



October 14, 2021

Yingxiang Glove Products Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211914

Trade/Device Name: Nitrile Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 7, 2021
Received: September 13, 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,

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

Indications for Use

510(k) Number (if known)

K211914

Device Name

Nitrile Patient Examination Gloves

Indications for Use (Describe)

The Nitrile Patient Examination Gloves are 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.

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510(k) Summary

K211914

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 submitter's information

Name: Yingxiang Glove Products Co., Ltd.
Address: No. 1, Zhendong Industrial Park, Huaqiao Town, Wuxue City,
Huanggang City, Hubei Province, 435400, China
Phone Number: +86-15982348869
Contact: Liu Peng
Date of Preparation: 2021.06.06

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: Nitrile Patient Examination Gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): 9-inch (S, M, L, XL), 12-inch (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: Ever Global (Vietnam) Enterprise Corp
Device: Disposable Powder Free Nitrile Examination Glove, White/
Blue/ Black/ Pink Color

510(k) number: K171422

5.0 Indications for Use

The Nitrile Patient Examination Gloves 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 Nitrile Patient Examination Gloves. 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 Technological Characteristics Comparison

Table1-General Comparison

Item	Proposed device	Predicated device	Comparison
510(k) number	K211914	K171422	
Product Code	LZA	LZA	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	The Nitrile Patient Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.	The Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color 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, Nitrile Patient Examination Gloves, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile Examination Glove, Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device(K171422)	Designation	Size					Tolerance
		XS	S	M	L	XL	

	Length, mm	230	230	230	230	230	min
	Width, mm	75	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.05					min
Proposed Device	Designation	Size					Tolerance
			S	M	L	XL	
	9-inch	Length, mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
	12-inch	Length, mm	220	230	230	230	min
		Width, mm	80	95	110	120	±10
	Thickness, mm:						
	9-inch	Finger	0.05				min
	12-inch	Palm	0.05				min
	Remark	Analysis1					

Table3 Performance Comparison

Item				Proposed device	Predicated device	Comparison	
Colorant				blue	White/ Blue/ Black/ Pink	Analysis2	
9-inch	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				0.08	Meet the requirements of ASTM D6124	SIMILAR
12-inch	Physical Properties	Before Aging	Tensile Strength	14MPa, min	14MPa, min	SAME	
			Ultimate	500%min	500%min	SAME	

		Elongation			
	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 ASTM D5151 AQL=2.5		Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	SAME
	Powder Content	0.11		Meet the requirements of ASTM D6124	SIMILAR

Analysis1: The proposed device has different sizes and tolerances to the predicate device.

Analysis2: The proposed device has different color to the predicate device.

Table4 Safety Comparison

Item		Proposed device	Predicated device	Comparison
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 conditions of the study, did not show potential toxicity to L-929 cells.	Comply with ISO10993-5	SIMILAR
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Summary of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications and acceptance criteria. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6319-19, Standard Specification For Nitrile Patient Examination Gloves For Medical Application.

ASTM D7160-16, Standard Practice for Determination of Expiration Dating for Medical Gloves

Table 5 Summary of Non-Clinical Performance Testing

9-inch				
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 71.6% It means the proposed device have no potential toxicity to L-929 in the MTT method
4	ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves	This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves	powder residue limit of 2.0 mg	0.08 mg /glove
5	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

6	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.	<p>Sterility: no need Freedom from holes: Dimensions: S: width 80 ± 10mm Length ≥ 220 mm M: width 95 ± 10mm Length ≥ 230 mm L: width 110 ± 10mm Length ≥ 230 mm XL: width 120 ± 10mm Length ≥ 230 mm Thickness: Finger ≥ 0.05 mm Palm ≥ 0.05 mm</p> <p>Physical properties: Before aging Tensile strength ≥ 14MPa Ultimate Elongation $\geq 500\%$ After Accelerated Aging Tensile strength ≥ 14MPa Ultimate Elongation $\geq 400\%$</p> <p>Powder-free Residue: pl. Refer to No. 4 in table 5</p>	<p>N.A. Dimensions: S: width: 81-87 mm Length 228-234 mm M: width 94-96 mm Length 242-254 mm L: width 100-109 mm Length 268-274 mm XL: width 112-119 mm Length 245-252 mm Thickness: Finger 0.11-0.13 mm Palm 0.07-0.08 mm</p> <p>Physical properties: Before aging Tensile strength 16.72-26.66 MPa Ultimate Elongation 518.19% - 849.65% After Accelerated Aging Tensile strength 15.34-21.73 MPa Ultimate Elongation 560.54% - 799.91%</p> <p>Powder-free Residue: pl. Refer to No. 5 in table 5</p>
12-Inch				
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			<p>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</p>	<p>The primary irritation index is 0. The response of the proposed device was categorized as negligible under the test condition</p>
3	<p>ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity</p>	<p>This part of ISO 10993 describes test methods to assess the in vitro cytotoxicity of medical devices.</p>	<p>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.</p>	<p>Viab.% of 100% test article extract is 70.9% It means the proposed device have no potential toxicity to L-929 in the MTT method</p>
4	<p>ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves</p>	<p>This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves</p>	<p>powder residue limit of 2.0 mg</p>	<p>0.11 mg /glove</p>
5	<p>ASTM D5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.</p>	<p>This test method covers the detection of holes in medical gloves.</p>	<p>Samples number: 125 gloves AQL: 2.5 (ISO 2859) Criterion ≤ 7 gloves for water leakage</p>	<p>no glove water leakage found</p>

6	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.	<p>Sterility: no need Freedom from holes: Dimensions: S: width 80 ± 10mm Length ≥ 220 mm M: width 95 ± 10mm Length ≥ 230 mm L: width 110 ± 10mm Length ≥ 230 mm XL: width 120 ± 10mm Length ≥ 230 mm Thickness: Finger ≥ 0.05 mm Palm ≥ 0.05 mm</p> <p>Physical properties: Before aging Tensile strength ≥ 14MPa Ultimate Elongation $\geq 500\%$ After Accelerated Aging Tensile strength ≥ 14MPa Ultimate Elongation $\geq 400\%$</p> <p>Powder-free Residue: pl. Refer to No. 4 in table 5</p>	<p>N.A. Dimensions: S: width: 85-88 mm Length 292-296 mm M: width 95-99 mm Length 305-310 mm L: width 106-109 mm Length 305-311 mm XL: width 116-118 mm Length 293-298 mm Thickness: Finger 0.11 mm Palm 0.13-0.14 mm</p> <p>Physical properties: Before aging Tensile strength 14.02-21.91 MPa Ultimate Elongation 593.30% - 898.44% After Accelerated Aging Tensile strength 15.45-19.64MPa Ultimate Elongation 523.51% - 805.28%</p> <p>Powder-free Residue: pl. Refer to No. 5 in table 5</p>
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9.0 Summary of Clinical Testing

Clinical testing is not needed for this device.

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.