September 15, 2021

Jiangsu Shenglijie Safety Products Co., Ltd
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212009
Trade/Device Name: Disposable Nitrile Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: June 21, 2021
Received: June 28, 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

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)*
K212009

Device Name
Disposable nitrile gloves

Indications for Use *(Describe)*
The Disposable nitrile 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 - K212009

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: 2021.06.21

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Tel: +86-21-50313932
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2.0 Device information

Trade name: Disposable nitrile 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 Indications for use

The Disposable nitrile 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 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	K212009	K171422	
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Indications for use	The Disposable nitrile 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 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

Single use	Yes	Yes	Same
Sterility or not	Non-Sterile	Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device(K171422)	Designation	Measured 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	Measured Size					Tolerance
		S		M	L	XL	
	Length, mm	238		241	244	237	min
	Width, mm	82-86		97-99	108-111	115-118	±2
	Thickness, mm:						
	Finger	0.13					min
	Palm	0.08					min

Analysis1： The measured sizes and tolerances of proposed device are different with those 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			Proposed device	Predicated device	Remark
Colorant			blue	White/ Blue/ Black/ Pink	Analysis 2
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	0.06 mg/glove	Meet the requirements of ASTM D6124	SIMILAR

Analysis 2：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 the conditions of the study, the device is potentially cytotoxic	Comply with ISO10993-5	SIMILAR
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 5 Summary of Non-Clinical Performance Testing

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Results
1	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	All grades are 0. All animals were survived and no abnormal signs were observed during the study.
2			Skin Irritation Test: If the primary irritation index is 0-0,4, the response category is Negligible. 0,5-1,9 means slight 2-4,9 means moderate 5-8 means severe	The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition

3	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	The viab.% of the 100% extract of the test article is the final result, and if viability is reduced to <70% of the blank, it has cytotoxic potential.	Viab.% of 100% test article extract is 71.75% It means the proposed device have no potential toxicity to L-929 in the MTT method
4	ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount ofresidual powder (or filter-retained mass) found on medical gloves	powder residue limit of 2.0 mg	0.06 mg /glove
5	ASTM D5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 125 gloves AQL: 2.5 (ISO 2859) Criterion ≤7 gloves for water leakage	no glove water leakage found
6	ASTM D6319-10(Reapproved 2015),Standard Specification For Nitrile Examination Gloves For Medical Application.	This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.	Sterility: no need Freedom from holes: pl. Refer to No. 5 in table 5 Dimensions: S: width 80±10mm Length ≥220 mm M: width 95±10mm Length ≥230 mm L: width 110±10mm Length ≥230 mm XL: width 120±10mm Length ≥230 mm Thickness: Finger ≥0.05 mm Palm ≥0.05 mm Physical properties: Before aging Tensile strength ≥ 14MPa	N.A. Please refer to No. 5 in table 5 Dimensions: S: width: 82-86 mm Length 238-245 mm M: width 97-99 mm Length 243-249 mm L: width 108-111 mm Length 244-254 mm XL: width 115-118 mm Length 237-246 mm Thickness: Finger 0.13-0.15 mm Palm 0.08 mm Physical properties: Before aging Tensile strength 14.12-22.10MPa Ultimate Elongation 537.05% - 907.44%

			Ultimate Elongation ⩾ 500% After Accelerated Aging Tensile strength ⩾ 14MPa Ultimate Elongation ⩾ 400% Powder-free Residue: pl. Refer to No. 4 in table 5	After Accelerated Aging Tensile strength 14.46-20.20MPa Ultimate Elongation 542.91% - 856.03% Powder-free Residue: pl. Refer to No. 4 in table 5

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10.0 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.