August 25, 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: K221143
Trade/Device Name: Nitrile Exam Gloves (Blue, Black)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: July 25, 2022
Received: July 25, 2022

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); 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,

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)*

K221143

Device Name

Nitrile Exam Gloves (Blue, Black)

Indications for Use *(Describe)*

Nitrile Exam Gloves (Blue, Black) is a disposable device intended for medical purpose 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.

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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: K221143

1. Date of Preparation: 8/23/2022

2. Sponsor Identification

Hebei Astro Medical Supply Co., Ltd.

Address: 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

Establishment Registration Number: 3015537296

Contact Person: Ning Zheng

Position: General Manager

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)

Ms. Jinlei Tang (Alternative Contact Person)

Mid-Link Consulting Co., Ltd

P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-2281-5850,

Fax: 360-925-3199

Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Nitrile Exam Gloves (Blue, Black)

Common Name: POWDER FREE NITRILE EXAMINATION GLOVES

Regulatory Information

Classification Name: polymer patient examination glove

Classification: I;

Product Code: LZA;
Regulation Number: 21CFR 880.6250
Review Panel: General Hospital;

Indication for Use:
Nitrile Exam Gloves (Blue, Black) is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.

Device Description
The proposed device is a power free medical glove. The device is provided in blue and black. The device meets the requirements of *ASTM D6319-19: Standard specification for Nitrile Examination Gloves for Medical Application*. The proposed gloves are available in six sizes, which are XS, S, M, L, XL, XXL, 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: K211457
Product Name: Powder Free Nitrile Examination Gloves, (Blue, Black, Indigo)

6. Summary of Technological characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K211457	Comparison
Product Code	LZA	LZA	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indication for use	Nitrile Exam Gloves (Blue, Black) is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Powder Free Nitrile Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Material	Nitrile	Nitrile	Same
Color	Blue, Black	Blue, Black, Indigo	Different
Sterility	Non-sterile	Non-sterile	Same
Single-use	Yes	Yes	Same
Surface Treatment /Powder or Powder Free	Powder Free	Powder Free	Same

	Size	XS, S, M, L, XL, XXL		XS, S, M, L, XL	Different
Dimensions (ASTM D6319-19)		Width			
		XS	75±5mm	XS	70±10mm
		S	85±5mm	S	80±10mm
		M	95±5mm	M	95±10mm
		L	105±5mm	L	110±10mm
		XL	115±5mm	XL	120±10mm
		XXL	125±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
		XXL	230mm min	/	/
		Thickness			
		Palm	0.05mm min	Palm	0.08-0.10 mm
		Finger	0.05mm min	Finger	0.10-0.12 mm
Physical Properties (ASTM D6319-19 and ASTM D412-16)		Before Aging			Same
		Tensile Strength	14MPa min	Tensile Strength	14MPa min
		Ultimate Elongation	500% min	Ultimate Elongation	500% min
		After Aging			
		Tensile Strength	14MPa min	Tensile Strength	14MPa min
		Ultimate Elongation	400% min	Ultimate Elongation	400% min
Power free residue (ASTM D6319-19 and ASTM D6124-17)		Less than 2mg per glove		Less than 2mg per glove	Same
Freedom from Holes (ASTM D5151-19)		Meet AQL 2.5 with G1		Meet AQL 1.5 with G1	Different
Biocompatibility					
Sensitization		Under the conditions of study, not a sensitizer		Under the conditions of study, not a sensitizer	Different
Intracutaneous Reactivity		Under the conditions of study, not an irritant		Under the conditions of study, not an irritant	
System Toxicity		Under the conditions of study, non-system toxicity		Not tested	
In Vitro Cytotoxicity		Not tested		Under the conditions of study, noncytotoxic	

Different - Color

The proposed device is provided in two colors, blue and black, and the predicate device is provided

in three colors, blue, black and indigo. The color of the proposed device can be covered by the predicate device.

Different - Size & Dimensions
The size and dimension of the proposed device is not exactly same as the predicate device. The user can select appropriate model depended on size of user's hand.

Different - Freedom from Holes
The freedom from holes of the proposed device is different from predicate device. The proposed device meets AQL 2.5 with G1, while the predicate device meets AQL 1.5 with G1.

Different - Biocompatibility
The biocompatibility test item of the proposed device is different from the predicate device. The proposed device was conducted for systemic toxicity and not for cytotoxicity. While the predicate device was conducted for cytotoxicity and not for systemic toxicity.

7. Summary of Non-Clinical Test

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate device. The test results demonstrated that the Nitrile Exam Gloves (Blue, Black) complies with the following standards:

- ASTM D6319-19 Standard Specification for Nitrile Examination 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 10993-11:2017 Biological evaluation of medical devices-Part 11: Tests for systemic

toxicity;

Table 2 Summary of Performance Testing

<table>
<tr><th>Name of the Test Methodology/ Standard</th><th>Purpose</th><th>Acceptance Criteria</th><th>Results</th></tr>
<tr><td>ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves</td><td>The test was performed in accordance with ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves to evaluate the detection of holes in medical gloves.</td><td>Gloves are free from water droplets, stream, or other types of water leakage.</td><td>Requirement met</td></tr>
<tr><td>ASTM D3767-03 (2020) Standard Practice for Rubber – Measurement of Dimensions</td><td>The test was performed in accordance with ASTM D3767-03 (2020) Standard Practice for Rubber – Measurement of Dimensions to evaluate the geometrical dimension of rubber products and specimens for physical tests.</td><td>The measurement results shall conform to the minimum values specified in the table below.
<table><tr><td colspan="2">Width</td></tr><tr><td>XS</td><td>75±5mm</td></tr><tr><td>S</td><td>85±5mm</td></tr><tr><td>M</td><td>95±5mm</td></tr><tr><td>L</td><td>105±5mm</td></tr><tr><td>XL</td><td>115±5mm</td></tr><tr><td>XXL</td><td>125±5mm</td></tr><tr><td>Length</td><td>230mm min</td></tr><tr><td colspan="2">Thickness</td></tr><tr><td>Palm</td><td>0.05mm min</td></tr><tr><td>Finger</td><td>0.05mm min</td></tr><tr><td></td><td></td></tr></table></td><td>Requirement met</td></tr>
<tr><td>ASTM D412–16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension</td><td>The test was performed in accordance with ASTM D412–16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension to evaluate the</td><td>The measurement results shall conform to the minimum values specified in the table below
Before Aging:
<table><tr><td>Tensile Strength</td><td>14MPa min</td></tr><tr><td>Ultimate Elongation</td><td>500% min</td></tr></table>
After Aging:</td><td>Requirement met</td></tr>
</table>

	tensile (tension) properties of vulcanized thermoset rubbers and thermoplastic elastomers.	Tensile Strength: 14MPa min Ultimate Elongation: 400% min	
ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves	The test was performed in accordance with ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves to evaluate the amount of residual powder (or filter- retained mass) found on medical gloves.	Less than 2mg per glove	Requirement met

Table 3 Summary of Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
System Toxicity	The test was performed in accordance with ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity to evaluate the systemic toxicity of the test sample.	Non-system toxicity	Under the conditions of the study, the proposed device was non-system toxicity.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.

	sensitization of the test sample.		
Intracutaneous Reactivity	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the test sample.	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K211457.