September 23, 2021

Changzhou Universal Medical Equipment Co. Ltd
Johnson Liu
Consultant
CNMED Consultant
31 Archer St
Upper MT Gravatt, QLD 4122
Australia

Re: K211667
Trade/Device Name: Disposable Medical Synthetic Nitrile Examination Gloves (Non-Sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 16, 2021
Received: August 24, 2021

Dear Johnson Liu:

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)*

K211667

Device Name

Disposable Medical Synthetic Nitrile Examination Gloves (Non-Sterile)

Indications for Use *(Describe)*

Disposable Medical Synthetic Nitrile Examination Gloves are disposable device intended for medical purpose that is worn on the examiner's hand 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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510(K) Summary
K211667

DISPOSABLE MEDICAL SYNTHETIC NITRILE EXAMINATION GLOVES, NON-STERILE

Preparation Date: Aug 16th, 2021

1. SUBMITTER
Company Name: **Changzhou Universal Medical Equipment Co.,Ltd**
Company Address: **No.6,Xinxi Road, Xinbei District Changzhou , CN 213000**
Contact Person: Johnson Liu
Telephone Number: +614-0158-9995
Email: Johnson@cnmed.com.au

2. NAME OF THE DEVICE
Trade Name / Proprietary Name: Disposable Synthetic Nitrile Examination Gloves (Non Sterile)
Device Name: Disposable Medical Synthetic Nitrile Examination Gloves (Non-Sterile)
Device Classification Name: Patient Examination Gloves
Device Class: Class I
Device Classification Number: 21 CFR 880.6250
Product Code: LZA

3. IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE
Primary Predicate Device: K102593
Applicant: Zibo Yingbo Medical Products Co., Ltd
Device Name: Synthetic Nitrile Patient Examination Gloves – Powder free, Blue Colour Device
Classification Name: Patient Examination Gloves Device
Classification Number: 21 CFR 880.6250
Device Class: Class I
Product Code: LZA
Review Panel: General Hospital

4. DEVICE DESCRIPTION
The subject device in this 510(k) Notification is Disposable Medical Synthetic Nitrile Examination Gloves, Non-sterile. The subject device is a patient examination glove made from nitrile and vinyl compound, blue color, powder free and non-sterile (Per 21 CFR 880.6250, Class I). The device meets the specifications in ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

5. INDICATIONS FOR USE OF THE DEVICE

Disposable Medical Synthetic Nitrile Examination Gloves, Non-sterile is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

6. TECHNOLOGICAL CHARACTERISTIC COMPARISON FOR THE PROPOSED AND PREDICATE DEVICES

CHARACTERISTICS	**DEVICE PERFORMANCE**		
	SUBJECT	PRIMARY PREDICATE	Result
510(k) Number	K211667	K102593	-
Device Name	Disposable Medical Synthetic Nitrile Examination Gloves Powder Free, Non sterile	Synthetic Nitrile Patient Examination Gloves – Powder free, Blue Color	-
Product Code	LZA	LZA	Same
Indications for Use	Disposable Nitrile Examination Gloves Non-sterile (Non sterile) is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner. The device is for over the-counter use.	A patient examination glove is a disposable device intended for medical purposes that is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personal and the patient's body, fluids, waste or environment	Same
Materials of Use	Nitrile and Vinyl compound	Synthetic Nitrile	Similar
Color	Blue	Blue	Same
Size (ASTM D6319-19)	Small, Medium, Large,	Small, Medium, Large, Extra Large	Same
Sterilization	Non-sterile	Non-sterile	Same
Usage	Single usage	Single usage	Same
Dimensions	Width: 80mm ±10mm (for small size) 95mm ±10mm (for medium size) 110 mm ±10mm (for large size) Length: 220mm (Minimum) (for small size) 230 mm (Minimum)(for medium, large size)	Comply with ASTM D6319-05	Same
Physical Properties	**Before Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 400% (ASTM D6319-19)	**Before Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength Min 14 Mpa Ultimate Elongation Min 400% (ASTM D6319-05)	Same

