April 21, 2021

Changzhou Universal Medical Equipment CO. LTD.
% Roxanne Dubois
Regulatory Consultant
R. Dubois Consulting, LLC
1399 Robnick Ct.
Campbell, California 95008

Re: K210145
Trade/Device Name: Nitrile Glove Powder Free Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 31, 2021
Received: April 5, 2021

Dear Roxanne Dubois:

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,

Clarence W. Murray, III
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210145

Device Name

Nitrile Glove Powder Free Blue

Indications for Use *(Describe)*

The Nitrile Glove Powder Free Blue 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 – K210145

1.0 Submitter's Information:

Name:	Changzhou Universal Medical Equipment Co. Ltd.
Address:	No 6, Xinxi Road, Xinbei District Changzhou, Jiangsu Province, 213000 China
Tel:	+86-519-85483888
Date of Preparation:	January 12, 2021

Contact Person:	Roxanne Dubois
Address:	R. Dubois Consulting, LLC 1399 Robnick Ct., Campbell, CA 95008
Tel:	408-828-5019
Email:	rduboisconsulting@gmail.com

2.0 Device Information

Trade name:	Nitrile Glove Powder Free Blue
Common name:	Patient Examination Gloves
Regulation name:	Non-powdered patient examination glove

3.0 Classification

Production code:	LZA
Regulation number:	21 CFR 880.6250
Classification:	Class I
Panel:	General Hospital

4.0 Predicate Device Information

Manufacturer:	Haining Medical Products Co. Ltd
Device:	Nitrile Glove Powder Free White
510(k) number:	K183068

5.0 Indications for Use

The Nitrile Glove Powder Free Blue is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

6.0 Device Description

The proposed device is powder free, non-sterile nitrile examination gloves.

Following FDA Code LZA, a "nitrile (or polymer) patient examination glove is a disposable device made of nitrile rubber or synthetic polymers that may or may not bear a trace amount of residual powder, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants."

7.0 Technological Characteristic Comparison Table

Table 1 General Comparison

Topic	Proposed Device	Predicate Device (K183068)	Comparison
Product Code	LZA	LZA	Same
Regulation No	21 CFR 880.6250 Non-powdered patient examination glove	21 CFR 880.6250 Non-powdered patient examination glove	Same
Identification	A non-powdered 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.	A non-powdered 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
Class	Class I reserved medical devices that require a 510(k) premarket notification	Class I reserved medical devices that require a 510(k) premarket notification.	Same
Indications For Use	The Nitrile Glove Powder Free Blue is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Nitrile Glove Powder Free Blue 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 Powder Free	Non-powdered	Non-powdered	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder-Free, Non Sterile	Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder-Free, Non Sterile	Same
Dimensions	Length: 230 mm Width: 85-115 mm Thickness: 0.05 mm	Length: 230 mm Width: 85-115 mm Thickness: 0.05 mm	Same
Colorant	Blue	White	Different

8.0 Discussion of Non-clinical and Performance Testing

Non-clinical tests were conducted to verify that the proposed device meets all design specifications, the FDA-recognized consensus standard, proposed labeling claims and pinhole acceptable quality level (AQL). The relevant standards and test results are provided below.

Table 2 Relevant Standards and Test Results

Test Methodology	Purpose	Acceptance Criteria	Results
ISO 10993-5 Biological evaluation of medical devices Test for *in vitro* cytotoxicity	To determine the potential cytotoxicity.	Non-cytotoxic	PASS
ISO 10993-11 Biological evaluation of medical devices Part 11: Tests for Systemic Toxicity	To determine the potential systemic toxicity.	Does not cause systemic toxicity	PASS
ISO 10993-10 Biological evaluation on medical device Part 10: Test for Irritation and Skin Irritation	To determine the potential for irritation and skin irritation.	Non-irritant, and Non skin irritant	PASS
ISO 10993-10 Biological evaluation on medical device Part 10: Test Skin Sensitization	To determine the potential skin sensitization.	Does not cause skin sensitization	PASS
ASTM D6319, Standard Specification for Nitrile Examination Gloves for Medical Application	To test for: (1) freedom from holes (2) physical dimensions (3) Aging	(1) Shall not leak (2) For size M (mm): Width: 110 +/- 10 Length: $\geq$ 230 Finger and palm thickness: median value $\geq$0.05 (3) After Aging: Tensile Strength: $\geq$14 MPa Ultimate elongation: $\geq$400%	PASS
EN 455-1, EN 455-2, Medical Gloves For Single Use	To test for: (1) freedom from holes (2) dimensions and strength	(1) Shall not leak (2) For size M (mm): Width: 110 Length: $\geq$ 240 Strength: Force at Break: $\geq$6N Force at break after challenge testing $\geq$6N at 7 days	PASS

9.0 Discussion of Clinical Testing

Clinical testing was not required to support this device.

10.0 Conclusion

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