February 18, 2022

Wuhan Zonsen Medical Products Co.,Ltd
℅ Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K213688
Trade/Device Name: Nitrile Examination Gloves (Model: ZMG1351)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 10, 2021
Received: November 23, 2021

Dear Doris Dong:

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)*
K213688

Device Name
Nitrile Examination Gloves (Model: ZMG1351)

Indications for Use *(Describe)*
Nitrile Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand 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

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K213688
Date:	February 3rd, 2022
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Wuhan Zonsen Medical Products Co.,Ltd No 8 Jinchao Road, Zhucheng Street, Xinzhou District, Wuhan City, Hubei Province, China Tel: +86-27-82737771 E-mail: Cynthia@zonsenmed.com
Contactor:	Doris Dong Shanghai CV Technology Co., Ltd. Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Nitrile Examination Gloves
Model:	ZMG1351
Size:	S, M, L, XL
Classification Name:	Non-powdered patient examination glove
Product Code:	LZA
Device Class:	1
Regulation Number:	21 CFR 880.6250
Review Panel:	General Hospital
Indications for use:	Nitrile Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.
Device Description:	Nitrile Examination Gloves are made from nitrile butadiene rubber that covers the hand up to the wrist. They are cuffed and equally wearable on either hand, free from differentiation between the left hand and the right. The device is available in four sizes, which are S, M, L, XL. It could be selected by the user depending on the size of hand. All sizes share the same blue color. The gloves are non-sterile, powder free and are for single use only.

3. Predicate Device Identification

510(k) Number:	K211319
Product Name:	Purism Non-Sterile Powder Free Nitrile Examination Gloves
Submitter/Manufacturer:	Dezhou Purism Medical Technology Co., Ltd.

4. Technological Characteristics Comparison

Table 1-

Parameters	New Device	Predicate Device	Comparison
510(k) Number	K213688	K211319	---
510(k) Owner	Wuhan Zonsen Medical Products Co.,Ltd	Dezhou Purism Medical Technology Co., Ltd.	---
Device Name	Nitrile Examination Gloves	Purism Non-Sterile Powder Free Nitrile Examination Gloves	---
Model	ZMG1351	/	--
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	1	1	Same
Intended use	Nitrile Examination Gloves are disposable devices intended for medical purposes that are worn on the examiner's hand to prevent contamination between patient and examiner.	The Purism Non-Sterile Powder Free Nitrile Examination Gloves is disposable devices intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Material	Nitrile Butadiene Rubber Latex	Nitrile Butadiene Rubber Latex	Same
Environment of use	OTC	OTC	Same
Design	Disposable (Single use)	Disposable (Single use)	Same
	Non-sterile	Non-sterile	Same
	Powder-free	Powder-free	Same
	Ambidextrous	Ambidextrous	Same
	Cuffed	Cuffed	Same
Size	S, M, L, XL	S, M, L, XL	Same
Color	Blue	Blue	Same
Specifications	Powder-free Nitrile Examination Gloves Meet ASTM D6319-19	Powder-free Nitrile Examination Gloves Meet ASTM D6319-19	Same
Dimensions - Overall Length	Meets ASTM D6319-19 S: Min 220mm M: Min 230mm L: Min 230mm XL: Min 230mm	Meets ASTM D6319-19 S: Min 230mm M: Min 230mm L: Min 230mm XL: Min 230mm	Similar
Dimensions - Palm Width	Meets ASTM D6319-19 S: 80±10mm M: 95±10mm L: 110±10mm XL: 120±10mm	Meets ASTM D6319-19 S: 80±10mm M: 95±10mm L: 110±10mm XL: ≥110mm	
Dimensions - Finger Thickness	Meets ASTM D6319-19 Min 0.05mm	Meets ASTM D6319-19 Min 0.10±0.02mm	
Dimensions - Palm Thickness	Meets ASTM D6319-19 Min 0.05mm	Meets ASTM D6319-19 Min 0.06±0.02mm	

