April 8, 2024

Yue Kang Anhui Medical Products Co., Ltd
Amy Gao
Quality Engineer
No 375, Yunjin Road
Huaibei, Anhui 235000
China

Re: K240021
Trade/Device Name: Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: March 8, 2024
Received: March 8, 2024

Dear Amy Gao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K240021

Device Name
Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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.
These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Test Chemotherapy drug are as followings:

Test Chemotherapy drug & Concentration	Minimum Breakthrough Detection Time (Minutes)
Carmustine (BCNU) (3.3mg/ml)	1.3
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin HCl (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	1.1

Test Fentanyl Citrate are as follows:	Minimum Breakthrough Detection Time in minutes
Fentanyl Citrate Injection 100mcg/2ml	>240

Warning: Do not use with Carmustine and Thiotepa.
Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 1.3 minutes and Thiotepa:1.1 minutes.

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
(K240021)

Date Prepared: April 3, 2024

1. Owner's Identification:

Applicant Name: Yue Kang Anhui Medical Products Co., Ltd
Location: No 375, Yunjin Road, Huaibei City, Anhui, China
Contact Person: Amy Gao
Tel：+86-18266365220

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Common Name: Exam Gloves
Classification Name: Non-Powdered Patient Examination Glove Specialty
Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Professional Latex Sdn Bhd
Powder Free Nitrile Examination Glove, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K220088)
Product code LZA, LZC, QDO, OPJ.

4. Device Description:

Powder Free Nitrile Examination Gloves 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes - Extra Small, Small, Medium, Large, Extra Large, Extra Extra Large. Gloves meet the specification of ASTM D6319- 19 and have been tested for resistance to permeation by chemotherapy drugs and Fentanyl Citrate as per ASTMD6978- 05(2019). The gloves are single use, disposable, and provided non-sterile.

5. Indications for Use:

Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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.
These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Test Chemotherapy drug & Concentration	Minimum Breakthrough Detection Time (Minutes)
Carmustine (BCNU) (3.3mg/ml)	1.3
Cisplatin (1mg/ml)	>240
Cyclophosphamide (20mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin HCl (2 mg/ml)	>240
Etoposide (20mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Paclitaxel (6mg/ml)	>240
Thiotepa (10mg/ml)	1.1

Test Fentanyl Citrate are as follows:	Minimum Breakthrough Detection Time in minutes
Fentanyl Citrate Injection 100mcg/2ml	>240

Warning: Do not use with Carmustine and Thiotepa.
Please note that the following drugs have extremely low permeation times: Carmustine (BCNU): 1.3 minutes and Thiotepa:1.1 minutes.

6. Comparison of Subject Device and Predicate Device:

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs & Fentanyl Citrate of the proposed and predicate devices.

General Comparison Table:

Device	Proposed Device	Predicate Device	Comparison
510K #	K240021	K220088	N/A
Product Name	Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Powder Free Nitrile Examination Glove, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate	Different
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Indications for use	Powder Free Nitrile Examination Glove 3.5, Blue Color, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate 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. These gloves were tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019)	Powder free Nitrile Examination Gloves, Non- Sterile and tested for use with Chemotherapy Drugs and Fentanyl Citrate is a patient medical exam gloves which is a disposal device intended for medical purposes that is worn on the examiners' hand or finger to prevent contamination between examiner and patient. The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM- D6978-05	Same

	Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Standard Practice for Assessment of Medical Gloves to permeation by chemotherapy Drugs	
Powder free	Yes	Yes	Same
Design feature	Ambidextrous	Ambidextrous	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Different
Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL	Different
Sterile	Non-Sterile	Non-Sterile	Same
Use	Single use	Single use	Same
Chemotherapy Drugs and Fentanyl Citrate Claim	See below comparison table	See below comparison table	Same

Analysis: The proposed device has size XS, S, M, L, XL, XXL, while the predicate device has size XS, S, M, L, XL. But performance testing has been done to the proposed device and the results showed that the device meets the requirements of standard ASTM D6319-19. Therefore, this difference does not raise any new safety or performance questions.

