February 21, 2022

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

Re: K213548
Trade/Device Name: Nitrylex Classic Powder Free Nitrile Blue Examination Gloves Tested for Use with Chemotherapy
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: January 31, 2022
Received: February 1, 2022

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 (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, PhD
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213548

Device Name

Nitrylex® Classic Powder Free Nitrile Blue Examination Gloves Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*

Nitrylex® Classic Powder Free Nitrile Blue Examination Gloves Tested for use with Chemotherapy Drugs are disposable devices intended for medical propose that are worn on the examiner's hands to prevent contamination between patent and examiner.

The proposed device was tested for use with Chemotherapy Drugs as per ASTM D678-05 Standard Practice for Assessment Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.
Chemotherapy Drugs Permeation.
The following chemicals have been tested with the proposed device.

Test Chemotherapy Drugs	Concentration	Breakthrough Detection (Time In Minutes)
Bleomycin Sulfatte	15 mg/ml (15,000 ppm)	>240 min.
Busulfan	6 mg/ml (6,000 ppm)	>240 min.
Carboplatin	10 mg/ml (10,000 ppm)	>240 min.
Cisplatin	1 mg/ml (1,000 ppm)	>240 min.
Cyclophosphamide (Cytoxan)	20.0 mg/ml (20,000 ppm)	>240 min.
Cytarabine HCl	100 mg/ml (100,000 ppm)	>240 min.
Cytovene	10 mg/ml (10,000 ppm)	>240 min.
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.
Daunorubicin HCl	5 mg/ml (5,000 ppm)	>240 min.
Docetaxel	10 mg/ml (10,000 ppm)	>240 min.
Doxorubicin HCl	2.0 mg/ml (2,000 ppm)	>240 min.
Epirubicin HCl	2 mg/ml (2,000 ppm)	>240 min.
Etoposide	20.0 mg/ml (20,000 ppm)	>240 min.
Fludarabine	25 mg/ml (25,000 ppm)	>240 min.
Fluorouracil	50.0 mg/ml (50,000 ppm)	>240 min.
Gemcitabine	38 mg/ml (38,000 ppm)	>240 min.
Idarubicin HCl	1 mg/ml (1,000 ppm)	>240 min.
Ifosfamide	50 mg/ml (50,000 ppm)	>240 min.
Irinotecan	20 mg/ml (20,000 ppm)	>240 min.
Mechlorethamine HCl	1 mg/ml (1,000 ppm)	>240 min.
Melphalan	5 mg/ml (5,000 ppm)	>240 min.
Methotrexate	25 mg/ml (25,000 ppm)	>240 min.
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.
Mitoxantrone	2 mg/ml (2,000 ppm)	>240 min.
Oxaliplatin	2 mg/ml (2,000 ppm)	>240 min.
Paclitaxel	6.0 mg/ml (6,000 ppm)	>240 min.
Rituximab	10 mg/ml (10,000 ppm)	>240 min.
Trisenox	1 mg/ml (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Vinorelbine	10 mg/ml (10,000 ppm)	>240 min.
Fentanyl Citrate Injection	100 mcg/2 ml	>240 min.

Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	34.8 (39.4, 38.7, 34.8)
ThioTepa	10.0 mg/ml (10,000 ppm)	47.4 (48.2, 50.0, 47.4)

Please note that the following drugs showed break through detected in less than 240 minutes:
- Carmustine (BCNU), 3.3 mg/ml: 34.8 minutes
- Thiotepa (THT) 10.0 mg/ml: 47.4 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.

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