July 9, 2021

Jiangxi Hongda Medical Equipment Group Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm 912, Building #15, XiYueHui, No.5, YiHe North Rd
FangShan District
Beijing, 102401
China

Re: K210821
Trade/Device Name: Medical PVC Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: April 9, 2021
Received: April 13, 2021

Dear Ray Wang:

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,

Jiangsong Jiang -S
(Affiliate)

For Ryan Ortega
Acting Assistant Director
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210821

Device Name
Medical PVC Examination Gloves

Indications for Use *(Describe)*
The Medical PVC Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands 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

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

The assigned 510(k) Number: K210821

1. Date of Preparation: 07/09/2021

2. Sponsor

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4. Proposed Device Identification

Trade Name: Medical PVC Examination Gloves
Common Name: Vinyl Patient Examination Gloves (Powder Free)

Regulatory Information:
Classification: I
Product Code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

Indication For Use Statement:

The Medical PVC Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

5. Predicate Device Identification

510(k) Number: K182043

Product Name: Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored)

Manufacturer: HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD

6. Device Description

The proposed device, Medical PVC Examination Gloves are disposable devices intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

The proposed device is Powder Free Vinyl Patient Examination Gloves. The proposed device is clear, non-colored. The design of proposed device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250.

The proposed device is not provided as sterilized

The proposed device is made of vinyl chloride.

Table 1 Device Size Specifications

Designation	Size					Tolerance
	XS	S	M	L	XL	
Length, mm	230	230	230	230	230	min
Width, mm	80	85	95	105	115	±5
Thickness, mm:						
Finger	0.08					min
Palm	0.08					min
Cuff	0.08					min

Table 2 Performance and Physical Specifications

Before Aging		After Aging		Pinhole AQL
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation	2.5
11 MPa, min	300 % min	11 MPa, min	300 % min	

The above data of size, performance, and physical specifications of proposed gloves meet all the

current specifications listed in the ASTM standard D5250.

7. Substantially Equivalent Comparison Conclusion

Table 1 General Comparison

ITEM	Proposed Device Medical PVC Examination Gloves	Predicate Device (K182043) Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored)	Remark
Product Code	LYZ	LYZ	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Indications For Use	The Medical PVC Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	SAME
Powdered or Powder free	Powder free	Powder free	SAME

Table 2 Device Dimensions Comparison

Proposed Device	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	230	230	230	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.08					min
	Palm	0.08					min
Predicate Device ((K182043)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	240	240	240	240	240	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.07					min
	Palm	0.08					min
Remark	Different (Analysis 1)						

Different Analysis 1:

The proposed device has different size specification to the predicate device, but all proposed devices are meet the specifications of ASTM D 5250.

So, this difference would not raise safety or effectiveness concerns.

Table 3 Performance Comparison

ITEM			Proposed Device Medical PVC Examination Gloves	Predicate Device (K182043) Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored)	Remark
Colorant			Clear, Non-Colored	Clear, Non-Colored	SAME
Physical Properties	Before Aging	Tensile Strength	11 MPa, min	15 MPa, min	Different (Analysis 2)
		Ultimate Elongation	300 % min	350 % min	
	After Aging	Tensile Strength	11 MPa, min	15 MPa, min	
		Ultimate Elongation	300 % min	350 % min	
	Comply with ASTM D5250			Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151	Be free from holes when tested in accordance with ASTM D5151	SAME
Powder Content			Less than 2 mg per glove when tested	Less than 2 mg per glove when	SAME

	in accordance with ASTM D6124	tested in accordance with ASTM D6124	

Different Analysis 2:
The proposed device has different Tensile Strength before aging specification to the predicate device, but all proposed device meets the specification requirements of ASTM D 5250.
So, this difference would not raise safety or effectiveness concerns.

Table 4 Safety Comparison

ITEM		Proposed Device Medical PVC Examination Gloves	Predicate Device (K182043) Single-use medical poly (vinyl chloride) examination glove (Clear, Non-Colored)	Remark
Material		Vinyl chloride	Vinyl chloride	SAME
Biocompatibility	Irritation	Under the conditions of the study (ISO 10993-10), not an irritant	Under the conditions of the study, not an irritant	SAME
	Sensitization	Under conditions of the study (ISO 10993-10), not a sensitizer.	Under conditions of the study, not a sensitizer.	
	Acute Systemic Toxicity	Under the condition of the study (ISO 10993-11), there is no mortality or evidence of systemic toxicity	/	Different (Analysis 3)
	Cytotoxicity	Data not available	Comply with ISO 10993-5	Different (Analysis 3)
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	SAME

Analysis 3
The proposed device has conducted the testing of Acute Systemic Toxicity which is the predicate device did not, the testing results shown that the proposed device has no systemic toxicity.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.
ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-17, Standard Test Method for Residual Powder on Medical Gloves.
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210821, the Medical PVC Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K182043.