November 21, 2023

Jiangsu Complete Sincerity Medical New Materials Co., Ltd.
℅ Diana Hong
General Manger
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K232576
Trade/Device Name: Medical 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: August 10, 2023
Received: August 25, 2023

Dear Diana Hong:

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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232576

Device Name
Medical nitrile examination gloves

Indications for Use *(Describe)*
Medical nitrile examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand 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.

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

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K232576

1. Date of Preparation: 10/20/2023

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Medical Nitrile Examination Gloves
Common Name: Medical Nitrile Examination Gloves

Regulatory Information

Classification Name: Non-powdered patient examination glove

Classification: I
Product Code: LZA;
Regulation Number: 21CFR 880.6250
Review Panel: General Hospital

Indications for use:
Medical nitrile examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Device Description
The proposed device, Medical Nitrile Examination Gloves, is a powder free patient examination glove, it is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner. The device is provided in blue, purple, white and black colors. The device meets the requirements of *ASTM D6319-19: Standard specification for Nitrile Examination Gloves for Medical Application*. The proposed gloves are available in four sizes, which are S, M, L, XL, it could be selected by the user depended on size of hand. The different between each size is just in the dimension. The proposed device is provided in non-sterile.

5. Identification of Predicate Device

510(k) Number: K220442
Product Name: Synguard Nitrile Exam Glove
Manufacturer: Tianjin Aoshang Outdoor Equipment Co., Ltd.

6. Technological Characteristics Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device		Predicate Device K220442		Remark
Product Code	LZA		LZA		Same
Regulation Number	21 CFR 880.6250		21 CFR 880.6250		Same
Class	I		I		Same
Indication for use	Medical nitrile examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.		Synguard Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.		Same
Material	NATEX CNBR LATEX		Acrylonitrile, Butadiene		Different 1
Color	Blue, White, Black, Purple		Blue		Different 2
Sterility	Non-sterile		Non-sterile		Same
Single-use	Yes		Yes		Same
Size	S, M, L, XL		S, M, L, XL		Different 3
Dimensions (ASTM D6319-19)	Width				
	S	80±10mm	S	84±5mm	
	M	95±10mm	M	94±5mm	
	L	110±10mm	L	110±5mm	
	XL	120±10mm	XL	120±5mm	
	Length				
	S	220mm min	S	230mm min	
	M	230mm min	M	230mm min	
	L	230mm min	L	240mm min	
	XL	230mm min	XL	240mm min	
	Thickness				
	Palm	0.05mm min	Palm	0.05mm min	
	Finger	0.05mm min	Finger	0.05mm min	
Physical Properties (ASTM D6319-19 and ASTM D412-16)	Before Aging				Same
	Tensile Strength	14MPa min	Tensile Strength	14MPa min	
	Ultimate Elongation	500% min	Ultimate Elongation	500% min	
	After Aging				

	Tensile Strength	14MPa min	Tensile Strength	14MPa min	
	Ultimate Elongation	400% min	Ultimate Elongation	400% min	
Powder free residue (ASTM D6319-19 and ASTM D6124-06)	Less than 2mg per glove		Less than 2mg per glove		Same
Freedom from Holes (ASTM D5151-19)	No water leakage occurs. AQL2.5		No water leakage occurs. AQL2.5		Same
Biocompatibility					
Skin Irritation	No Irritation		No Irritation		Same
Sensitization	No Sensitization		No Sensitization		
Acute System Toxicity	No Acute Systemic Toxicity		No Acute Systemic Toxicity		

Different 1- Material

The material of the proposed device is different from the predicate device. However, the biocompatibility and specification performance tests have been performed on each of the proposed devices and the test results show no significant concerns. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different 2- Color

The color of the proposed device is different from the predicate device. However, the biocompatibility and specification performance tests have been performed on each of the proposed devices and the test results show no significant concerns. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Different 3- Size& Dimensions

The size and dimension of the proposed device is not exactly same as the predicate device. However, the size and dimension of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user's hand. In addition, its dimension has been tested and met the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

7. Summary of Non-Clinical Testing

Non clinical tests were conducted to verify that the performance of the proposed device met all design specifications of the applicable and current standards. The test results demonstrated that the proposed device complies with the following standards:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D3767-03 (2020) Standard Practice for Rubber-Measurement of Dimensions
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves
- ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity;

Table 2 Summary of non-clinical performance testing

Test Methodology	**Purpose**	**Acceptance Criteria**			**Results (Pass/Fail)**
ASTM D6319-19, ASTM D3767-03 (2020)	Physical Dimensions	Width	S	80±10mm	Pass
			M	95±10mm	
			L	110±10mm	
			XL	120±10mm	
		Length	S	220mm min	
			M	230mm min	
			L	230mm min	
			XL	230mm min	
		Thickness	Palm	0.05mm min	
			Finger	0.05mm min	
ASTM D6319-19, ASTM D412-16	Physical Properties	Before Aging	Tensile Strength	14MPa min	Pass
			Ultimate Elongation	500% min	
		After Aging	Tensile Strength	14MPa min	
			Ultimate Elongation	400% min	
ASTM D5151-19	Freedom from Holes	Be free from holes when tested in accordance with ASTM D5151			Pass
ASTM D6124-06	Powder free residue	Less than 2mg per glove			Pass
ISO 10993-10:2010	Irritation	Non-Irritating			Pass

ISO 10993-10:2010	Sensitization	Non-Sensitizing	Pass
ISO 10993-11:2009	Acute Systemic toxicity	Non-toxicity	Pass

8. Summary of Clinical Testing

No clinical study is included in this submission.

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K220442.