October 6, 2023

3A Glove Sdn. Bhd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K230777
Trade/Device Name: Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 6, 2023
Received: September 7, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control

and Plastic and Reconstructive 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)*
K230777

Device Name
Patient Examination Gloves

Indications for Use *(Describe)*
The Patient 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K230777

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

1.0 submitter's information

Name: 3A Glove Sdn. Bhd.
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Phone Number: +60127708756
Contact: Poh Seng Ping
Date of Preparation: 2023.09.26

Designated Submission Correspondent

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

Trade name: Patient Examination Gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): S, M, L, XL
Colors： FERN GREEN/ MIDNIGHT BLACK/ SKY BLUE

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 Patient 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 a nitrile patient examination glove. The design of proposed device addresses the standard specification requirements of ASTM D6319-19. The proposed device is non-sterile and powder free, with fern green, midnight black and sky blue three colors.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

Item	Proposed device	Predicate device	Remark
510(k) number	K230777	K171422	
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Indications for use	The Patient 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 Powder free	Powder free	Powder free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Patient 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	Analysis1						

Analysis1：The sizes and tolerances of proposed device are different with those of the predicate, but they all meet the requirements of ASTM D6319-19.

Table3 Performance Comparison

Item			Proposed device	Predicate device	Remark
Color			FERN GREEN/ MIDNIGHT BLACK/ SKY 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			Fern Green 0.6 mg/glove Midnight black 1.1 mg/glove Sky blue 1.0 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 performance tests.

Table4 Safety Comparison

Item		Proposed device	Predicate 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	Analysis 3
	Systemic toxicity	Under the conditions of the study, the device does not elicit an acute systemic toxicity response.	Complies with ISO 10993-11 Third edition 2017-09	
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

Analysis 3: The proposed device is potentially cytotoxic, but all proposed devices passed the acute systemic toxicity test.

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	Acceptance Criteria	Results	Pass / Fail
1	Tests For Skin Sensitization	ISO 10993-10:2021.	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	**Fern Green:** No sensitization response was observed in control and treatment group animals. Based on results of the study, it is inferred that the polar and non-polar extracts of the test item "Powder Free Nitrile Examination Gloves Color: Fern Green" is classified as "non-sensitizer" and has met the skin sensitization test requirement of ISO 10993-10:2021.	Pass
				Blue Sky: No sensitization response was observed in control	Pass

				and treatment group animals. Based on results of the study, it is inferred that the polar and non-polar extracts of the test item "Powder Free Nitrile Examination Gloves Color: Blue Sky" is classified as "non-sensitizer" and has met the skin sensitization test requirement of ISO 10993-10:2021.	
				Midnight Black: No sensitization response was observed in control and treatment group animals. Based on results of the study, it is inferred that the polar and non-polar extracts of the test item "Powder Free Nitrile Examination Gloves Color: Midnight Black" is classified as "non-sensitizer" and has met the skin sensitization test requirement of ISO 10993-10:2021.	Pass
2	Tests For skin Irritation	ISO 10993-23:2021.	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	**Fern Green:** At necropsy, there was no abnormality detected in any of the animals. the test item "POWDER FREE NITRILE EXAMINATION GLOVES COLOR: FERN GREEN" is "non-irritant" to the New Zealand white rabbits and has met the skin irritation test requirement of ISO 10993-23:2021.	Pass
				Blue Sky: At necropsy, there was no abnormality detected in any of the animals. Based on results of the study, it is inferred that the polar and non-polar extracts of the test item "POWDER FREE NITRILE EXAMINATION GLOVES COLOR: Blue Sky" is "non-irritant" to the New Zealand white rabbits and has met the skin irritation test requirement of ISO 10993-23:2021.	Pass
				Midnight Black: At necropsy, there was no abnormality detected in any of the animals. Based on results of the study, it is inferred that the polar and non-polar extracts of the test item "POWDER FREE NITRILE EXAMINATION GLOVES COLOR: Midnight Black" is "non-irritant"	Pass

