January 5, 2022

Hebei Astro Medical Supply Co., Ltd
Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K213019
Trade/Device Name: Vinyl Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: November 26, 2021
Received: December 8, 2021

Dear Diana Hong:

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)*
K213019

Device Name
Vinyl Exam Gloves

Indications for Use *(Describe)*
Vinyl Exam Gloves 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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K213019

1. Date of Preparation: 01/03/2022

2. Sponsor Identification

Hebei Astro Medical Supply Co., Ltd
East of Xiaoxixian, West of Jingsan Street, South of Weiwu Road, North of Weiqi Road, Jinzhou Economic Development Zone, Hebei Province, P.R.China, 052260

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

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Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Vinyl Exam Gloves
Common Name: Examination Vinyl Gloves

Regulatory Information

Classification Name: Vinyl Patient Examination Glove
Classification: I;
Product Code: LYZ;
Regulation Number: 21CFR 880.6250
Review Panel: General Hospital;

Indication for Use:
Vinyl Exam Gloves 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.

Device Description
The proposed device is a powder free medical glove. The device is available in transparent. The device meets the requirements of *ASTM D5250-19: Standard specification for Poly (vinyl chloride) Gloves for Medical Application*. The proposed gloves are available in five sizes, which are XS, S, M, L, XL, it could be selected by the user depended on size of hand. The different between each size is just in the dimension. The proposed device is provided in non-sterile.

5. Identification of Predicate Device

510(k) Number: K210799
Product Name: Powder Free Vinyl Patient Examination Glove

6. Non-Clinical Test Conclusion

Non clinical 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 D3767-03 (2020) Standard Practice for Rubber-Measurement of Dimensions
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension

- ASTM D6124-06 (Reapproved 2017) 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 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity;

7. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device K213019		Predicate Device K210799		Remark
Product Code	LYZ		LYZ		Same
Regulation Number	21 CFR 880.6250		21 CFR 880.6250		Same
Class	I		I		Same
Indication for use	Vinyl Exam Gloves 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.		The Powder Free Patient Examination Glove 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.		Same
Material	Vinyl		Vinyl		Same
Color	Clear		Clear		Same
Sterility	Non-sterile		Non-sterile		Same
Single-use	Yes		Yes		Same
Size	XS, S, M, L, XL		XS, S, M, L, XL		Same
Dimensions (ASTM D5250-19)	Width				Same
	XS	75±5mm	XS	75±5mm	
	S	85±5mm	S	85±5mm	
	M	95±5mm	M	95±5mm	
	L	105±5mm	L	105±5mm	
	XL	115±5mm	XL	115±5mm	
	Length				
	XS	230mm min	XS	230mm min	
	S	230mm min	S	230mm min	
	M	230mm min	M	230mm min	
	L	230mm min	L	230mm min	
	XL	230mm min	XL	230mm min	
	Thickness				

	Palm	0.08mm min	Palm	0.08mm min	
	Finger	0.08mm min	Finger	0.08mm min	
Physical Properties (ASTM D5250-19 and ASTM D412-16)	Before Aging				Same
	Tensile Strength	11MPa min	Tensile Strength	11MPa min	
	Ultimate Elongation	300% min	Ultimate Elongation	300% min	
	After Aging				
	Tensile Strength	11MPa min	Tensile Strength	11MPa min	
	Ultimate Elongation	300% min	Ultimate Elongation	300% min	
Power free residue (ASTM D6124-06)	Less than 2mg per glove		Less than 2mg per glove		Same
Freedom from Holes (ASTM D5151-19)	No water leakage occurs.		No water leakage occurs.		Same
Biocompatibility					
Skin Irritation	Under the conditions of the study, not an Irritant		Under the conditions of the study, not an Irritant		Same
Sensitization	Under the conditions of the study, not a Sensitization		Under the conditions of the study, not a Sensitization		
Cytotoxicity	Under the conditions of the study, the device is non-cytotoxic.		Under the conditions of the study, the device is non-cytotoxic.		

8. Summary of Non-Clinical Performance Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Table 2. Summary of Non-Clinical Performance Testing

No.	Name of the Test Methodology / Standard	Purpose	Acceptance Criteria	Test Results
1	ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation And Skin Sensitization	Evaluated for the potential to cause delayed dermal contact sensitization and skin irritation	Magnusson and Kligman grade shall be less than control group No significant reaction than the control group	No skin sensitization No skin irritation
2	ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity	Evaluated for the potential cytotoxicity	The viability shall be not reduced to less than 70%	No cytotoxic
3	ASTM D6124-06 (Reapproved	Evaluate the	Less than 2.0mg	Less than 2.0mg

	2017), Standard Test Method for Residual Powder on Medical Gloves	residue powder		
4	ASTM D5151-06(Reapproved 2015), Standard Test Method for Detection of Holes in Medical Gloves.	Detection the holes that allow water leakage	Do not show droplet, stream or other type of water leakage	No leakage
5	ASTM D6319-10 (Reapproved 2015), Standard Specification for Nitrile Examination Gloves for Medical Application.	Evaluate the glove physical dimension	Length: > 230 mm Width (±5mm) XS = 75mm S = 85mm M = 95mm L = 105mm XL = 115mm Thickness at Finger (mm) All Sizes ≥ 0.08 mm Thickness at Palm All Sizes ≥ 0.08 mm	Length Larger than 230mm Width XS: within 75±5mm S: within 85±5mm M: within 95±5mm L: within 105±5mm XL: within 115±5mm Thickness Larger than 0.08mm
6	ASTM 412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension	Evaluate the physical requirement	Tensile strength: 11Mpa Ultimate elongation: 300%	Larger than 11Mpa and 300%

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device K210799.