DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 21, 2016

Zibo Daiyang Plastic Company
% Chu Xiaoan
Official Correspondent
Beijing Easylink Co., LTD
Rm. F302 Bldg., 41,
Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang,
Beijing, CN 100121

Re: K162259
Trade/Device Name: DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: November 8, 2016
Received: November 22, 2016

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*
K162259

Device Name
DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)

Indications for Use *(Describe)*
DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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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510(K) Summary

The assigned 510(k) number is: K162259

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Zibo Daiyang Plastic Company
Submitter's address :	North of Shiji Rd,Zhuangyuan Industrial Park, Zhangdian,Zibo,Shandong,255087,China
Phone number :	0086-533-3813666
Fax number :	0086-533-3811696
Name of contact person:	Yang Yan Hong
Date of preparation :	2016-12-16

2.0 Name of the Device

Device Name:	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Proprietary/Trade name:	DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Common Name:	Exam gloves
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel:	General Hospital
Product Code:	LYZ

3.0 Predicate device

Device Name:	Powder-Free Vinyl Patient Examination Glove (Non-colored)
Company name:	Zhang Jia Gang Fengyuan Plastic Product Co. Ltd.
510(K) Number:	K091663.

4.0 Device Description:

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

4.2 **Scientific concepts that form the basis for the device**
The PVC 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 Poly (vinyl chloride) glove acts as a barrier to prevent contamination between patient and examiner. The glove is manufactured in accordance with the requirements of ASTM D5250 and ASTM D5151.

5.0 Device Intended Use (Indication for use):

DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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:

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	**Standard**		
Dimension	ASTM D 5250-06(Reapproved 2011).		
	Length	≥230mm	
	Width	Small	80-90 mm
		Medium	90-100mm
		Large	100-110mm
		X large	110-120 mm
	Thickness	Fingertip	≥0.05mm
		Palm	≥0.08mm
Physical Properties	ASTM D 5250-06(Reapproved 2011).		
	Tensile strength (Before & After aging)		≥11MPa
	Elongated rate (Before & After aging)		≥300%
Freedom from pinholes	• 21 CFR 800.20 • ASTM D5250-06(Reapproved 2011) • ASTM D5151-06(Reapproved 2011)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 5250-06 (Reapproved 2011).and D6124-06(Reaffirmation 2011)		Meets <2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01		Passes Not a Primary Skin Irritation
	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01		Passes Not a Dermal sensitization

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

DAIYANG Powder Free Vinyl Patient Examination Gloves, Clear (non-colored), meet requirements per ASTM D5250-06 (Reapproved 2011), per ASTM D6124-06 Reaffirmation 2011), per 21 CFR 800.20 and ISO 10993-10:2010-08-01.

The performance test data of the nonclinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

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.

9.0 Substantial Equivalence Comparison:

Features & Description			Predicate Device	Subject Device	Result of Comparison
Company			Zhang Jia Gang Fengyuan Plastic Product Co.Ltd.	Zibo Daiyang Plastic Company	--
510(K) Number			K091663	K162259	--
Product name			Powder Free Vinyl Patient Examination Gloves, Clear (Non-colored)	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)	same
Product Code			LYZ	LYZ	same
Size			Small/ Medium/ Large/X large	Small/ Medium/ Large/X large	same
Intend for use			Powder free Vinyl Patient Examination Gloves, Clear(Non-colored)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.	DAIYANG Powder free Vinyl Patient Examination Gloves, Clear (non-colored) 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	Similar
Device Description and Specifications			Meets ASTM D5250-06	Meets ASTM D5250-06 (Reapproved 2011)	Similar
Dimensions Length（mm） ILS-2 AQL4.0	≥230mm		231-241mm	232-240mm	Similar
Dimensions Width （mm） IL S-2 AQL4.0	Small	80-90	81-89	81-87	Similar
	Medium	90-100	93-99	93-98	
	Large	00-110	102-110	102-109	
	X large	110-120	111-1119	113-118	
Dimensions Thickness （mm） IL S-2 AQL4.0	Finger	≥0.05	0.05-0.10	0.08-0.11	Similar
	Palm	≥0.08	0.09-0.13	0.10-0.12	
Physical Properties IL S-2 AQL4.0	Before aging/after aging				Similar
	Elongation ≥300%		340-410%	350-420%	
	Tensile Strength ≥ 14MPa		15-25 MPa	15-20 MPa	
Freedom from Pinholes	Holes at Inspection Level I AQL2.5		Holes at Inspection Level I AQL2.5	Holes at Inspection Level I AQL2.5	Similar

Residual Powder	below 2mg of residual powder	0.3mg	0.1mg	Similar
Materials used to fabricate the devices		PVC	PVC	Similar
Dusting or Donning Powder: name		Surface Coating Agent	Surface Coating Agent	Similar
Compare performance data supporting substantial equivalence		Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Similar
Single Patient Use		Single Patient Use	Single Patient Use	Similar
Biocompatibility		Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10:2002/Amd. 1:2006	Under the conditions of this study, not an irritant and Under the conditions of this study, not a sensitizer. SKIN IRRITATION DERMAL and SENSITIZATION STUDIES Meets ISO 10993-10 Third Edition 2010-08-01	Similar
Labeling for the legally marketed device to which substantial equivalence is claimed.		-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	-Powder Free -Patient Examination Glove -Single Use Only - Manufactured For: - Lot	Similar

10.0 Substantial Equivalence Comparison:

Discussion: The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meeting labeling claims.
The subject device The Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) has the same intended use and technological and performance characteristics as the predicate device Powder-Free Vinyl Patient Examination Glove (Non-colored) Zhang Jia Gang Plastic Product Co., Ltd. K091663, and therefore the devices are substantially equivalent.

Conclusion: Based on the nonclinical tests data, it can be concluded that the Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) is as safe, as effective, and performs as well as the predicate device, Powder-Free Vinyl Patient Examination Glove (Non-colored) Zhang Jia Gang Plastic Product Co., Ltd. K091663.