



July 30, 2021

Shenzhen Shiqiao Science and Technology Co. LTD
Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211264

Trade/Device Name: Disposable Nitrile Examination Gloves

Regulatory Class: 21 CFR 880.6250

Product Code: LZA

Dated: July 8, 2021

Received: July 14, 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.
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)

K211264

Device Name

Disposable Nitrile Examination gloves

Indications for Use (Describe)

The Disposable Nitrile Examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands 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-K211264

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

1.0 submitter's information

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Date of Preparation: 2021.04.21

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
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2.0 Device information

Trade name: Disposable Nitrile Examination gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): 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: Ever Global (Vietnam) Enterprise Corp
Device: Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color

510(k) number: K171422

5.0 Intended use

The Disposable Nitrile Examination gloves are disposable devices intended for medical purposes that are worn on the examiner’s hands to prevent contamination between patient and examiner.

6.0 Device description

The proposed device is Powder Free Disposable Nitrile Examination gloves. The proposed device is blue. The design of proposed device is addressing the standards as ASTM D6124,ASTM D5151, and ASTM D6319. The proposed device is non-sterile.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

Item	Proposed device	Predicated device	Remark
510(k) number	K211264	K171422	
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Disposable Nitrile Examination gloves is a disposable device intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.	The Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Nitrile Examination gloves, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove, Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device(K171422)	Designation	Size					Tolerance	
		XS	S	M	L	XL		
	Length, mm	230	230	230	230	230	min	
	Width, mm	75	85	95	105	115	±5	
Thickness, mm:								
	Finger	0.05					min	
	Palm	0.05					min	
Proposed Device	Designation	Size					Tolerance	
		S	M	L	XL			
		Length, mm	220	230	230	230	min	
		Width, mm	80	95	110	120	±10	
	Thickness, mm:							
		Finger	0.05					min
	Palm	0.05					min	
Remark	SAME							

Table3 Performance Comparison

Item			Proposed device	Predicated device	Remark
Colorant			blue	White/ Blue/ Black/ Pink	Analysis 1
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	
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	SAME
Powder Content			0.04 mg/glove	Meet the requirements of ASTM D6124	SIMILAR

Analysis1: The proposed device has different color to the predicate device, but all proposed devices are conducted the biocompatibility test, the test results shown that the color difference do not effect the safety of proposed device

Table4 Safety Comparison

Item		Proposed device	Predicated device	Remark
Material		Nitrile	Nitrile	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO10993-10	SAME
	Sensitization	Under conditions of the study, not a sensitizer.		
	Cytotoxicity	Under conditions of the study, did not show potential toxicity to L-929 cells.	Comply with ISO10993-5	SIMILAR
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Discussion of non-clinical and clinical test performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies 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

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 Disposable Nitrile Examination gloves For Medical Application.

Clinical testing is not needed for this device.

Table 5 Performance Data

Test Method	Purpose	Acceptance Criteria				Results				Status
Watertight: ASTM D5151 (Standard Test Method for Detection of Holes in Medical Gloves)	To detect holes that leak water and thereby compromise the usefulness of the glove.	Immediately inspected the glove visually for water leakage. Let the glove hang for 2 min and again inspect for water leakage. Batch size: 35000, Sample size: 125 pcs, Inspection level: I, AQL: 2.5, Ac=7, Re=8				During the test, 0 piece was found with leaks. Hence it falls within the acceptance criteria.				Pass
Physical Properties: ASTM D412 (Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension)	To evaluate the tensile (tension) properties of glove.	Batch size: 35000, Inspection level: S-2, Sample size: 8 pcs,, AQL: 4.0, Ac=1, Re=2				Before Aging		After Accelerated Aging		Pass
		Before Aging		After Accelerated Aging						
		Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation	Tensile Strength (Average)	Ultimate Elongation (Average)	Tensile Strength (Average)	Ultimate Elongation (Average)	
		≥14MPa	≥500%	≥14MPa	≥400%	16.41MPa	540.56%	16.41MPa	532.98%	

Physical Dimensions: (ASTM D 3767-03(2014)). Standard Practice for Rubber—Measurement of Dimensions	To measure the length, width and thickness of glove	Length	S M L XL	Min. 220 mm Min. 230 mm Min. 230 mm Min. 230 mm	Length	S M L XL	Min. 243 mm Min. 249 mm Min. 251 mm Min. 271 mm	Pass
		Width	S M L XL	80±10mm 95±10mm 110±10mm 120±10mm	Width	S M L XL	86-89mm 97-99mm 106-109mm 110-120mm	
		Thickness	Finger Palm	Min.0.05 mm Min.0.05 mm	Thickness	Finger Palm	Min.0.08 mm Min.0.08 mm	
Residual Powder: ASTM D6124 (Standard Test Method for Residual Powder on Medical Gloves)	To determine the amount of residual powder and non-powder solids found on gloves.	Less than 2 mg per glove			Sample size : 5 pcs Result: 0.04 (mg/glove)			Pass

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.