



July 15, 2021

Edma Group, LLC
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801, No.161 Lujiazui East Rd., Pudong
Shanghai, 200120
China

Re: K211547

Trade/Device Name: Edma 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: May 12, 2021
Received: May 19, 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,

Ryan Ortega, PhD
Acting 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

Indications for Use

510(k) Number (if known)
K211547

Device Name
Edma Nitrile 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
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	22.8 Minutes
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240 Minutes
Cyclophosphamide (Cytosan)	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
Paclitaxel	6.0 mg/ml(6,000 ppm)	>240 Minutes
Thio Tapa	10.0 mg/ml(10,000 ppm)	26.1 Minutes

Please note that the following drugs have low permeation times:

Carmustine (BCNU) 3.3 mg/ml 22.8 Minutes

Thio-Tepa 10.0 mg/ml 26.1 Minutes

Warning: Please do not use with Carmustine (BCNU) and Thiotepa.

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

(K211547)

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

1.0 Submitter's Information

Name: Edma Group, LLC.
Address: 3634 E Piccadilly Rd, Phoenix, AZ 85018.
Contact: Mr. Vio Cretu
Date of Preparation: Jul.13,2021

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: Edma Nitrile 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, Tested For
Use With Chemotherapy Drugs, Disposable Powder Free
Nitrile Examination Glove, Tested For Use With Chemotherapy
Drugs, Orange Color

510(k) number: K190860

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 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
Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	22.8
Cisplatin	1.0 mg/ml(1,000 ppm)	> 240
Cyclophosphamide (Cytosan)	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
Paclitaxel	6.0 mg/ml(6,000 ppm)	> 240
Thio Tapa	10.0 mg/ml(10,000 ppm)	26.1

Please note that the following drugs have low permeation times:
Carmustine (BCNU) 3.3 mg/ml 22.8 Minutes;
Thio Tapa 10.0 mg/ml 26.1 Minutes.

Warning: Please do not use with Carmustine (BCNU) and Thiotepa.

7.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device (K211547)	Predicate Device (K190860)	Remark
Product Code	LZA,LZC	LZA,LZC	Same

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
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.	Similar

Table2 Device Dimensions Comparison

Predicate Device(K190860)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	70	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Subject Device(K211547)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	NA	220	230	230	230	min

	Width, mm	NA	80	95	110	120	±10
	Thickness, mm:						
	Finger	0.08					min
	Palm	0.08					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 (K211547)	Predicate device (K190860)	Remark	
Colorant		Blue	White, Orange	Different	
Physical Properties	Before Aging	Tensile Strength	14MPa, min	14MPa, min	Same
		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		0.07 mg per glove, Meet the requirements of ASTM D6124	Meet the requirements of ASTM D6124	Same	
		Carmustine (BCNU) 3.3 mg/ml: 22.8 Minutes	Carmustine (BCNU) 3.3 mg/ml: White:11.8 Minutes; Orange:31.6Minutes	Similar	
		Cisplatin 1.0 mg/ml: > 240 Minutes	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	
		Dacarbazine (DTIC) 10.0 mg/ml: > 240 Minutes	Dacarbazine (DTIC) 10.0 mg/ml: >240 Minutes	Same	
		Doxorubicin HCl 2.0 mg/ml: > 240 Minutes	Doxorubicin Hydrochloride 2.0	Same	

Chemotherapy Drugs Tested with Minimum Breakthrough Detection Time as Tested per ASTM D 6978		mg/ml: >240 Minutes	
	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
	Paclitaxel 6.0 mg/ml: > 240 Minutes	Paclitaxel (Taxol) 6.0 mg/ml: >240 Minutes	Same
	Thio Tapa 10.0 mg/ml: 26.1 Minutes	Thio-Tapa 10.0 mg/ml: White:16.9 Minutes; Orange: 72.5 Minutes	Similar

Analysis: The color of the subject device is different of that of the predicate. Biocompatibility testing was successfully completed for the subject device, demonstrating that any color differences do not affect the safety of the proposed device.

Table4 Safety Comparison

Item		Subject device (K211547)	Predicated device (K190860)	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 -	Under conditions of the study, device extract is not cytotoxic	Under conditions of the study, device extract is not cytotoxic	Same

	Part 5: Tests For In Vitro Cytotoxicity)			
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8.0 Summary of Non-Clinical Testing

Biocompatibility Testing

The biocompatibility evaluation for Edma Nitrile Examination Gloves (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.

10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Edma Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs), K211547, is as safe, as effective, and performs as well as or better than the legally marketed predicated device under K190860.