January 11, 2022

Xingyu Medical Tech Co., Ltd.
℅ Eva Li
Consultant
Shanghai Sungo Management Consulting Company Limited
Room 1309, Dongfang Building, 1500#Century Ave
Shanghai, Shanghai 200122
China

Re: K212735
Trade/Device Name: Nitrile disposable 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: December 16, 2021
Received: December 16, 2021

Dear Eva Li:

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)*
K212735

Device Name
Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)

Indications for Use *(Describe)*
The Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs) are a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Summarized in Table 1 below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05（2019） Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough time
Carmustine (BCNU)	3.3mg/ml (3,300ppm)	47.9(68.2,47.9,69.3)
Cyclophosphamide (Cytoxan)	20.0mg/ml (20,000ppm)	>240 min
Doxorubicin HCI	2.0 mg/ml (2,000ppm)	>240 min
Etoposide	20.0 mg/ml (20,000ppm)	>240 min
Fluorouracil	50.0 mg/ml (50,000ppm)	>240 min
Paclitaxel	6.0 mg/ml (6,000ppm)	>240 min
ThioTepa	10.0 mg/ml (10,000ppm)	>240 min
Bleomycin Sulfate(Blenoxane)	15mg/ml (15,000ppm)	>240 min
Carboplatin	10 mg/ml (10,000ppm)	>240 min
Cisplatin	1.0 mg/ml（1,000ppm）	>240 min
Cytarabine	100mg/ml(100,000ppm)	>240 min
Dacarbazine	10.0mg/ml (10,000ppm)	>240 min
Idarubicin HCL	1mg/ml (1,000ppm)	>240 min
Ifosfamide	50mg/ml (50,00ppm)	>240 min
Mechlorethamine HCL	1mg/ml (1,000ppm)	>240 min
MESNA	100mg/ml (100,000ppm)	>240 min
Methotrexate	25mg/ml (25,000ppm)	>240 min
Mitomycin C	0.5 mg/ml (500ppm)	>240 min
Mitoxantrone	2mg/ml(2,000ppm)	>240 min
Trisenox	1 mg/ml(1,000ppm)	>240 min
Vincristine Sulfate	1 mg/ml (1,000ppm)	>240 min

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.

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510K Summary

The assigned 510(k) number is: K212735

Premarket Notification [510(k)] Summary

1. Submitter / 510(k) Sponsor：

Submitter's name : XINGYU MEDICAL TECH CO.,LTD.
Submitter's Address: NO.2189 YAOQIAN ROAD, GAOMI ECONOMIC DEVELOPMENT ZONE, WEIFANG CITY, SHANDONG PROVINCE, CHINA
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Submission Correspondent
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Tel: +86-21-68828050
Email: fda.sungo@gmail.com

Date of Preparation: 2021-12-14

2. Proposed Device

Device Name / Classification Trade Name: Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)
Common Name: Patient examination glove
Classification Name: Medical Gloves with Chemotherapy Labeling Claims – Test For Use with Chemotherapy Drugs
Product Code: LZA. LZC
Classification Panel: General Hospital
Regulatory Class: Class I
Regulation Number: 21 CFR 880.6250

3. Predicate Device

Device Name: Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with

Chemotherapy Drugs)
Company Name: Medline Industries, Inc.
510(K) Number: K200960

4. Device Description

The Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs) are non-sterile, single use only, disposable examination gloves intended for medical purposes to be worn by examiners to prevent contamination between the patient and the examiner. The gloves are blue, powder free, nitrile gloves. The gloves are offered in sizes small, medium, large, extra large, and packaged in a color paper box.
The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard and are tested for use with chemotherapy drugs per ASTM D6978-05(2019).

5. Indications for Use

The Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs) are a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Summarized in Table 1 below, the proposed device was tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough time
Carmustine (BCNU)	3.3mg/ml (3,300ppm)	47.9 (68.2,47.9,69.3)
Cyclophosphamide (Cytoxan)	20.0mg/ml (20,000ppm)	> 240 min
Doxorubicin HCI	2.0 mg/ml (2,000ppm)	> 240 min
Etoposide	20.0 mg/ml (20,000ppm)	> 240 min
Fluorouracil	50.0 mg/ml (50,000ppm)	> 240 min
Paclitaxel	6.0 mg/ml (6,000ppm)	> 240 min
ThioTepa	10.0 mg/ml (10,000ppm)	> 240 min
Bleomycin Sulfate(Blenoxane)	15mg/ml (15,000ppm)	> 240 min
Carboplatin	10 mg/ml (10,000ppm)	> 240 min
Cisplatin	1.0 mg/ml（1,000ppm）	> 240 min
Cytarabine	100mg/ml(100,000ppm)	> 240 min
Dacarbazine	10.0mg/ml (10,000ppm)	> 240 min
Idarubicin HCL	1mg/ml (1,000ppm)	> 240 min
Ifosfamide	50mg/ml (50,00ppm)	> 240 min
Mechlorethamine HCL	1mg/ml (1,000ppm)	> 240 min
MESNA	100mg/ml (100,000ppm)	> 240 min
Methotrexate	25mg/ml (25,000ppm)	> 240 min
Mitomycin C	0.5 mg/ml (500ppm)	> 240 min
Mitoxantrone	2mg/ml(2,000ppm)	> 240 min

Trisenox	1 mg/ml(1,000ppm)	> 240 min
Vincristine Sulfate	1 mg/ml (1,000ppm)	> 240 min

Do Not Use with Carmustine (BCNU).

