**Table 1- General Comparison:**

Items	Predicate Device: K211714	Subject Device: K213306	Comparison
Product Code	LZA, LZC	LZA, LZC	Same
Device Class	Class I	Class I	Same
Indication for use (IFU)	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.	The Powder Free Nitrile Examination Gloves, Blue, Tested For Use With Chemotherapy Drugs is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs.	Similar
Regulation No	21 CFR 880.6250	21 CFR 880.6250	Same
Powder free	yes	yes	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non-Sterile	Non-Sterile	Same
Material	Nitrile	Nitrile	Same

Former Release Chemical	Calcium Stearate Dispersion	Calcium Stearate Dispersion	Same
Device Description and Specifications	Comply with ASTM D6319-19	Comply with ASTM D6319-19	Similar
Label and Labeling	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 ofthe testing results.	Single-use indication, powder free, device color, device name, glove size and quantity, Non-Sterile, a statement of standard ASTM D6978-05 (2019) compliance and a summary of the testing results.	Same

1) Table 2- Device Dimension and Performance Comparison

Items	Predicate Device: K211714	Subject Device: K213306	Comparison
Color	White, Blue	Blue	Similar, Note 1
Length mm	Complies with ASTM D6319-19: S: ⩾220 mm；M/L/XL: ⩾230 mm.	Minimum 230 mm	Similar
Palm	Complies with ASTM D6319-19 Palm:⩾0.05mm	0.08+/-0.03 mm	Similar, Note 2
Cuff		0.08+/-0.03 mm	
Finger	Complies with ASTM D6319-19 Finger: ⩾0.05mm	0.08+/-0.03mm	
Before aging	Complies with ASTM D6319-19: ⩾500%	500% min	Same
After aging	⩾400% min	400% min	Same
Before aging	Complies with ASTM D6319-19 ⩾14MPa	15MPa min	Similar
After aging	⩾14MPa	14MPa min	Same

Palm width （mm）	Complies with ASTMD6319-19: S:80±10mm; M:95±10mm; L: 110±10mm; XL: 120±10mm;	X-Small: 70+/- 10mm Small:80 +/- 10mm Medium: 95+/- 10mm Large:110 +/- 10mm X-large: 120 +/- 10mm	Same
Freedom from pinholes	Complies with ASTM D6319-19 and ASTM D5151-19 G-1, AQL 2.5	Be free from holes when tested in accordance with ASTM D5151, and meet the standard ASTM D6319	Same
Residual powder	Complies with ASTM D6319-19, < 2 mg per glove	Meet ASTM D6124-06 (2017) Results generated values below 2 mg of residual powder, meet the requirement of ASTM D6319.	Similar, all meet ASTM D6319.
Chemotherapy drugs tested with minimum Breakthrough Detection Time as Tested per ASTM D6978	Carmustine (BCNU), 3.3 mg/ml , 23.6 min	Carmustine (BCNU),3.3 mg/ml , 16.9mins	Similar note 3
	Cisplatin 1 mg/ml , ＞ 240 mins	Cisplatin, 1.0mg/ml, >240 mins	Same
	Cyclophosphamide, 20 mg/ml , ＞240 mins	Cyclophosphamide (Cytoxan), 20.0 mg/ml, ＞240 mins	Same
	Dacarbazine (DTIC), 10.0 mg/ml, ＞240 min	Dacarbazine (DTIC), 10.0 mg/ml, ＞240 mins	Same
	Doxorubicin Hydrochloride, 2.0 mg/ml, ＞240 min	Doxorubicin Hydrochloride, 2.0 mg/ml, ＞240 mins	Same
	Etoposide (Toposar), 20.0 mg/ml, ＞240 min	Eotoposide (Toposar), 20.0 mg/ml, ＞240 mins	Same
	Fluorouracil, 50.0 mg/ml, ＞ 240 min	Fluorouracil, 50.0mg/ml, ＞ 240 mins	Same
	/	Mechlorethamine, 1.0 mg/ml, ＞ 240 mins	Meet ASTM D6978
	Methotrexate 25 mg/ml, ＞240 min	Methotrexate, 25.0 mg/ml, ＞ 240 mins	Same
	Mitomycin C 0.5 mg/ml, ＞240 min	Mitomycin C, 0.5 mg/ml, ＞240 min	Same
	Paclitaxel, 6.0 mg/ml, ＞240 min	Paclitaxel (Taxol), 6.0 mg/ml, ＞ 240 mins	Same

	Thiotepa, 10.0 mg/ml 57.4mins ,	Thiotepa, 10.0 mg/ml, 22.6 mins	Similar note 3
	Vincristine Sulfate 1.0 mg/ml, ＞240 min	Vincristine Sulfate, 1.0 mg/ml, ＞ 240 mins	Same

Notes:

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.
2. The physical properties are a little different with that of the predicate, but they all meet the requirements of ASTM D6319-19.
3. Breakthrough detection times of Carmustine (BCNU) and Thio Tepa are different. The IFU Statement has clearly defined on the labeling.

2) Table 3- Biocompatibility Testing

	Items	Predicate Device: K211714	Subject Device: K213306	Remark
Bio-compatibility	Irritation (ISO 10993-10:2010 Biological Evaluation of Medical Devices -Part 10: Tests For Irritation And Skin Sensitization)	Complies with ISO 10993-10 (2010) *Under the conditions of the study, the device is a nonirritant and a non-sensitizer.	The test result showed that the response of the test article extract was categorized as negligible under the test condition.	Same
	Sensitization (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization)		Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.	Same
	Cytotoxicity (ISO 10993-5:2009 Biological Evaluation of Medical Devices -Part 5: Tests For In Vitro Cytotoxicity)	Complies with ISO 10993-5 (2009) * Under the conditions of the study, the device is not cytotoxic.	Under the conditions of this study, the test article extract did not show potential toxicity to L929 cells.	Same

7.0 Summary of Non-Clinical Performance Data:

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151	Water tightness Test for Detection of Holes	Meet the requirements of ASTM D5151 AQL 2.5	**Pass** Total 200 pcs of gloves were tested, 0 pcs rejected
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. **Thickness (mm)**: Finger: ≥0.05 Palm: ≥0.05	**Pass** 13 pcs each size,total 65 pcs of gloves were tested, 0 pcs rejected.
ASTM D412	Physical properties	**Before Aging** Tensile Strength ≥14MPa Ultimate Elongation ≥500% **After Aging** Tensile Strength ≥14MPa Ultimate Elongation≥500%	**Pass** 13 pcs each size, total 65 pcs of gloves were tested, 0 pcs rejected.
ASTM D6124	Residual Powder Content	Meet the requirements of ASTM D6124 < 2.0mg	**Pass** 5 pcs each size, total 25 pcs of gloves were tested, 0 pcs rejected.
ISO 10993-10	Skin irritation	non-irritating	**Pass** The test result showed that the response of the test article extract was categorized as negligible under the test condition.
ISO 10993-10	Skin Sensitization	non-sensitizing	**Pass** Under the conditions of this study, the test article extract showed no significant evidence of causing skin

			sensitization in the guinea pig. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.
ISO 10993-5	Cytotoxicity	Non-cytotoxicity.	**Pass** Under the conditions of this study, the test article extract did not show potential toxicity to L929 cells.

Biocompatibility Testing

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 Subject Device were evaluated per ASTM D6319-19, 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 Subject 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 device met the acceptance criteria in 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.

8.0 Summary of Clinical Test:

Clinical data was not needed for this device.

9.0 Conclusion:

Based on the nonclinical tests data, it can be concluded that the Disposable Powder Free Nitrile Examination Glove, 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 K211714.