DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 17, 2015

Daxwell, LLC
c/o Chu Xiaoan
Beijing Easylink CO., LTD
Rm. F302 Bldg., 41, Jing Cheng Ya Ju
Courtyard 6 of Southern Dou Ge Zhang
Chaoyang District
Beijing 100121
CHINA

Re: K151682
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient examination glove
Regulatory Class: Class I
Product Code: LYZ
Dated: October 4, 2015
Received: October 16, 2015

Dear Mr. 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" (21CFR 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 I. 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)*
K151682

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

Indications for Use *(Describe)*
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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section C 510(k) Summary

510(K) Summary

"The assigned 510(k) number is: K151682 "

Premarket Notification [510(k)] Summary

0.0 Application correspondent:

Company name	Beijing Easy-Link Company
Company address	Rm. F302 Bldg., 41, Jing Cheng Ya Ju, Courtyard 6 of Southern Dou Ge Zhuang, Chaoyang District, Beijing 100121, P.R.China
Contact Person	Chu Xiaoan
Contact E-mail address	easylink_bj@aliyun.com

1.0 Submitter:

Submitter's name :	Daxwell, LLC
Submitter's address :	Address: 2825 Wilcrest Dr., Suite# 500 Houston, TX 77042,USA.
Phone number :	(281)669-0622
Fax number :	(281)669-0617
Name of contact person:	Frank Zhang
Date of preparation :	2015-11-17

2.0 Name of the Device

Device Name:	Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Proprietary/Trade name:	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 (80)
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 body fluids and bloodborne Pathogens

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:**
Poly (vinyl chloride) 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 D5250 and ASTM D5151 requirements.

5.0 Device Intended Use (Indication 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.

6.0 Summary of the Technological Characteristics of the Device:

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

Characteristics	Standard			Device performance
Dimension	ASTM D 5250-06(Reapproved 2011).			
	Length	≥230mm		232-240mm
	Width	Small	80-90 mm	81-90mm
		Medium	90-100mm	93-98mm
		Large	100-110mm	102-109mm
		X large	110-120 mm	110-118mm
	Thickness	Fingertip	≥0.05mm	0.08-0.11 mm
		Palm	≥0.08mm	0.09-0.12 mm
Physical Properties	ASTM D 5250-06(Reapproved 2011).			
	Tensile strength (Before & After aging)		≥11MPa	15-20MPa
	Elongated rate (Before & After aging)		≥300%	360-420%
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:

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 non clinical 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 required for this submission.

9.0 Substantial Equivalence Comparison:

Features & Description	Predicate Device	Subject Device	Result of Comparison
Company	Zhang Jia Gang Fengyuan Plastic Product Co.Ltd.	Daxwell, LLC	--
510(K) Number	K091663	K151682	
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.	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.	Substantially equivalent
Device Description and Specifications	Meets ASTM D5250-06 (Reapproved 2011)	Meets ASTM D5250-06 (Reapproved 2011)	Substantially equivalent
Dimensions --Length	Meets ASTM D5250 -06 (Reapproved 2011) ≥230mm min	230mm min for all sizes	Substantially equivalent
Dimensions -- Width	Meets ASTM D5250-06 (Reapproved 2011) Small 80-90 mm Medium 90-100mm Large 100-110mm X large 110-120 mm	 Small 81-90 mm Medium 93-98mm Large 102-109mm X large 110-118 mm	Substantially equivalent
Dimensions --Thickness	Meets ASTM D5250-06 (Reapproved 2011) Finger 0.05mm min. Palm 0.08mm min.	 Thickness (mm) min. Finger 0.08-0.11 Palm 0.09-0.11	Substantially equivalent

Physical Properties	Meets ASTM D 5250-06 (Reapproved 2011) Before aging/after aging Elongation ≥300% Tensile Strength≥ 14MPa	Before aging/after aging Elongation : 360-420% Tensile Strength:15-20 MPa	Substantially equivalent
Freedom from Pinholes	Meets • 21 CFR 800.20 • ASTM D5250-06 (Reapproved 2011) • ASTM D 5151-06 (Reapproved 2011)	Meets ASTM D5151-06 (Reapproved 2011) Holes at Inspection Level I AQL2.5	Substantially equivalent
Residual Powder	Meets ASTM D 6124-06 (Reapproved 2011) below than 2 mg of residual powder per glove	Meets ASTM D 6124-06 (Reapproved 2011) below than 2 mg of residual powder per glove	Substantially equivalent
Materials used to fabricate the devices	PVC	PVC	Substantially equivalent
Dusting or Donning Powder:	PU	PU	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 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)	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. 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	Substantially equivalent
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	Substantially equivalent

10.0 Substantial Equivalence Comparison:

It can be concluded that 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., meet labeling claims.

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 Fengyuan Plastic Product Co., Ltd. K091663.

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.