May 14, 2021

Shandong Shangwei Medical Products Co.,Ltd
% Chu Xiaoan
Official Correspondent
Beijing Easy-Link Company
Rm. F302 Bldg., 41, Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang, Chaoyung District
Beijing, 100121
China

Re: K210780
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: February 8, 2021
Received: March 15, 2021

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. 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
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210780

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)

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: K210780 "

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Shandong Shangwei Medical Products Co.,Ltd
Submitter's address :	North Road, Fumin Avenue,Qinghe Street, Caoxian County,Heze City, Shandong Province, 274400,P.R. China
Phone number:	0086-530-2069711 0086-530-2069778
Name of contact person:	Ms.Li Hua
Date of preparation :	2021-02-08

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:	Vinyl Patient Examination Glove
Classification Name:	Non-powdered 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 Gloves, Clear (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:**
Poly Vinyl Chloride (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 Indications for Use Statement:

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:

Provided below is the Technological Characteristics Comparison Table that provides a comparison between the subject device and the predicate device.

Characteristics	**Standard**		
Dimension	ASTM D 5250-06(Reapproved 2015).		
	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 2015).		
	Tensile strength (Before & After aging)		≥11MPa
	Elongated rate (Before & After aging)		≥300%
Freedom from pinholes	• 21 CFR 800.20 • ASTM D5250-06(Reapproved 2015) • ASTM D5151-19		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D 5250-06 (Reapproved 2015).and D6124-06(Reapproved 2017)		Meets <2mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01		Passes Under the conditions of the study, the subject device is not a primary skin irritant.
	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01		Passes Under the conditions of the study, the subject device is not a skin sensitizer.
	The test article was added to L929 cells measured by MTT assay ISO 10993-5: 2009		Pass Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells.

Features & Description			Predicate Device	Subject Device	Result of Comparison
Dimensions Width	Small	80-90	81-89	82-88	Similar

（mm） IL S-2 AQL4.0	Medium	90-100	93-99	94-98	
	Large	100-110	102-110	103-109	
	X large	110-120	111-1119	114-117	
Dimensions Thickness（mm） IL S-2 AQL4.0	Finger	≥0.05	0.05-0.10	0.09-0.10	Similar
	Palm	≥0.08	0.09-0.13	0.10-0.11	
Physical Properties IL S-2 AQL4.0	Before aging/after aging				Similar
	Elongation ≥300%		380-410%	350-420%	
	Tensile Strength ≥ 14MPa		16-20 MPa	15-22 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	Same
Residual Powder	below 2mg of residual powder		0.3mg	0.1mg	Similar
Materials used to fabricate the devices			PVC	PVC	Same
Compare performance data supporting substantial equivalence			Meets ASTM D5151-06 (Reapproved 2011) ASTM D5250-06 (Reapproved 2011) ASTM D6124-06 (Reaffirmation 2011)	Meets ASTM D5151-19 ASTM D5250-06 (Reapproved 2015) ASTM D6124-06 (Reapproved 2017)	Same
Single Patient Use			Single Patient Use	Single Patient Use	Same
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 Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells.	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	Same

7.0 Summary of Non-Clinical Performance Data:

Non-clinical tests were conducted to verify that the proposed device will meet acceptance criteria for each test. The test results demonstrated that the proposed device met the acceptance criteria found in the following standards below:

ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10:2010	Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
ASTM D5151-19	Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D5250-06 (Reapproved 2015)	Standard specification for poly (vinyl chloride) gloves for medical application.
ASTM D6124-06 (Reapproved 2017)	Standard Test Method for Residual Powder on Medical Gloves

Characteristics	**Standard**		
Dimension	ASTM D 5250-06(Reapproved 2015).		
	Length	≥230mm	
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		Medium	90-100mm
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	Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01		Passes Under the conditions of the study, the subject device is not a skin sensitizer.
	The test article was added to L929 cells measured by MTT assay ISO 10993-5: 2009		Pass Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells.

8.0 Summary of Clinical Performance Data:

Clinical testing is not needed for this device.

9.0 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.