6. Summary of Technological Characteristics

Table2：Comparison of Proposed and Predicate Devices

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)	Medline Nitrile Powder Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs)	
510(k) Reference	K212735	K200960	
Product Owner	XINGYU MEDICAL TECH CO.,LTD.	Medline	
Product Code	LZA, LZC	LZA, LZC	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.	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.	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Design Configurations	Blue	Dark Blue	Similar
Materials	Nitrile	Nitrile	Same
Prescription vs. OTC	OTC	OTC	Same
Contact Durations	Limited ≤ 24 hours	Limited ≤ 24 hours	Same
Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
Dimensions-Width	Complies with: ASTM D6319-19 70mm min	Complies with: ASTM D6319-10 70mm min	Same
Dimensions-	Complies with: ASTM D6319-19	Complies with: ASTM D6319-10	Same

<table>
<tr><td>Thickness</td><td>Palm – 0.05mm min. Finger – 0.05mm min</td><td>Palm – 0.05mm min. Finger – 0.05mm min</td><td></td></tr>
<tr><td>Physical Properties</td><td>Complies with: ASTM D6319-19
minimum:
Tensile Strength:
Before Aging ≥14 MPa, min.
After Aging ≥14 MPa, min.
Elongation: Before Aging 500%, min.
After Aging 400%, min.</td><td>Complies with: ASTM D6319-10
minimum:
Tensile Strength:
Before Aging ≥14 MPa, min.
After Aging ≥14 MPa, min.
Elongation: Before Aging 500%, min.
After Aging 400%, min.</td><td>Same</td></tr>
<tr><td>Freedom from holes</td><td>Complies with: ASTM D6319-19 and ASTM D5151-19 G-1,
AQL 1.5</td><td>Complies with: ASTM D6319-10 and ASTM D5151-06 G-1,
AQL 1.5</td><td>Same</td></tr>
<tr><td>Powder or Powder Free</td><td>Powder Free</td><td>Powder Free</td><td>Same</td></tr>
<tr><td>Residual Powder</td><td>Complies with ASTM D6319-19</td><td>Complies with ASTM D6319-10</td><td>Same</td></tr>
<tr><td>Biocompatibility</td><td>Complies with AAMI/ANSI/ISO 10993-10: Not a skin irritant Not a skin sensitizer AAMI/ANSI/ ISO 10993-11: Non-Toxic</td><td>Complies with AAMI/ANSI/ISO 10993-10: Not a skin irritant
Not a skin sensitizer
AAMI/ANSI/ ISO 10993-11: Non-Toxic</td><td>Same</td></tr>
<tr><td>Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as tested per ASTM D6978</td><td>
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration</th><th>Breakthrough time</th></tr>
<tr><td>Carmustine (BCNU)</td><td>3.3mg/ml (3,300ppm)</td><td>47.9
(68.2,47.9,69.3)</td></tr>
<tr><td>Cyclophosphamide (Cytoxan)</td><td>20.0mg/ml (20,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Doxorubicin HCl</td><td>2.0 mg/ml (2,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Etoposide</td><td>20.0 mg/ml (20,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Fluorouracil</td><td>50.0 mg/ml (50,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Paclitaxel</td><td>6.0 mg/ml (6,000ppm)</td><td>> 240 min</td></tr>
<tr><td>ThioTepa</td><td>10.0 mg/ml (10,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Bleomycin Sulfate(Blenoxane)</td><td>15mg/ml (15,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Carboplatin</td><td>10 mg/ml (10,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Cisplatin</td><td>1.0 mg/ml （1,000ppm）</td><td>> 240 min</td></tr>
<tr><td>Cytarabine</td><td>100mg/ml(100,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Dacarbazine</td><td>10.0mg/ml (10,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Idarubicin HCL</td><td>1mg/ml (1,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Ifosfamide</td><td>50mg/ml (50,00ppm)</td><td>> 240 min</td></tr>
<tr><td>Mechlorethamine HCL</td><td>1mg/ml (1,000ppm)</td><td>> 240 min</td></tr>
<tr><td>MESNA</td><td>100mg/ml (100,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Methotrexate</td><td>25mg/ml (25,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Mitomycin C</td><td>0.5 mg/ml (500ppm)</td><td>> 240 min</td></tr>
<tr><td>Mitoxantrone</td><td>2mg/ml(2,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Trisenox</td><td>1 mg/ml(1,000ppm)</td><td>> 240 min</td></tr>
<tr><td>Vincristine Sulfate</td><td>1 mg/ml (1,000ppm)</td><td>> 240 min</td></tr>
</table>
Do Not Use with Carmustine (BCNU).
</td><td>
<table>
<tr><th>Chemotherapy Drug</th><th>Concentration</th><th>Breakthrough time</th></tr>
<tr><td>Carmustine (BCNU)</td><td>3.3 mg/ml (3,300 ppm)</td><td>12.4 minutes</td></tr>
<tr><td>Cisplatin</td><td>1.0 mg/ml (1,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Cyclophosphamide (Cytoxan)</td><td>20.0 mg/ml (20,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Dacarbazine (DTIC)</td><td>10.0 mg/ml (10,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Doxorubicin Hydrochloride</td><td>2.0 mg/ml (2,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Etoposide (Toposar)</td><td>20.0 mg/ml (20,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Fluorouracil</td><td>50.0 mg/ml (50,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Methotrexate</td><td>25 mg/ml (25,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Mitomycin C</td><td>0.5 mg/ml (500 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Paclitaxel (Taxol)</td><td>6.0 mg/ml (6,000 ppm)</td><td>>240 minutes</td></tr>
<tr><td>Thio Tepa</td><td>10.0 mg/ml (10,000 ppm)</td><td>27.4 minutes</td></tr>
<tr><td>Vincristine Sulfate (Oncovin)</td><td>1.0 mg/ml (1,000 ppm)</td><td>>240 minutes</td></tr>
</table>
Do Not Use with Carmustine or Thiotepa
</td><td>Simliar</td></tr>
</table>

