DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 12, 2016

Suqian Xingye Glove Co., Ltd.
c/o Mr. Chu Xiaoan
Beijing Easylink Co., Ltd.
Room F302 Bldg. 41, Jing Cheng Ya Ju
Courtyard 6 of Southern Dou Ge Zhuang
Beijing 100121
CHINA

Re: K151680
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 3, 2016
Received: January 11, 2016

Dear Mr. 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 and Part 809); 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 and Part 809), 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith, M.S.
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)*
K151680

Device Name
Powder Free Nitrile Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*
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 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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Section 6 510(k) Summary

510(K) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K 151680 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Suqian Xingye Glove Co,Ltd
Submitter's address :	Dongwu Road,Economic Development Zone,Suqian City,Jiangsu Province,223800,China
Phone number :	0086-527-82860533
Fax number :	0086-527-82860080
Name of contact person:	Jian Zhong Deng
Date of preparation :	2015-11-07

2.0 Name of the Device

Device Name:	Powder Free Nitrile Patient Examination Gloves, Blue Color
Proprietary/Trade name:	Powder Free Nitrile Patient Examination Gloves, Blue 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:	Nitrile Powder Free Patient Examination Gloves, Cloured (Blue)
Company name:	Tangshan Zhonghong Pulin Plastic Co.,Ltd.
510(K) Number:	K120970

4.0 Device Description:

4.1 **How the device functions:**
Nitrile films form a barrier to body fluids and bloodborne Pathogens

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:**
Nitrile glove is known to create a barrier to bloodborne pathogens and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The glove is manufactured in accordance with the requirements of ASTM D6319 and ASTM D5151 requirements.

5.0 Device Intended Use (Indication for use):

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 contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

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

Characteristics	**Standard**			**Device performance**
Dimension	ASTM standard D 6319-10.			
	Length	≥230mm		234-243mm
	Width	Small	70-90 mm	78-85mm
		Medium	85-105mm	95-99mm
		Large	100-120mm	108-113mm
		X large	110-130 mm	117-126mm
	Thickness	Fingertip	≥0.05mm	0.08-0.11 mm
		Palm	≥0.05mm	0.08-0.12 mm
Physical Properties	ASTM standard D 6319-10.			
	Tensile strength (Before aging)		≥14MPa	20-23MPa
	Tensile strength (After aging)			18-21 MPa
	Elongated rate (Before aging)		≥500%	560-600%
	Elongated rate (After aging)		≥400%	530-580%
Freedom from pinholes	• 21 CFR 800.20 • ASTM standard D 6319-10. Test method in accordance with ASTM D5151-06(Reapproved 2011)			Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 6319-10. Test method in accordance with D6124-06(Reaffirmation 2011)			0.1mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01			Under the conditions of the study, the device was a non-irritant.
	Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01			Under the conditions of the study, the device was a non-sensitizer.

7.0 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, Blue Color made by Suqian Xingye Glove 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,
- Tensile strength (Before aging/ After aging) and Elongated rate (Before aging/ After aging) per ASTM D6319-10,
- Water leak test on pinhole per ASTM D6319-10 and per 21 CFR 800.20,
- Powder Residual tests per ASTM D6319-10(Reapproved 2011)
- Biocompatibility test per ISO 10993-10: Third Edition 2010-08-01.

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data:

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

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	Tangshan Zhonghong Pulin Plastic Co., Ltd.	Suqian Xingye Glove Co,Ltd	--
510(K) Number	K120970	K151680	
Product name	Nitrile Powder Free Patient Examination Gloves, Cloured (Blue)	Powder Free Nitrile Patient Examination Gloves, Blue Color	same
Product Code	LZA	LZA	same
Size	Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	same
Intend for use	Nitrile Powder Free Patient Examination Gloves, Cloured (Blue) 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, Blue 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.	Substantially equivalent
Device Description and Specifications	Meets ASTM D6319-10	Meets ASTM D6319-10	Substantially equivalent

Dimensions --Length	Meets ASTM D6319-10 ≥230mm min		234 mm min for all sizes		Substantially equivalent
Dimensions -- Width	Meets ASTM D6319-10				Substantially equivalent
	Small	70-90 mm	Small	78-85 mm	
	Medium	85-105mm	Medium	95-99 mm	
	Large	100-120mm	Large	108-113mm	
	X large	110-130 mm	X large	117-126 mm	
Dimensions --Thickness	Meets ASTM D6319-10 Finger 0.05mm min. Palm 0.05mm min.		Thickness (mm) min. Finger 0.08 Palm 0.08		Substantially equivalent
Physical Properties	Meets ASTM D D6319-10 Before aging/after aging Elongation ≥500% Tensile Strength≥ 14MPa		Aging	Before	After
			Elongation (%)	560-600	530-580
			Tensile Strength (MPa)	20-23	18-21
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D6319-10 Test method in accordance with ASTM D5151-06 (Reapproved 2011)		Meets • 21 CFR 800.20 • ASTM D6319-10 Tested in accordance with ASTM D5151 (Reapproved 2011) with acceptable results		Substantially equivalent
Residual Powder	Meets ASTM D 6124-06 (Reapproved 2011) below 2mg of residual powder		Meets ASTM D 6124-06 (Reapproved 2011) Results generated values below 2mg of residual powder		Substantially equivalent
Materials used to fabricate the devices	Nitrile		Nitrile		Substantially equivalent
Dusting or Donning Powder:	PU		PU-120C		Substantially equivalent
Dusting or Donning Powder: name	Surface Coating Agent		Surface Coating Agent		Substantially equivalent
Compare performance data supporting substantial equivalence	Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)		Meets ASTM D5151-06 (Reapproved 2011) ASTM D6319-10 ASTM D6124-06 (Reapproved 2011)		Substantially equivalent
Single Patient Use	Single Patient Use		Single Patient Use		Substantially equivalent
Biocompatibility	Under the conditions of this study, the test article was a non- irritant or non-sensitizer.		Under the conditions of this study, the test article was a non-irritant or non-		Substantially equivalent

	SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd.1:2006	sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10: Third Edition 2010-08-01.	
Labeling for the legally marketed device to which substantial equivalence is claimed.	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot -Blue color - Non sterile	Substantially equivalent

10.0 Conclusion:

It can be concluded that the Powder Free Nitrile Patient Examination Gloves, Blue Color is as safe, as effective, and performs as well as the predicate device, Nitrile Powder Free Patient Examination Gloves, Cloured (Blue), Tangshan Zhonghong Pulin Plastic Co., Ltd., K120970.

The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the predicate device.