July 29, 2021

Hebei Titans Hongsen Medical Technology Co., 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, Beijing 102401
China

Re: K211229
Trade/Device Name: Vinyl compound examination gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: July 13, 2021
Received: July 19, 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,

For Clarence W. Murray, III, Ph.D.
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)*

K211229

Device Name

Vinyl compound examination gloves

Indications for Use *(Describe)*

The Vinyl compound 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: K211229

1. Date of Preparation: 07/28/2021

2. Sponsor

HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD.
Eastern Industrial Zone, NANGONG, HEBEI, 051800, CHINA
Contact Person: Feng Shuangyan
Position: Quality Management Representative
Tel: +86-13733285059
Email: STQAFSY@126.COM

3. Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401
Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: ray.wang@believe-med.com

4. Proposed Device Identification

Trade Name: Vinyl compound 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 Vinyl compound 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, Vinyl compound 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 Blue. 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	75	85	95	105	115	±5
Thickness, mm:						
Finger	0.08					min
Palm	0.08					min

Table 2 Performance and Physical Specifications

Before Aging		After Aging		Pinhole AQL
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation	4.0
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. Comparison of Technological Characteristics

Table 1 General Comparison

ITEM	Proposed Device Vinyl compound examination gloves (K211229)	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
Intended Use	The Vinyl compound 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 Powered free	Powdered free	Powdered free	SAME

Table 2 Device Dimensions Comparison

	Designation	Size					Tolerance
		XS	S	M	L	XL	
Proposed Device (K211229)	Length, mm	230	230	230	230	230	min
	Width, mm	75	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.08					min
	Palm	0.08					min
	Designation	Size					Tolerance
		XS	S	M	L	XL	
Predicate Device ((K182043)	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	Analysis 1						

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 we consider this as the proposed device is as safe, as effective, and performs as well as the predicate

device.

Table 3 Performance Comparison

ITEM			Proposed Device Vinyl compound examination gloves (K211229)	Predicate Device (K182043) Single-use medical poly (vinyl chloride) examination glove (Clear, Non-colored)	Remark
Colorant			Blue	Clear, Non-colored	Analysis 2
Physical Properties	Before Aging	Tensile Strength	11 MPa, min	15 MPa, min	Analysis3
		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 in accordance with ASTM D6124	Less than 2 mg per glove when tested in accordance with ASTM D6124	SAME

Analysis 2:

The proposed device has different color to the predicate device, this different may causes potential biocompatibility risk, for this risk we conducted the biocompatibility test according to the ISO 10993-5 and ISO 10993-10, the test results showed that the proposed devices with blue colorant did not raise biocompatibility risk.

So we consider this as the proposed device is as safe, as effective, and performs as well as the predicate device.

Analysis 3:

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 we consider this as the proposed device is as safe, as effective, and performs as well as the predicate device.

Table 4 Safety Comparison

ITEM	Proposed Device Vinyl compound examination gloves (K211229)	Predicate Device (K182043) Single-use medical poly (vinyl chloride) examination glove (Clear, Non-colored)	Remark

Material		Vinyl chloride	Vinyl chloride	SAME
Biocompatibility	Cytotoxicity	Under conditions of the study, not a cytotoxicity.	Under conditions of the study, not a cytotoxicity.	SAME
	Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	SAME
	Sensitization	Under conditions of the study, not a sensitizer.	Under conditions of the study, not a sensitizer.	

8. Summary of Non-Clinical Tests

Bench tests were conducted to demonstrate 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 10993-5:2009, 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.

Table 5 Performance Test Results Summary

Test Method	Purpose	Acceptance Criteria	Results
ASTM D5151	Testing for Freedom from holes	Freedom from holes	No water leakage is inspected form 200 samples
ASTM D6124	Determine the powder residue for powder free gloves	<2.0 mg per glove	Residual Powder of Size XS: Average 0.28 mg; Residual Powder of Size S: Average 0.25 mg; Residual Powder of Size M: Average 0.31 mg; Residual Powder of Size L: Average 0.25 mg; Residual Powder of Size XL: Average 0.35mg;
ASTM D412 ASTM D573	Testing for Physical property characteristics	Tensile Strength: 11 MPa min. Ultimate Elongation: 300% min.	Tensile Strength: ≥ 12 MPa; Ultimate Elongation: ≥ 321%.
ASTM D3767	Testing For physical dimensions specification	Length: 230 mm min. for all size (XS, S, M, L, XL); Width: 75±5 mm for XS; 85±5 mm for S; 95±5 mm for M; 105±5 mm for L; 115±5 mm for XL. Finger Thickness: ≥0.08 mm; Palm Thickness: ≥0.08 mm; All acceptance criteria above meet the	Length of Size XS: ≥ 237 mm; Width of Size XS: 75±1 (74-76) mm; Palm Thickness of Size XS: ≥0.08 mm; Finger Thickness of Size XS: ≥0.09 mm. Length of Size S: ≥ 235 mm; Width of Size S: 85±1 (85-86) mm;

		requirements in Table 2 Dimensions and Tolerances of ASTM D5250	Palm Thickness of Size S: ≥0.08 mm; Finger Thickness of Size S: ≥0.09 mm. Length of Size M: ≥ 235 mm; Width of Size M: 95±2 (95-97) mm; Palm Thickness of Size M: ≥0.08 mm; Finger Thickness of Size M: ≥0.09 mm. Length of Size L: ≥ 235 mm; Width of Size L: 105±2 (105-107) mm; Palm Thickness of Size L: ≥0.08 mm; Finger Thickness of Size L: ≥0.09 mm. Length of Size XL: ≥ 234 mm; Width of Size XL: 115±3 (115-118) mm; Palm Thickness of Size XL: ≥0.08 mm; Finger Thickness of Size XL: ≥0.09 mm.
ISO 10993-5	Evaluate the endpoint of Cytotoxicity for biocompatibility	The test article showed "negative" cytotoxicity	Under the conditions of the study, the test article showed "negative" cytotoxicity.
ISO 10993-10	Evaluate the endpoint of irritant for biocompatibility	The response of the test article extract is negligible.	The test result showed that the response of the test article extract was categorized as negligible under the test condition.
	Evaluate the endpoint of sensitization for biocompatibility	The test article showed no evidence of causing delayed dermal contact sensitization.	The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

9. Summary of Clinical Test

No clinical study is included in this submission.

10. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Proposed Device Vinyl compound examination gloves cleared under K182043.