7. Summary of Non-Clinical Testing

Physical performance qualities of the proposed 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 proposed device was tested according to ASTM D6978-05(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

To summarize, the performance testing of the subject device were conducted to adequately demonstrate the effectiveness of the device in accordance with the relevant test methods cited below:

ASTM D 6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D 6124-06 (2017) Standard Test Method for Residual Powder on Medical Gloves
ASTM D 5151-19 Standard Test Method for Detection of Holes in Medical Gloves
ASTM D 6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

Test standard followed	**Test conducted**	**Acceptance criteria**					**Conclusion**
ASTM D6319-19	Physical Dimensions		S	M	L	XL	__
		Length（mm）	≥220	≥230			pass
		Width（mm）±10	80±10	95±10	110±10	120±10	pass
		Thickness Finger	≥0.05 mm				pass
		Thickness Palm	≥0.05 mm				pass
	Physical properties	Before Aging	Tensile≥14Mpa; Elongation ≥ 500%				pass
		After Aging	Tensile≥14Mpa; Elongation ≥ 400%				pass
ASTM D6319-19 Test method in accordance with ASTM D5151-19	Watertightness Test for detection of holes	Batch size=35000, sample 125 ≤7					pass
ASTM standard D 6319-19 Test method in accordance with D6124-06(2017)	Powder Residual	≤2（mg/glove）					pass

ASTM D 6978-05(2019)	Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time		——

Chemotherapy Drug	Concentration	Breakthrough time
Carmustine (BCNU)	3.3mg/ml (3,300ppm)	47.9 (68.2,47.9,69.3)
Cyclophosphamide (Cytoxan)	20.0mg/ml (20,000ppm)	> 240 min
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Carboplatin	10 mg/ml (10,000ppm)	> 240 min
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Mitoxantrone	2mg/ml(2,000ppm)	> 240 min
Trisenox	1 mg/ml(1,000ppm)	> 240 min
Vincristine Sulfate	1 mg/ml (1,000ppm)	> 240 min

Do Not Use with Carmustine (BCNU).

8. Biocompatibility

The following tests were performed to evaluate the biocompatibility of the Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs)

- ISO 10993-10: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Acute Systemic Toxicity

Test conducted	Standard	Acceptance criteria	Result
Biocompatibility	Skin Irritation Test Extraction Method ISO 10993-10: 2010	non-irritation	Passes Under the conditions of the study, the subject device is non-irritation
	Skin sensitization the guinea pig maximization ISO 10993-10: 2010	non- sensitization	Passes Under the conditions of the study, the subject device is non-sensitization
	Acute Systemic Toxicity Test ISO 10993-11：2017	non- acute systemic toxicity	Passes Under the conditions of the study, the subject device is non-acute systemic toxicity

9. Conclusion

Based on the nonclinical tests data, it can be concluded that the Nitrile disposable examination gloves (Tested for use with Chemotherapy Drugs) is as safe, as effective, and performs as well as the predicate device, Medline Nitrile Powder-Free Dark Blue Examination Gloves (Tested for use with Chemotherapy Drugs) by Medline Industries, Inc. K200960.