Physical Properties	Meets ASTM D6319-19 *Before Aging:* - Tensile Strength: min 14Mpa - Ultimate Elongation: min 500%	Meets ASTM D6319-19 *Before Aging:* - Tensile Strength: min 14Mpa - Ultimate Elongation: min 500%	Same
	Meets ASTM D6319-19 *After aging:* - Tensile Strength: min 14Mpa - Ultimate Elongation: min 400%	Meets ASTM D6319-19 *After aging:* - Tensile Strength: min 14Mpa - Ultimate Elongation: min 400%	Same
Freedom from Holes	Meets ASTM D6319-19 Pass at AQL 2.5	ASTM D5151-06 Pass at AQL 2.5	Similar
Powder residue	Meets ASTM D6319-19 Below 2mg/glove of residual powder	Meets ASTM D6124-06 Below 2mg/glove of residual powder	
Biocompatibility	Meets ISO 10993-10:2010; **Skin Irritation:** Under the condition of the test, not an irritant. **Skin Sensitization:**Under the condition of the test, not a sensitizer.	Meets ISO 10993-10:2010; **Skin Irritation:** Under the condition of the test, not an irritant. **Skin Sensitization:**Under the condition of the test, not a sensitizer.	Similar
	Meets ISO 10993-11:2017; **Acute Systemic Toxicity:** Under the condition of the test, not a systemic toxicity.	Meets ISO 10993-11:2017; **Acute Systemic Toxicity:** Under the condition of the test, not a systemic toxicity.	
	/	Meets ISO 10993-5:2009; **In Vitro Cytotoxicity:** Under the condition of the test, cytotoxic.	

5. Non-clinical Testing Summary

Bench 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:

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11 Third edition 2017-09, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Test Method	Purpose	Acceptance Criteria		Test Results
Dimension- ASTM D6319-19	Evaluate the glove palm width	*Size*	*(mm)*	*(mm)*
		S	80±10	84~86
		M	95±10	96~98
		L	110±10	104~106
		XL	120±10	113~115
	Evaluate the	*Size*	*(mm)*	*(mm)*

	glove length	S	Min 220	241~251	
		M	Min 230	236~249	
		L	Min 230	237~245	
		XL	Min 230	240~249	
	Evaluate the glove finger thickness	*Size*	*(mm)*	*(mm)*	
		S	Min 0.05	0.111~0.137	
		M	Min 0.05	0.124~0.150	
		L	Min 0.05	0.112~0.133	
		XL	Min 0.05	0.117~0.137	
	Evaluate the glove palm thickness	*Size*	*(mm)*	*(mm)*	
		S	Min 0.05	0.080~0.097	
		M	Min 0.05	0.087~0.098	
		L	Min 0.05	0.074~0.086	
		XL	Min 0.05	0.077~0.094	
Physical Properties- ASTM D6319-19	Evaluate the glove physical propertiesbefore and after aging	*Before Aging*	*After aging*	*Before Aging*	*After aging at*
		Tensile strength: min 14Mpa	Tensile strength: min 14Mpa	Tensile strength: 19.9~27.4Mpa	Tensile strength: 20.1~35.1Mpa
		Ultimate elongation: min 500%	Ultimate elongation: min 400%	Ultimate elongation: 509~553%	Ultimate elongation: 454~504%
Freedom from Holes- ASTM D6319-19	Detect the holes that allow water leakage	Do not show droplet, stream or other type of water leakage		No leakage Pass at AQL 2.5	
Powder residue- ASTM D6319-19	Evaluate the residue powder	≦2mg/glove		Pass	
Skin Irritation - ISO 10993-10:2010	Evaluated for the potential to cause skin irritation	Under the condition of the test, not an irritant.		No- irritant	
Sensitization - ISO 10993-10:2010	Evaluated for the potential to cause skin sensitization	Under the condition of the test, not a sensitizer.		No- sensitization	
Acute Systemic Toxicity- ISO 10993-11:2017	Evaluated for acute systemic toxicity	Under the condition of the test, not a systemic toxicity.		No- acute systemic toxicity	

6. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission, the Nitrile Examination Gloves, are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K211319.