May 10, 2021

Anhui Bytech Medical Supplies Co., Ltd.
℅ Ivy Wang
Technical Manager
Shanghai SUNGO Management Consultanting Co., Ltd.
13th F, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K201504
Trade/Device Name: Single-use medical poly (vinyl chloride) examination glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: June 5, 2020
Received: June 5, 2020

Dear Ivy 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 and Part 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.
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)*
K201504

Device Name
Single-use medical poly (vinyl chloride) examination glove

Indications for Use *(Describe)*
The Single-use medical poly (vinyl chloride) examination glove 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.

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K201504

510(K) Summary

K201504
Date of preparation: 05 -10-2021

A. Applicant

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B. Device

Trade Name: Single-use medical poly (vinyl chloride) examination glove
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: Class I.
Product code: LYZ
Regulation Number: 21 CFR 880.6250
Review Panel: General Hospital

C. Predicate device

Sponsor	HUIFU TRADING CO., LTD.
Device Name	Vinyl Examination Glove (Clear, Non-Colored)

510(k) Number	K180849
Product Code	LYZ
Regulation Number	880.6250
Regulation Class	I

D. Indications for use of the device:

The Single-use medical poly (vinyl chloride) examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

E. Device Description:

The proposed device is Powder Free Vinyl Patient Examination Gloves which is made of poly vinyl chloride. 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.

F. Comparison with predicate device

Table 1 General Comparison

ITEM	Proposed Device (K201504)	Predicate Device (K180849)	Remark
Product Code	LYZ	LYZ	SAME
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	SAME
Class	I	I	SAME
Intended Use	The Single-use medical poly (vinyl chloride) examination glove 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 Powered free	Powdered free	Powdered free	SAME
Design Feature	ambidextrous	ambidextrous	SAME
Surface Feature	Smooth	Smooth	SAME
Device Materials	Vinyl	Vinyl	SAME
Color	Clear	Clear	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	SAME

Table 2 Device Dimensions Comparison

ITEM	Proposed Device (K201504)					Predicate Device (K180849)				Remark
Size	XS	S	M	L	XL	S	M	L	XL	similar
Length, mm	Minimum 230					Minimum 230	Minimum 235	Minimum 245	Minimum 245	similar
Width, mm	78±3	85±3	95±3	105±3	115±3	85±5	95±5	105±5	115±5	similar
Thickness, mm	Finger: minimum 0.05					Finger: minimum 0.08				Different
	Palm: minimum 0.08					Palm: minimum 0.08				Same

Discussion: The proposed device has slight difference on the dimensions of Length, width and finger thickness to the predicate device. However, the testing results meet the specification as stated in ASTM D5250. This difference will not affect the safety and effectiveness of the proposed device.

Table 3 Performance Comparison

ITEM			Proposed Device (K201504)	Predicate Device (K180849)	Remark
Colorant			Clear, Non-Colored	Clear, Non-Colored	Same
Physical Properties	Before Aging	Tensile Strength	11 MPa, min	15 MPa, min	Similar
		Ultimate Elongation	300 % min	380 % min	
	After Aging	Tensile Strength	11 MPa, min	15 MPa, min	
		Ultimate Elongation	300 % min	380 % min	
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	Same

Powder Content	Meets Applicable Definition for Powder Free: ≤ 2 mg per glove	0.5 mg	Similar

Discussion: The proposed device has slight difference on the performance of physical properties and powder content to the predicate device. However, the testing results meet the specification as stated in ASTM D5250 and ASTM D6124. This difference will not affect the effectiveness of the proposed device. The proposed device use the same AQL=1.5 as the predicate device, which is the requirement for European market and also meet the specification as stated in ASTM D5151. This will not affect the safety and effectiveness of the proposed device.

Table 4 Safety Comparison

ITEM		Predicate Device (K180849)	Proposed Device (K201504)	Remark
Biocompatibility	Irritation	Comply with ISO 10993-10	Under the conditions of the study not an irritant	Similar
	Sensitization		Under conditions of the study, not a sensitizer.	
	Cytotoxicity	Comply with ISO 10993-5	Under conditions of the study, did not show potential toxicity to L-929 cells.	
Label and Labeling		Meet FDA's Requirements	Meet FDA's Requirements	Same

G. Summary of non-clinical performance testing

Test item		Test method	Pass criteria	Test results/ Verdict
Dimension (mm)	Overall Length	ASTM D5250	Min 230	＞230/ Pass
	Width		XS: 76±6 S: 85±5 M: 95±5 L: 105±5 XL: 115±5	XS: 79-81/ Pass S: 85-87 /Pass M: 95-97/ Pass L: 105-107/ Pass XL: 115-117/ Pass
	Finger thickness		0.05	0.09-0.12/ Pass
	Palm thickness		0.08	0.08-0.09/ Pass
Freedom from Holes		ASTM D5151	Meet the requirements of ASTM D5151 AQL 1.5	0/125, 1/ 125, 4/315, 5/500, 3/200 leaks / Pass
Powder Content		ASTM D6124	Meet the requirements of ASTM D6124 < 2.0mg	0.3 – 0.42/ Pass
Physical properties	Tensile Strength (MPa)	ASTM D412	Meet the requirements of ASTM D412 Min 11	14-19/ Pass
	Ultimate Elongation (%)		Meet the requirements of ASTM D412 Min 300%	390 – 430/ Pass
Biocompatibility	Irritation	ISO 10993-10	Non-irritating	Under the conditions of

				the study, not an irritant/ Pass
	Sensitization	ISO 10993-10	Non-sensitizing	Under conditions of the study, not a sensitizer./ Pass
	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells./ Pass

Biocompatibility testing:

- **Skin sensitization & Irritation** -- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- **Cytotoxicity** -- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

Performance testing:

- **Residue Powder** -- ASTM D6124-06 (Reaffirmation 2017), Standard Test Method for Residual Powder on Medical Gloves
- **Freedom from holes** -- ASTM D5151-06 (Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.
- **Physical properties & Dimensions** -- 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.

H. Summary of Clinical Performance Test

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201504, the Single-use medical poly (vinyl chloride) examination glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K180849.