Technological Characteristic and Biocompatibility Comparison Table:

Item	**Standard**	**Proposed device**	**Predicate device** K220088	**Result**
Dimension	ASTM D6319-19	Length: Min 230mm Width(mm): XS: 70±10 S: 80±10 M: 95±10 L： 110±10 XL： 120±10 XXL： 130±10 Thickness(mm): Palm: Minimum 0.05 Finger: Minimum 0.05	Length: Min 240mm Width(mm): XS: 70±10 S: 80±10 M: 95±10 L： 110±10 XL ： 120±10 XXL: / Thickness:(mm) Palm: Minimum 0.05 Finger: Minimum 0.05	Similar
Physical properties **Before aging** Tensile strength Ultimate elongation **After aging** Tensile strength Ultimate elongation	ASTM D6319-19 ASTM D412-16	 14MPa, min 500%, min 14MPa, min 400%, min	 14MPa, min 500%, min 14MPa, min 400%, min	 Same Same
Freedom from holes	ASTM D6319-19 ASTM D5151-19	G-I, AQL2.5	G-I, AQL2.5	Same

Residual Powder	ASTM D6319-19 ASTM D6124-06	≤ 2 mg per glove	≤ 2 mg per glove	Same
Biocompatibility	Irritation ISO 10993-23	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.	Under the conditions of the study, the subject device is non- irritating	Similar①
	Sensitization ISO 10993-10	The sample extract elicits no sensitization reactions under the test conditions	Under the condition of the study, the subject device is non-sensitizer	Similar
	Acute Systemic Toxicity Test ISO 10993 -11	No death or acute systemic toxicity was observed in the mice which received injection of the extract	Under the conditions of the study, the subject showed no adverse biological reaction	Similar

① The new version of standard for Skin Irritation we refer is ISO 10993-23:2021, the test method and process is the same as the old version ISO 10993-10

Chemotherapy drug Permeation and Fentanyl Citrate Comparison Claim:

Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)		Remark
	Proposed device	**Predicate device** K220088	
Carmustine (BCNU) (3.3mg/ml)	1.3	24.3	Different
Cisplatin (1mg/ml)	>240	>240	Same
Cyclophosphamide (20mg/ml)	>240.	>240	Same
Dacarbazine (10.0 mg/ml)	>240	>240	Same
Doxorubicin HCl (2 mg/ml)	>240	>240	Same
Etoposide (20mg/ml)	>240	>240	Same
Fluorouracil (50mg/ml)	>240	>240	Same
Paclitaxel (6mg/ml)	>240	>240	Same
Thiotepa (10mg/ml)	1.1	48.6	Different
Ifosfamide (50.0 mg/ml)	/	>240	Different
Mitoxantrone (2.0 mg/ml)	/	>240	Different
Vincristine Sulfate (1.0 mg/ml)	/	>240	Different

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this different does not raise questions of safety and effectiveness.*

Fentanyl Citrate	Minimum Breakthrough Detection Time (Minutes)		Remark
	Proposed device	**Predicate device** K220088	
Fentanyl Citrate Injection, 100mcg/2mL	>240	>240	Same

Summary of Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met the performance criteria with the following standards:

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D6319- 19	Physical Dimensions Length	Minimum 220mm for size XS and S, 230mm for size M, L, XL	Pass
ASTM D6319- 19	Physical Dimensions Palm Width	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL：120±10mm XXL： 130±10mm	Pass
ASTM D6319- 19	Physical Dimensions Thickness	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
ASTM D6319- 19 ASTM D412- 16 (2021)	Physical Properties	Before aging: 14MPa, min 500%, min After aging: 14MPa, min 400%, min	Pass
ASTM D6319- 19 ASTM D5151- 19	Water leak test	G-I, AQL 2.5 (ISO 2859- 1)	Pass
ASTM D6319- 19 ASTM D6124-06 (2017)	Powder Residue	Max 2mg/glove	Pass
ASTM D6978-05 (2019)	Permeation by Chemotherapy Drugs	Refer the above table 1	Pass
ISO 10993-10:2021	Skin Sensitization	No Skin sensitization	The sample extract elicits no sensitization reactions under the test conditions
ISO 10993-23:2021	Irritation	No Skin irritation	Under the conditions of this study, the irritation response category of the test article is classified as Negligible for polar extract and Negligible for non-polar extract.
ISO 10993-11:2017	Acute systemic toxicity study	Subject showed no adverse biological reaction	No death or acute systemic toxicity was observed in the mice which received injection of extract

. 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 D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

. ASTM D412-16（2021）Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

. ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.

. ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

. ISO10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation.

. ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

7. **Summary of Clinical Testing:**

Not provided for the subject device.

8. Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K220088, Powder Free Nitrile Examination Glove, Non-Sterile, and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.