August 9, 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: K211540
Trade/Device Name: Edma Synthetic Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
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,

For Clarence W. Murray III, Ph.D.
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)*
K211540

Device Name
Edma Synthetic Nitrile Examination Gloves

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

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

(K211540)

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: 07/03/2021

Designated Submission Correspondent

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

2.0 Device Information

Trade name: Edma Synthetic Nitrile Examination Gloves
Common name: Patient Examination Glove
Classification name: Non-powdered patient examination glove
Model(s): M, L, XL

3.0 Classification

Production code: LZA
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate Device Information

Manufacturer: Careglove Global Sdn Bhd
Device: Powder Free Nitrile Examination Gloves, Blue (colored)
510(k) number: K172015

5.0 Indication for Use

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

6.0 Device Description

The subject device is powder free synthetic Nitrile patient examination gloves. The subject device is blue. The design of subject device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D6319. The subject device is non-sterile.

7.0 Technological Characteristic Comparison Table

Item		Subject device		Predicate device		Comparison
510(k) number		K211540		K172015		--
Product Code		LZA		LZA		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 upon the examiner's hands or finger to prevent contamination between patient and examiner.		A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hand or finger to prevent contamination between patient and examiner.		Same
Powdered or Powered free		Powdered free		Powdered free		Same
Main Material		Nitrile		Nitrile		Same
Colorant		Blue		Blue		Same
Design Feature		Ambidextrous		Ambidextrous		Same
Single Use		Yes		Yes		Same
Sterility status		Non-Sterile		Non-Sterile		Same
Dimensions(mm)		Length:≥230； Width: M:95±10； L:110±10； XL:120±10；		Length: XS/S:≥220； M/L/XL: ≥230； Width: XS:70±10; S:80±10; M:95±10； L:110±10； XL:120±10；		Similar
Physical	Before	Tensile	14MPa,min	Tensile	14MPa,min	Same

Properties	Aging	Strength		Strength		
		Ultimate Elongation	500%min	Ultimate Elongation	500%min	Same
	After Aging	Tensile Strength	14MPa,min	Tensile Strength	14MPa,min	Same
		Ultimate Elongation	400%min	Ultimate Elongation	400%min	Same
Freedom from Holes		Be free from holes when tested in accordance with ASTM D5151 AQL=2.5		Meet AQL 1.5 Meet AQL 2.5		Same
Powder Content		＜0.07 mg per glove. Meet the requirements of ASTM D6124		Meet 2mg/glove max. Meet the requirements of ASTM D6124		Same
Biocompatibility		Irritation: Under the conditions of the study, not an irritant or a sensitizer.		Under the conditions of this study the test material did not cause an irritant response.		Same
		Sensitization: Under conditions of the study, not a sensitizer.		Under the conditions of this study,the test material did not produce a skin sensitization effect		
		Cytotoxicity: Under conditions of the study, did not show potential toxicity to L-929 cells.		/		
Labeling Information		Single use, powder free, device color, device name, glove size and quantity, Non-Sterile		Single use, powder free, device color, device name, glove size and quantity, Non-Sterile		Same

8.0 Summary of Non-clinical Testing

Non clinical tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The subject device were evaluated according to the following standards:

ASTM D6319-19, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

ASTM D6124-06 (Reapproved 2017), *Standard Test Method for Residual Powder on Medical Gloves*

ASTMD5151-19, *Standard Test Method for Detection of Holes in Medical Gloves.*

Biocompatibility Testing:

The biocompatibility evaluation for the subject device were evaluated

according to the following standard:

ISO 10993-5:2009 *Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.*

ISO 10993-10:2010 *Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.*

Biocompatibility testing including cytotoxicity test, sensitization test and irritation test according to ISO 10993-1 standards, have been conducted on the Edma Synthetic Nitrile Examination Gloves.

Under the parameters of the tests it is concluded that they are biocompatible, and that there are no new issues of biocompatibility regarding their use as intended.

Table 2: Performance Characteristic Comparison

Test Methodology	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Length(mm):≥230； Width(mm): M: 95±10; L: 110±10; XL: 120±10			Length:＞230 Width: M: 96-99 L: 106-109 XL: 114-118 Pass
		Thickness (mm): Finger: ≥0.08 Palm: ≥0.08			Finger: 0.08-0.13 Palm: 0.08-0.09 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			0.07 mg Pass
ASTM D412	Physical properties	Before Aging	Tensile Strength	≥14MPa	15-18.5 Pass

			Ultimate Elongation	≥500%	506-576 Pass
		After Aging	Tensile Strength	≥14MPa	14-17.6 Pass
			Ultimate Elongation	≥400%	400-522 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

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 proposed device, K211540 is as safe, as effective, and performs as well as or better than the legally marketed predicated device.