December 27, 2021

ChuZhou Harmony Gloves Medical Technology Co.,Ltd
Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K212716
Trade/Device Name: Dermoaroma Disposable Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 19, 2021
Received: November 29, 2021

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 (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)*
K212716

Device Name
Dermoaroma Disposable Nitrile Examination Glove

Indications for Use *(Describe)*
The Dermoaroma Disposable Nitrile Examination Gloveare 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR 807.92(a)(1).

1.0 Submitter's information

Name: ChuZhou Harmony Gloves Medical Technology Co.,Ltd
Address: Technology Road 6, branching stream economic development zone, LaiAn Town,Chuzhou City ,AnHui Province,China
Phone Number: +86-18689321491
Contact: WeiHong Ou
Date of Preparation: December 7, 2021

Designated Submission Correspondent
Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Dermoaroma Disposable Nitrile Examination Glove
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): S, M, L, XL

3.0 Classification

Production code: LZA
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Jiangxi Surefine Medical Co., Ltd.
Device: Blue Nitrile Exam Gloves
510(k) number: K211341

5.0 Indications for Use

The Dermoaroma Disposable Nitrile Examination Glove 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 Powder Free Dermoaroma Disposable Nitrile Examination Glove. The proposed device is blue. The design of proposed device is addressing the standards as ASTM D6124,ASTM D5151, and ASTM D6319. The proposed device is non-sterile.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

Item	Proposed device	Predicated device	Remark
510(k) number	K212716	K211341	
Product Code	LZA	LZA	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Indications for Use	The Dermoaroma Disposable Nitrile Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Blue Nitrile Exam Gloves 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 Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Dermoaroma Disposable Nitrile Examination Glove, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Blue Nitrile Exam Gloves, Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device(K211341)	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
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	Same					

Analysis1：The proposed device has same sizes to the predicate device, and all proposed devices are conducted the properties test, the test results shown that the sizes comply with the requirements of standard ASTM D6319-19, Standard Specification For Dermoaroma Disposable Nitrile Examination Glove For Medical Application.

Table3 Performance Comparison

Item			Proposed device	Predicated device	Remark
Colorant			blue	Blue	SAME
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			0.13mg -0.16 mg	0.03 mg	SIMILAR Analysis2

Analysis2：The proposed device has different powder content to the predicate device, but the proposed device is conducted the biocompatibility and performance tests, the test results shown that the difference does not affect the safety and efficacy of proposed device.

Table4 Biocompatibility Testing Comparison

Item		Proposed device	Predicated 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	SIMILAR
	Systemic toxicity	Under the conditions of the study, the device does not elicit a systemic toxicity response in the model animal.		

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	Purpose	Acceptance Criteria	Results
1	ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.	This part of ISO 10993 assesses possible contact hazards from chemicals released from medical devices, which may produce skin and mucosal irritation, eye irritation or skin sensitization.	Skin Sensitization Test: provided grades less than 1, otherwise sensitization.	All grades are 0. All animals were survived and no abnormal signs were observed during the study.
2			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	The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition

3	ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity	This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.	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.	Viab.% of 100% test article extract is 20.8% It means the proposed device have potential toxicity to L-929 in the MTT method
4	ISO 10993-11: 2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	To evaluate the potential for medical device materials to cause adverse systemic reactions.	Within the monitoring period (72 h), if the toxicosis response of testing group is not greater than that of control group, the testing sample is regarded as acceptable.	No toxicosis response in testing group. It means the test article has no potential acute system toxicity on ICR mice in the extraction method.
5	ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount ofresidual powder (or filter-retained mass) found on medical gloves	powder residue limit of 2.0 mg	0.13mg -0.16 mg /glove
6	ASTM D5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.	This test method covers the detection of holes in medical gloves.	Samples number: 125 gloves AQL: 2.5 (ISO 2859) Criterion ≤7 gloves for water leakage	no glove water leakage found
7	ASTM D6319-10(Reapproved 2015),Standard Specification For Nitrile Examination Gloves For Medical Application.	This specification covers certain requirements for nitrile rubber gloves used in conducting medical examinations and diagnostic and therapeutic procedures.	Sterility: no need Freedom from holes: pl. Refer to No. 5 in table 5 Dimensions: S: width 80±10mm Length ≥220 mm M: width 95±10mm Length ≥230 mm L: width 110±10mm Length ≥230 mm	N.A. Please refer to No. 5 in table 5 **Lot no.:202100505** Dimensions: S: width: 80-87 mm Length 240-246 mm M: width 93-98 mm Length 240-245 mm L: width 103-110 mm Length 249-252 mm XL: width 118-123 mm

			XL: width 120±10mm Length ⩾230 mm Thickness: Finger ⩾0.05 mm Palm ⩾0.05 mm Physical properties: Before aging Tensile strength ⩾ 14MPa Ultimate Elongation ⩾ 500% After Accelerated Aging Tensile strength ⩾ 14MPa Ultimate Elongation ⩾ 400% Powder-free Residue: pl. Refer to No. 4 in table 5	Length 265-270 mm Thickness: Finger 0.10-0.12 mm Palm 0.07-0.10 mm Physical properties: Before aging Tensile strength 15.3-19.8 MPa Ultimate Elongation 508.480% - 669.787% After Accelerated Aging Tensile strength 14.3-15.2MPa Ultimate Elongation 435.176% - 542.968% Powder-free Residue: pl. Refer to No. 4 in table 5 **Lot no.:202100520** Dimensions: S: width: 80-85 mm Length 245-251 mm M: width 89-96 mm Length 240-245 mm L: width 105-112 mm Length 249-253 mm XL: width 118-125 mm Length 259-264 mm Thickness: Finger 0.10-0.12 mm Palm 0.08-0.10 mm Physical properties: Before aging Tensile strength 14.9-19.8 MPa Ultimate Elongation 508.480% - 669.787% After Accelerated Aging Tensile strength 14.3-15.2MPa Ultimate Elongation 503.493% - 644.640%

				Powder-free Residue: pl. Refer to No. 4 in table 5 **Lot no.:202100601** Dimensions: S: width: 82-90 mm Length 241-245 mm M: width 95-103 mm Length 240-245 mm L: width 103-112 mm Length 248-255 mm XL: width 114-120 mm Length 258-265 mm Thickness: Finger 0.09-0.12 mm Palm 0.08-0.09 mm Physical properties: Before aging Tensile strength 15.1-19.9 MPa Ultimate Elongation 521.280% - 665.453% After Accelerated Aging Tensile strength 14.1-15.9MPa Ultimate Elongation 430.518% - 513.693% Powder-free Residue: pl. Refer to No. 5 in table 5

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 predicated device.