DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 31, 2017

Shandong Xingyu Gloves Co., Ltd
% Chu Xiaoan
Official Correspondent
Beijing Easylink CO., LTD
Rm. F302 Bldg., 41, Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang,
Beijing, 100121, China

Re: K171615
Trade/Device Name: Xingyu Nitrile Powder Free Patient Examination Gloves, White color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 9, 2017
Received: July 19, 2017

Dear Chu Xiaoan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark S. Fellman -S

for Lori Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171615

Device Name
Xingyu Powder Free Nitrile Patient Examination Gloves, White Color

Indications for Use *(Describe)*

Xingyu Powder Free Nitrile Patient Examination Gloves, White Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the 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

"The assigned 510(k) number is: K171615 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Shandong Xingyu Gloves Co.,Ltd
Submitter's address :	No.2158,Yaoqian Road,Economic Development Zone, Gaomi City,Shandong,261502,China
Phone number :	0086-536-2588123
Fax number :	0086-536-2586328
Name of contact person:	Xu Qiang
Date of preparation :	2017-07-07

2.0 Name of the Device

Device Name:	Powder Free Nitrile Patient Examination Gloves,White Color
Proprietary/Trade name:	Xingyu Powder Free Nitrile Patient Examination Gloves,White Color
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital (80)
Product Code:	LZA

3.0 Predicate device

Device Name:	Powder Free Nitrile Patient Examination Gloves, White Color
Company name:	JiangSu DongLing Plastic & Rubber Co., Ltd.
510(K) Number:	K110248

4.0 Device Description:

4.1 **How the device functions:**
Nitrile films form a barrier to prevent contamination between patient and examiner.

4.2 **Scientific concepts that form the basis for the device**
The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

4.3 **Physical and performance characteristics such as design, materials and physical properties:**

The Nitrile glove acts as a barrier to prevent contamination between patient and examiner. The glove is manufactured in accordance with the requirements of ASTM D6319-10(Reapproved 2015) and ASTM D5151-06(Reapproved 2015).

5.0 Indication for use:

Xingyu Powder Free Nitrile Patient Examination Gloves,White Color is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

Xingyu Powder Free Nitrile Patient Examination Gloves,White Color, non-sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	**Standard**		
Dimension	ASTM standard D 6319-10(Reapproved 2015)		
	Length	≥230mm	
	Width	Small	70-90 mm
		Medium	85-105mm
		Large	100-120mm
		X large	110-130 mm
	Thickness	Fingertip	≥0.05mm
		Palm	≥0.05mm
Physical Properties	ASTM standard D 6319-10(Reapproved 2015)		
	Tensile strength(Before aging)		≥14MPa
	Tensile strength(After aging)		
	Elongated rate(Before aging)		≥500%
	Elongated rate(After aging)		≥400%
Freedom from pinholes	• 21 CFR 800.20 • ASTM standard D 6319-10(Reapproved 2015). Test method in accordance with ASTM D5151-06(Reapproved 2015)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 6319-10(Reapproved 2015) Test method in accordance with D6124-06(Reaffirmation 2011)		Meets 0.1mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01		Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01		Passes Not a Primary Skin Irritation

7.1 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data:

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Powder Free Nitrile Patient Examination Gloves,White Color made by Shandong

Xingyu Gloves Co.,Ltd met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- Dimension per ASTM D6319-10(Reapproved 2015),
- Tensile strength (Before aging/ After aging) and Elongated rate (Before aging/ After aging) per ASTM D6319-10(Reapproved 2015),
- Water leak test on pinhole per ASTM D6319-10(Reapproved 2015) and per 21 CFR 800.20,
- Powder Residual tests per ASTM D6319-10(Reapproved 2015)
- Biocompatibility test per ISO 10993-10: Third Edition 2010-08-01.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data was not needed to demonstrate that the subject glove is substantially equivalent to the predicate glove. So determination of substantial equivalence is not based on an assessment of clinical performance data.

9.0 Substantial Equivalence Comparison:

Features & Description	Predicate Device		Subject Device		Result of Comparison
Company	JiangSu DongLing Plastic & Rubber Co., Ltd.		Shandong Xingyu Gloves Co.,Ltd		--
510(K) Number	K110248		K171615		
Product name	Powder Free Nitrile Patient Examination Gloves,White Color		Powder Free Nitrile Patient Examination Gloves,White Color		Same
Product Code	LZA		LZA		Same
Size	Small/ Medium/ Large/X large		Small/ Medium/ Large/X large		Same
Intended use	Powder Free Nitrile Patient Examination Gloves, White Color 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.		Powder Free Nitrile Patient Examination Gloves,White Color 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
Device Description and Specifications	Meets ASTM D6319-10		Meets ASTM D6319-10(Reapproved 2015)		Same
Dimensions --Length ILS-2 AQL4.0	Meets ASTM D6319-10 ≥230mm min		232 mm min for all sizes		Same
Dimensions -- Width IL S-2 AQL4.0	Meets ASTM D6319-10				Same
	Small	70-90 mm	Small	80-88 mm	
	Medium	85-105mm	Medium	89-102 mm	
	Large	100-120mm	Large	104-118mm	
	X large	110-130 mm	X large	115-129 mm	

Dimensions --Thickness IL S-2 AQL4.0	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.	Thickness (mm) min. Finger 0.08 Palm 0.08			Same
Physical Properties IL S-2 AQL4.0	Meets ASTM D D6319-10 Before aging/after aging Tensile Strength≥ 14MPa Before aging Elongation ≥500% After aging Elongation ≥400%	Aging	Before	After	Same
		Elongation (%)	560-600	460-560	
		Tensile Strength (MPa)	18-25	17-21	
Freedom from Pinholes Inspection Level I AQL2.5	Meets • 21 CFR 800.20 • ASTM D6319-10 Test method in accordance with ASTM D5151-06 (Reapproved 2015)	Meets • 21 CFR 800.20 • ASTM D 6319-10(Reapproved 2015) Tested in accordance with ASTM D5151 (Reapproved 2015) with acceptable results			Same
Residual Powder	Meets ASTM D 6124-06 (Reaffirmation 2011) below 2mg of residual powder	Meets ASTM D 6124-06 (Reaffirmation 2011) Results generated values below 2mg of residual powder			Same
Materials used to fabricate the devices	Nitrile	Nitrile			Same
Dusting or Donning Powder: name	Surface Coating Agent	Surface Coating Agent			Same
Standards	Meets ASTM D5151-06 (Reapproved 2015) ASTM D6319-10 ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-06 (Reapproved 2015) ASTM D6319-10 (Reapproved 2015) ASTM D6124-06 (Reaffirmation 2011)			Same
Single Patient Use	Single Patient Use	Single Patient Use			Same

Biocompatibility	Under the conditions of this study, the test article was a non- irritant or non-sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006	Under the conditions of this study, the test article was a non-irritant or non-sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10: Third Edition 2010-08-01.	Same
Labeling	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -White color -Non sterile	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -White color -Non sterile	Same

10.0 Conclusion:

Based on the nonclinical tests data, it can be concluded that the Xingyu Powder Free Nitrile Patient Examination Gloves,White Color is as safe, as effective, and performs as well as the predicate device, Powder Free Nitrile Patient Examination Gloves, White Color, JiangSu DongLing Plastic & Rubber Co., Ltd., K110248.