Thickness	Palm min 0.05 mm Finger min 0.05 mm (ASTM D6319-19)	Palm min 0.05 mm Finger min 0.05 mm (ASTM D6319-05)	Same
Powder Free	≤2 mg/glove (ASTM D6319-19)	≤2 mg/glove (ASTM D6319-05)	Same
Freedom from Holes (Water Tight -1000 ml) AQL2.5	Passed ASTM D6319-19 (Cross Reference D5151	Passed ASTM D6319-05 (Cross Reference D5151)	Same
Biocompatibility -SKIN SENSITIZATION - ISO 10993-10: 2010 (E)	Under the conditions of the study not a sensitizer	Under the conditions of the study not a sensitizer	Same
Biocompatibility -SKIN IRRITATION - ISO10993-10: 2010 (E)	Under the conditions of study not an irritant	Under the conditions of study not an irritant	Same
Biocompatibility - *IN VITRO* CYTOTOXICITY – ISO 10993-5: 2009(E)	Under the conditions of the cytotoxicity study, testing results showed mild systemic toxicity and cytotoxic level was 2.	No Testing Result available	Different
Manufacturer(s)	Changzhou Universal Medical Equipment Co.,Ltd	Zibo Yingbo Medical Products Co., Ltd	--

To sum up, the subject device and predicate devices are equivalent in terms of intended use, design, safety and performance.

7. NON-CLINICAL TESTING SUMMARY

PERFORMANCE DATA

Test Method	**Purpose**	**Acceptance Criteria**	**Result**
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Dimensions Test	To determine the width, length, and thickness of the gloves	**Width:** 80 mm (±10mm) (for small size) 95 mm (±10mm) (for medium size) 110 mm (±10mm) (for large size) **Length:** 220 mm (Minimum)(for small size) 230 mm (Minimum)(for medium, large size) **Thickness:** (for all sizes) *Finger* –0.05 mm (Minimum) *Palm* –0.05mm (Minimum)	Passed
ASMT D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application - Physical Requirements Test	To determine the tensile strength and ultimate elongation before and after acceleration aging	**Before Acceleration Aging:** Tensile Strength (MPa): 14 (Minimum) Ultimate Elongation (%): 500 (Minimum) **After Acceleration Aging:** Tensile Strength (MPa): 14 (Minimum) Ultimate Elongation (%): 400(Minimum)	Passed
ASTM D6319-19 (ASTM D5151-11) Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Passed
ASMT D6319-19 (ASTM D6124-11) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	$\leq$ 2.0 mg/glove	0.6 mg/glove, Passed

BIO-COMPATIBILITY DATA

Test Method	Purpose	Acceptance Criteria	Result
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the potential of the material under test to produce skin irritation in rabbits	Under the condition of study not an irritant	Under the condition of study not an irritant
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for skin irritation and skin sensitization	To determine the skin sensitization potential of the material both in terms of induction and elicitation in guinea pigs.	Under the conditions of the study not a sensitizer.	Under the conditions of the study not a sensitizer.
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	To evaluate the in vitro cytotoxic potential of the test item (both inner and outer surface) Extracts in L-929 mouse fibroblasts cells using elution method	No more than grade 2 cytotoxicity at 100% extract concentration	Under the conditions of the cytotoxicity study, the extract of the test article showed mild cytotoxicity to L-929 cells and the cytotoxic level was 2.

8. CLINICAL TESTING SUMMARY

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

9. CONCLUSION

The conclusions drawn from the non-clinical test demonstrate that the subject device in 510(k) submission, the Disposable Medical Synthetic Nitrile Examination Gloves Non sterile is as safe, as effective, and performs as well as or better than the legally marketed predicate device K102593- Synthetic Nitrile Patient Examination Gloves – Powder free, Blue.