October 6, 2021

Changzhou Xingrong Medical Technology Co. LTD
Amber Pang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan
Shanghai, 200071
China

Re: K211719
Trade/Device Name: ZinRom powder-free 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 6, 2021
Received: August 13, 2021

Dear Amber Pang:

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)*
K211719

Device Name
Zinrom powder-free nitrile examination gloves

Indications for Use *(Describe)*
The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

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-K211719

I. Submitter

CHANGZHOU XINGRONG MEDICAL TECHNOLOGY CO., LTD.
No. 528, Daqiaotou, Chaoyang Cunwei, Hengshanqiao Town, Economic Development District, Changzhou

Contact person: Ray
Position: Sales Manager
Tel.: +86-13775218805
E-mail: ray@zinrom.com

Preparation date: Oct. 7, 2021

II. Proposed Device

Device Trade Name:	ZinRom powder-free nitrile examination gloves
Common name:	Patient Examination Glove
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LZA
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K181106
Trade name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Common name:	Patient Examination Gloves
Classification:	Class I
Product Code:	LZA
Manufacturer	JiangSu Dongxin Medical Technology Co., Ltd.

IV. Device description

The propose devices is powder free nitrile examination gloves, provided as non-sterile and disposable device. The proposed devices are blue color and there are four sizes, includes small (S"), medium (M"), large (L"), X-large (XL") for optional. The gloves are provided with blue color. The examination glove is smooth surface and a rolled rim at the cuff edge.
The gloves are manufactured in accordance with the requirements of ASTM

D6319-19 and Medical Glove Guidance Manual.

V. Indication for use

The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Patient Examination Glove

Item	Standard	Proposed device (K211719)	Predicate device (K181106)	Comparison
Product name	-	ZinRom powder-free nitrile examination gloves	Powder Free Nitrile Patient Examination Gloves, Blue Color	-
Product Code	-	LZA	LZA	Same
Regulation No.	-	21 CFR 880.6250	21 CFR 880.6250	Same
Classification	-	Class I	Class I	Same
Powder free	-	Yes	Yes	Same
Indication for use	-	The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-	Powder Free Nitrile Patient Examination Gloves, Blue Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent	Same

		free, non-sterile device.	contamination between patient and examiner.	
Main Material	ASTM D6319-19	Nitrile rubber	Nitrile rubber	Same
Color	-	Blue	Blue	Similar*
Size	ASTM D6319-19	Small, Medium, Large, X large	Small, Medium, Large, X large	Same
Palm width	ASTM D6319-19 Width: Range value - S : Width: 80 ± 10 mm M : Width: 95 ± 10 mm L : Width: 110 ± 10 mm XL : Width: 120 ± 10 mm	Small (83-87 mm) Medium (97-98 mm) Large (103-109 mm) X large (118-120 mm)	Small (76-90mm) Medium (89-102mm) Large (108-119mm) X large (115-128mm)	Similar Minor difference of palm width does not affect the intended use
Length	ASTM D6319-19 Length: Range value - S: Length : 220mm min, M : Length : 230mm min,	S (238-245 mm) M (238-247 mm) L (241-248 mm) XL(231-248 mm)	232 mm min for all size	Similar The length of the predicate device is shorter than the subject's.

	L : Length : 230mm min, XL : Length : 230mm min,			
Thickness	ASTM D6319-19 For all size: Finger: 0.05 min Palm: 0.05 min	Palm: 0.05mm min Finger: 0.05mm min	Thickness (mm) min: Palm: 0.08mm Finger tip : 0.08mm	Similar The thickness of the subject device is thinner than the predicates
Freedom from holes	ASTM D5151-19 ASTM D6319-19 Inspection Level I AQL2.5	Inspection Level I AQL2.5, and Accept criteria Ac 10, Re 11. Pass.	1) Inspection Level I AQL2.5,and Accept/Reject criteria of 10/11 2) Water leakage test: 5 noncompliance is allowed	Similar
Physical Properties (before aging)	ASTM D6319-19 ASTM D412-16 ASTM D573-04(2019) Before Aging Range: Tensile Strength min: > 14 Mpa Ultimate Elongation	Before aging: Elongation: 500-550% Tensile Strength: 16-24 MPa	Before aging: Elongation: 550-600% Tensile Strength: 18-25 MPa	Similar Only the different standard version. The requirements of physical properties given in the standard