				to the New Zealand white rabbits and has met the skin irritation test requirement of ISO 10993-23:2021.	
3	In Vitro Cytotoxicity	ISO 10993-5:2009	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.	**Fern Green:** Cell viability post treatment with 25, 50 and 100 % test item extracts in MTT test observed was less than 70% when compared to the vehicle control at all the concentrations except at the 12.5% test item concentration. Hence, test item extract was considered to be cytotoxic.	Fail
				Blue Sky: Cell viability post treatment with 25, 50 and 100 % test item extracts in MTT test observed was less than 70% when compared to the vehicle control at all the concentrations except at the 12.5% test item concentration. Hence, test item extract was considered to be cytotoxic.	Fail
				Midnight Black: Cell viability post treatment with 25, 50 and 100 % test item extracts in MTT test observed was less than 70% when compared to the vehicle control at all the concentrations except at the 12.5% test item concentration. Hence, test item extract was considered to be cytotoxic.	Fail
4	Systemic toxicity	ISO 10993-11:2017	To evaluate the potential for medical device materials to cause adverse systemic reactions.	**Fern Green:** No animal deaths or loss in body weight. Based on results of the study, it is inferred that the test item “POWDER FREE NITRILE EXAMINATION GLOVES COLOR: FERN GREEN” did not reveal systemic toxicity and has met the acute systemic toxicity test requirement of ISO 10993-11:2017.	Pass
				Blue Sky: No animal deaths or loss in body weight. Based on results of the study, it is inferred that the test item “POWDER FREE NITRILE EXAMINATION GLOVES COLOR: BLUE SKY” did not reveal systemic toxicity and has met the acute systemic toxicity test requirement of ISO 10993-11:2017.	Pass

				Midnight Black: No animal deaths or loss in body weight. Based on results of the study, it is inferred that the test item “POWDER FREE NITRILE EXAMINATION GLOVES COLOR: MIDNIGHT BLACK” did not reveal systemic toxicity and has met the acute systemic toxicity test requirement of ISO 10993-11:2017.	Pass
5	Residual Powder on Medical Gloves	ASTM D6124-06 (2022)	powder residue limit of 2.0 mg/glove	**Fern Green:** Average: 0.6 mg/glove	Pass
				Blue Sky: Average: 0.9 mg/glove	Pass
				Midnight Black: Average: 0.8 mg/glove	Pass
6	Detection of Holes in Medical Gloves	ASTM D5151-2006	Freedom free hole AQL: 2.5 (ISO 2859)	**Fern Green:** 0 Glove leakage	Pass
				Blue Sky: 0 Glove leakage	Pass
				Midnight Black: 0 Glove leakage	Pass
7	Physical dimensions	ASTM D6319-19	S: width 80± 10mm Length ⩾ 220 mm	**Fern Green:** Average Length: 241 mm Average width: 85 mm	Pass
				Blue Sky: Average Length: 242 mm Average width: 82 mm	Pass
				Midnight Black: Average Length: 240 mm Average width: 84 mm	Pass
			M: width 95 ±10mm Length ⩾ 230 mm	**Fern Green:** Average Length: 253 mm Average width: 97 mm	Pass
				Blue Sky: Average Length: 251 mm Average width: 97 mm	Pass

				Midnight Black: Average Length: 253 mm Average width: 98 mm	Pass
			L: width 110 ±10mm Length ⩾ 230 mm	**Fern Green:** Average Length: 255mm Average width: 110 mm	Pass
				Blue Sky: Average Length: 254 mm Average width: 111 mm	Pass
				Midnight Black: Average Length: 254 mm Average width: 109 mm	Pass
			XL: width 120±10mm Length ⩾ 230 mm	**Fern Green:** Average Length: 257 mm Average width: 118 mm	Pass
				Blue Sky: Average Length: 254 mm Average width: 118 mm	Pass
				Midnight Black: Average Length: 253 mm Average width: 119 mm	Pass
	Thickness	ASTM D3767-03(2003)	Finger ⩾ 0.05 mm	**Fern Green:** Average thickness: 0.11 mm	Pass
				Blue Sky: Average Length: 0.09 mm	Pass
				Midnight Black: Average Length: 0.10 mm	Pass
			Palm ⩾0.05 mm	**Fern Green:** Average Length: 0.06 mm	Pass
				Blue Sky: Average Length: 0.08 mm	Pass
				Midnight Black: Average Length: 0.07 mm	Pass
	Physical properties: Before aging	ASTM D412-16			
	Tensile		⩾14MPa	**Fern Green:**	Pass

	strength			Average Tensile strength：17.23 MPa	
				Blue Sky: Average Tensile strength：17.17 MPa	
				Midnight Black: Average Tensile strength：17.25 MPa	
	Ultimate Elongation		⩾500%	**Fern Green:** Average Ultimate Elongation：540%	Pass
				Blue Sky: Average Ultimate Elongation：539%	
				Midnight Black: Average Ultimate Elongation：541%	
	After Accelerated Aging				
	Tensile strength		⩾14MPa	**Fern Green:** Average Tensile strength：16.30 MPa	Pass
				Blue Sky: Average Tensile strength：16.32 MPa	
				Midnight Black: Average Tensile strength：16.23 MPa	
	Ultimate Elongation		⩾400%	**Fern Green:** Average Ultimate Elongation：450%	Pass
				Blue Sky: Average Ultimate Elongation：449%	
				Midnight Black: Average Ultimate Elongation：452%	

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 predicate device, K171422.