



September 21, 2018

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, 102401 Cn

Re: K182043

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

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: Class I

Product Code: LYZ

Dated: July 23, 2018

Received: July 30, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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 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

Indications for Use

510(k) Number (if known)

K182043

Device Name

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

Indications for Use (Describe)

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.

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 is being submitted in accordance with Title 21, CFR Section 807.92.

The assigned 510(k) Number: K182043

1. Date of Preparation: 2018/08/18
2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

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

Common Name: Vinyl Patient Examination Gloves (Powder Free)

Model(s): XS S M L XL

Regulatory Information

Classification Name: Vinyl Patient Examination Gloves (Powder Free)

Classification:1

Product Code: LYZ

Regulation Number: 21 CFR 880.6250

Review Panel: General Hospital

Indication for use Statement:

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.

5. Device Description

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 non-sterile.

6. Identification of Predicate Device(s)

Predicate Device

K163168

Vinyl Patient Examination Gloves (White, Blue, Yellow)

Hebei Hongtai Plastic Products Company Limited

K180849

Vinyl Examination Glove (Clear, Non-Colored)

HUIFU TRADING CO., LTD.

7. Technological Comparison

Table 1 General Comparison

ITEM	Proposed Device (K182043)	Predicate Device (K163168)	Predicate Device (K180849)	Remark
Product Code	LYZ	LYZ	LYZ	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	I	SAME
Intended Use	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.	The Vinyl Examination Glove (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Vinyl Patient 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 Powdered free	Powdered free	Powdered free	Powdered free	SAME
Design Feature	ambidextrous	ambidextrous	ambidextrous	SAME
Surface Feature	Smooth	Smooth	Smooth	SAME
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	SAME

Table 2 Device Dimensions Comparison

Proposed 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	
Predicate Device (K163168)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	235	245	245	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
Palm	0.08					min	
Predicate Device (K180849)	Designation	Size				Tolerance	
		S	M	L	XL		
	Length, mm	230	235	245	245	min	
	Width, mm	85	95	105	115	±5	
	Thickness, mm:						
	Finger	0.05					min
Palm	0.08					min	
Remark	Analysis 1						

Table 3 Performance Comparison

ITEM			Proposed Device (K182043)	Predicate Device (K163168)	Predicate Device (K180849)	Remark
Colorant			Clear, Non-Colored	White, Blue, Yellow	Clear, Non-Colored	Analysis 2
Physical Properties	Before Aging	Tensile Strength	15 MPa, min	15 MPa, min	15 MPa, min	Analysis 3
		Ultimate Elongation	350 % min	380 % min	380 % min	
	After Aging	Tensile Strength	15 MPa, min	15 MPa, min	15 MPa, min	
		Ultimate Elongation	350 % min	380 % min	380 % min	
	Comply with ASTM D5250			Comply with ASTM D5250	Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL=1.5	Be free from holes when tested in accordance with ASTM D5151 AQL=1.5	Be free from holes when tested in accordance with ASTM D5151 AQL=1.5	SAME
Powder Content			0.33 mg	Meet the requirements of ASTM 5250	Meet the requirements of ASTM 5250	SAME

Table 4 Safety Comparison

ITEM		Proposed Device (K182043)	Predicate Device (K163168)	Predicate Device (K180849)	Remark
Material		Vinyl	Vinyl	Vinyl	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	Comply with ISO 10993-10	SAME
	Sensitization	Under conditions of the study, not a sensitizer.		Comply with ISO 10993-5	
	Cytotoxicity	Under conditions of the study, did not show potential toxicity to L-929 cells.	/	Comply with ISO 10993-5	
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	Meet FDA's Requirements	SAME

Analysis 1:

The proposed device has different Length to the predicate device, but all proposed devices are conducted the test according ASTM 5250, the test results shown that the Length of proposed device meet the

requirements of standard.

Analysis 2:

The proposed device has different color to the predicate device, but all proposed devices are conducted the test according ISO 10993-5 and ISO 10993-10 for Irritation, Sensitization and Cytotoxicity, and other non-clinical bench test.

The test results shown that the performance of proposed device meet the requirements of standard and no potential biocompatibility issues.

So, the different color would not effects the safety and effectiveness of proposed device.

Analysis 3:

The proposed device has different Ultimate Elongation to the predicate device, but all proposed devices are conducted the test according ASTM 5250, the test results shown that the Ultimate Elongation of proposed device meet the requirements of standard.

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ASTM D6124-06 (Reaffirmation 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 (Reapproved 2015), 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.
- ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.

9. Clinical Test Conclusion

Clinical testing is not needed for this device.

10. 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 predicate device.