	Min: 500%			are the same.
Physical Properties (after aging)	ASTM D6319-19 ASTM D412-16 ASTM D573-04(2019) After Aging Range: Tensile Strength min: > 14 Mpa Ultimate Elongation Min: 400%	After aging: Elongation: 450-520% Tensile Strength: 15-22 MPa	After aging: Elongation: 450-570% Tensile Strength: 17-22 MPa	Similar Only the different standard version. The requirements of physical properties given in the standard are the same.
Powder residual	ASTM D6319-19 ASTM D6124-06(2017) Range: < 2 mg/glove	≤ 0.4 mg/gloves	1) Checked on 5pcs sub-samples (N=5). 2) Result as following: Mean: 0.1mg/pcs	Similar
Sterility	-	Non-sterile	Non-sterile	Same
For single use	Medical Glove Guidance Manual - Labelling	Yes	Yes	Same
Type of use	-	Over the counter use	Over the counter use	Same
Shelf-life	ASTM D7160-16	3 years	NA	Different

Biocompatibility - Skin Sensitization Test	ISO 10993-10:2010	Under the test condition of study not an sensitizer	Under the test condition of study not an sensitizer	Same
Biocompatibility - Skin Irritation Test	ISO 10993-10:2010	Under the test condition of study not an irritant	Under the test condition of study not an irritant	Same
Biocompatibility - Cytotoxicity Test	ISO 10993-5:2009	Under the test conditions, the test article was shown potential toxicity to L-929 cells.	Under the test conditions, the test article was non cytotoxic to L-929 cells.	Different
Biocompatibility - acute systemic toxicity Test	ISO 10993-11:2017	Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.	Unkonw	Different

*As above comparison, the difference in the dimensions and reference standard version of the subject and predicate device does not raise additional questions for safety and effectiveness of the device. The biocompatibility test and performance test of the subject devices have been performed on the final finished device. The test results shows pass the requirements.

VII. Non-Clinical Testing

Non clinical tests were conducted in accordance with following standards to verify that the proposed device met all design specifications.

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D7160-16, Standard Practice for Determination of Expiration Dating for Medical Gloves
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 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

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151 ASTM D6319-19	Testing for Freedom from holes	Inspection Level I AQL2.5, and Accept criteria Ac 10, Re 11.	Pass. No water leakage is inspected form 200 samples
ASTM D6124-06(2017) ASTM D6319-19	Determine the powder residue for powder free gloves	< 2 mg/glove	≤ 0.4 mg/gloves

ASTM D412-16 ASTM D573-04(2019) ASTM D6319-19	Testing for Physical property characteristics	After Aging Range: Tensile Strength min: > 14 Mpa Ultimate Elongation Min: 400% After Aging Range: Tensile Strength min: > 14 Mpa Ultimate Elongation Min: 400%	Before aging: Elongation: 500-550% Tensile Strength: 16-24 Mpa After aging: Elongation: 450-520% Tensile Strength: 15-22 MPa
ASTM D412-16 ASTM D573-04(2019) ASTM D6319-19	Testing For physical dimensions specification	Length for size (S);: 220 mm min. Length for size (M, L,XL): 230 mm min. Width: 80±10 mm for S; 95±10 mm for M; 110±10 mm for L; 120±10 mm for XL. Finger Thickness: ≥0.05 mm; Palm Thickness: ≥0.05 mm; All acceptance criteria above meet the requirements in Table 1 Dimensions and Tolerances of ASTM D6319	Length of Size S: 238-245 mm; Width of Size S: 83-87 mm; Palm Thickness of Size S: ≥0.05 mm; Finger Thickness of Size S: ≥0.05 mm. Length of Size M: 238-247 mm; Width of Size M: 97-98 mm; Palm Thickness of Size M: ≥0.05 mm; Finger Thickness of Size M: ≥0.05 mm. Length of Size L: 241-248 mm; Width of Size L: 103-109 mm; Palm Thickness of Size L: ≥0.05 mm; Finger Thickness of Size L: ≥0.05 mm. Length of Size XL: 231-248 mm; Width of Size XL: 118-120 mm; Palm Thickness of Size XL: ≥0.05 mm; Finger Thickness of Size XL: ≥0.05 mm.
ISO 10993-10:2010	Evaluate the endpoint of irritant for	The response of the test article extract is negligible.	Under the test condition of study not an sensitizer.

	biocompatibility		
	Evaluate the endpoint of sensitization for biocompatibility	The test article showed no evidence of causing delayed dermal contact sensitization.	Under the test condition of study not an irritant.
ISO 10993-5:2009	Evaluate the endpoint of Cytotoxicity for biocompatibility	The test article showed no evidence of Cytotoxicity from the extract.	Under the test conditions, the test article was shown potential toxicity to L-929 cells.
ISO 10993-11:2017	Evaluate the endpoint of Systemic Cytotoxicity for biocompatibility	The test article showed no evidence of systemic toxicity from the extract.	Under the condition of acute systemic toxicity test, the test article did not show acute systemic toxicity in vivo.

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

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