May 12, 2022

Tianjin Aoshang Outdoor Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd.
P.O.box 120-119
Shanghai, 200120
China

Re: K220442
Trade/Device Name: Synguard Nitrile Exam Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 11, 2022
Received: February 16, 2022

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 (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,

Clarence W. Murray, III, PhD
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)*

K220442

Device Name
Synguard Nitrile Exam Glove

Indications for Use *(Describe)*
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.

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.

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: K220442

1. Date of Preparation: 02/11/2022

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Synguard Nitrile Exam Glove
Common Name: POWDER FREE NITRILE EXAMINATION GLOVES

Regulatory Information

Classification Name: polymer patient examination glove

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

Indication for Use:
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.

Device Description
The proposed device is a powder free medical glove. The device is blue in color. 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: K172015
Product Name: Powder Free Nitrile Examination Gloves, Blue (colored)

6. Technological Characteristics Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Subject Device K220442		Predicate Device K172015		Comparison
Product Code	LZA		LZA		Same
Regulation Number	21 CFR 880.6250		21 CFR 880.6250		Same
Class	I		I		Same
Indication for use	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.		A patient examination 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	Acrylonitrile, Butadiene		Nitrile		Different
Color	Blue		Blue		Same
Sterility	Non-sterile		Non-sterile		Same
Single-use	Yes		Yes		Same
Size	S, M, L, XL		XS, S, M, L, XL		Different
Dimensions (ASTM D6319-19)	Width				
	/	/	XS	70±10mm	
	S	84±5mm	S	80±10mm	
	M	94±5mm	M	95±10mm	
	L	110±5mm	L	110±10mm	
	XL	120±5mm	XL	120±10mm	
	Length				
	/	/	XS	220mm min	
	S	230mm	S	220mm min	
	M	230mm	M	230mm min	
	L	240mm	L	230mm min	
	XL	240mm	XL	230mm 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	
Power 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.		Before aging: Meet AQL 1.5 After aging: Meet AQL 2.5		Different
Biocompatibility					
Skin Irritation	No Irritation		No Irritation		Different
Sensitization	No Sensitization		No Sensitization		
Systemic Toxicity	No Toxicity		/		

Different- Material
The material of the proposed device is different from predicate device.

Different- Size& Dimensions
The size and dimension of the proposed device is not exactly same as the predicate device.

Different- Freedom from Holes
The performance description of freedom from holes of the proposed device is different from predicate device.

Different- Biocompatibility
The biocompatibility test item of the proposed device is different from the predicate device.

7. Non-Clinical Test Conclusion

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	84±5mm	Pass
			M	94±5mm	
			L	110±5mm	
			XL	120±5mm	
		Length	S	230mm	
			M	230mm	
			L	240mm	
			XL	240mm	
		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	400% min	

			Elongation		
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	The polar and nonpolar device extracts did not cause an irritation response in the animal model.			Pass
ISO 10993-10:2010	Sensitization	The polar and nonpolar device extracts did not cause a sensitizing response in the animal model.			Pass
ISO 10993-11:2009	System toxicity	The polar and nonpolar device extracts did not cause a systemic toxicity response in the animal model.			Pass

8. Clinical Test Conclusion

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 K172015.