November 17, 2025

Mercator Medical (Thailand) LTD
% Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K251141
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue colored, Non-sterile Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Patient Examination Glove, Black colored, Non-sterile 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, OPJ, QDO
Dated: October 23, 2025
Received: October 23, 2025

Dear Kevin Walls:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251141

Device Name
Powder Free Nitrile Patient Examination Glove, Blue colored, Non-sterile Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Indications for Use *(Describe)*
Powder-Free Nitrile Patient Examination Glove, Blue colored, Non-sterile Tested for Use with Chemotherapy Drugs and Fentanyl Citrate are disposable devices intended for medical propose that are worn on the examiner's hands to prevent contamination between patent and examiner.

Test Chemotherapy Drugs and Fentanyl Citrate	Concentration	Breakthrough Detection Time In Minutes
Bleomycin Sulfate	15.0 mg/ml (15,000 ppm)	>240 min.
Busulfan	6.0 mg/ml (6,000 ppm)	>240 min.
Carboplatin	10.0 mg/ml (10,000 ppm)	>240 min.
Carmustine	3.3 mg/ml (3,300 ppm)	12.3 (12.3, 12.3, 12.6)
Cisplatin	1.0 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20.0 mg/ml (20,000 ppm)	>240 min.
Cytarabine	100.0 mg/ml (100,000 ppm)	>240 min.
Cytovene	10.0 mg/ml (10,000 ppm)	>240 min.
Dacarbazine	10.0 mg/ml (10,000 ppm)	>240 min.
Daunorubicin HCI	5.0 mg/ml (5,000 ppm)	>240 min.
Docetaxel	10.0 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCI	2.0 mg/ml (2,000 ppm)	>240 min.
Epirubicin HCI	2.0 mg/ml (2,000 ppm)	>240 min.
Etoposide	20.0 mg/ml (20,000 ppm)	>240 min.
Fludarabine	25.0 mg/ml (25,000 ppm)	>240 min.
Fluorouracil	50.0 mg/ml (50,000 ppm)	>240 min.
Gemcitabine	38.0 mg/ml (38,000 ppm)	>240 min.
Idarubicin HCI	1.0 mg/ml (1,000 ppm)	>240 min.
Ifosfamide	50.0 mg/ml (50,000 ppm)	>240 min.
Irinotecan	20.0 mg/ml (20,000 ppm)	>240 min.
Mechlorethamine	1.0 mg/ml (1,000 ppm)	>240 min.
Melphalan	5.0 mg/ml (5,000 ppm)	>240 min.
Methotrexate	25.0 mg/ml (25,000 ppm)	>240 min.
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.
Mitoxantrone HCI	2.0 mg/ml (2,000 ppm)	>240 min.
Oxaliplatin	5.0 mg/ml (5,000 ppm)	>240 min.
Paclitaxel	6.0 mg/ml (6,000 ppm)	>240 min.
Rituximab	10.0 mg/ml (10,000 ppm)	>240 min.
Thiotepa	10.0 mg/ml (10,000 ppm)	19.6 (23.2, 23.5, 19.6)
Trisenox	1.0 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	>240 min.
Vinorelbine Tartrate	10.0 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate Injection	50.0 mcg/mL (50 ppm)	>240 min.
Xylazine HCI	100.0 mg/ml (100,000 ppm)	>240 min.

Please note that the following drugs showed break through detected in less than 240 minutes:
1. Carmustine 3.3 mg/ml (3,300 ppm): 12.3 minutes
2. Thiotepa 10.0 mg/ml (10,000 ppm): 19.6 minutes
Warning - Not for Use with Carmustine and Thiotepa

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
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Indications for Use *(Describe)*
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Test Chemotherapy Drugs and Fentanyl Citrate	Concentration	Breakthrough Detection Time In Minutes
Carmustine	3.3 mg/ml (3,300 ppm)	13.4 (13.4, 13.5, 13.7)
Cisplatin	1.0 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide	20.0 mg/ml (20,000 ppm)	>240 min.
Doxorubicin HCI	2.0 mg/ml (2,000 ppm)	>240 min.
Etoposide	20.0 mg/ml (20,000 ppm)	>240 min.
Fluorouracil	50.0 mg/ml (50,000 ppm)	>240 min.
Paclitaxel	6.0 mg/ml (6,000 ppm)	>240 min.
Thiotepa	10.0 mg/ml (10,000 ppm)	33.0 (33.0, 35.4, 35.4)
Vincristine Sulfate	1.0 mg/ml (1,000 ppm)	>240 min.
Fentanyl Citrate Injection	100.0 mcg/2mL	>240 min.
Xylazine HCI	100.0 mg/ml (100,000 ppm)	>240 min.

Please note that the following drugs showed break through detected in less than 240 minutes:
1. Carmustine 3.3 mg/ml (3,300 ppm): 13.4 minutes
2. Thiotepa 10.0 mg/ml (10,000 ppm): 33.0 minutes
Warning - Not for Use with Carmustine and Thiotepa

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)

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