May 23, 2022

Motex Healthcare (Anhui) Co., Ltd.
% Jen Ke-Min
Official Correspondent
Roc Chinese-European Industrial Research Society
No. 58, Fu Chiun Street
Hsin Chu City, Taiwan 300113
Taiwan

Re: K220155
Trade/Device Name: Powder-free Nitrile Examination Gloves Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC
Dated: April 6, 2022
Received: April 13, 2022

Dear Jen Ke-Min:

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,

Bifeng Qian, M.D., Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220155

Device Name

Powder-free Nitrile Examination Gloves Tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Permeation:

Chemotherapy Drugs Tested	Breakthrough Time
Bleomycin Sulfate, 15 mg/ml (15,000 ppm)	>240 minutes
Bortezomib (Velcade), 1 mg/ml (1,000ppm)	>240 minutes
Busulfan, 6 mg/ml (6,000 ppm)	>240 minutes
Carboplatin, 10 mg/ml (10,000 ppm)	>240 minutes
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	45.4 minutes*
Chloroquine, 50 mg/ml (50,000 ppm)	>240 minutes
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240 minutes
Cytarabine, 100 mg/ml (100,000 ppm)	>240 minutes
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 minutes
Daunorubicin HCI, 5 mg/ml (5,000 ppm)	>240 minutes
Docetaxel, 10 mg/ml (10,000 ppm)	>240 minutes
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 minutes
Gemcitabine, 38 mg/ml (38,000 ppm)	>240 minutes
Idarubicin HCI, 1 mg/ml (1,000 ppm)	>240 minutes
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 minutes
Irinotecan, 20 mg/ml (20,000 ppm)	>240 minutes
Mechlorethamine HCI, 1 mg/ml (1,000 ppm)	>240 minutes
Melphalan, 5 mg/ml (5,000 ppm)	>240 minutes
Methotrexate, 25 mg/ml (25,000ppm)	>240 minutes
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 minutes
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240 minutes
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 minutes
ThioTepa, 10.0 mg/ml (10,000 ppm)	15.6 minutes*
Triclosan, 2 mg/ml (2,000 ppm)	>240 minutes
Trisenox, 1 mg/ml (1,000 ppm)	>240 minutes
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240 minutes

*WARNING: Not recommended for use with Carmustine and ThioTepa.

The maximum testing time is 240 minutes. Please note that the following drugs have low permeation times:

Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	45.4 minutes
ThioTepa, 10.0 mg/ml (10,000 ppm)	15.6 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.

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