July 24, 2023

Central Medicare Sdn. Bhd.
Chua Kah Ying
Product Executive
PT 2609-2620, Batu 8, Jalan Changkat Jong
Teluk Intan, Perak 36000
Malaysia

Re: K223752
Trade/Device Name: Black Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Chloroquine, Cyclosporin A, Retrovir, Gastric Acid and Fentanyl
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: June 22, 2023
Received: June 22, 2023

Dear Chua Kah Ying:

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 -S

Bifeng Qian, M.D., 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)*
K223752

Device Name
Black Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Chloroquine, Cyclosporin A, Retrovir, Gastric Acid and Fentanyl

Indications for Use *(Describe)*
Black Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Chloroquine, Cyclosporin A, Retrovir, Gastric Acid and Fentanyl is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs, with chloroquine, cyclosporin A, retrovir, gastric acid and fentanyl citrate in accordance with ASTM D6978-05(2019).

Tested chemotherapy drugs and average breakthrough detection time (minutes) are as follows:

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Bleomycin Sulfate	15.0 mg/ml	> 240 mins
Busulfan	6.0 mg/ml	> 240 mins
Carboplatin	10.0 mg/ml	> 240 mins
Carmustine (BCNU)	3.3 mg/ml	13.2 mins
Cisplatin	1.0 mg/ml	> 240 mins
Cyclophosphamide (Cytoxan)	20.0 mg/ml	> 240 mins
Cytarabine (Cytosine)	100.0 mg/ml	> 240 mins
Dacarbazine	10.0 mg/ml	> 240 mins
Daunorubicin HCl	5.0 mg/ml	> 240 mins
Docetaxel	10.0 mg/ml	> 240 mins
Doxorubicin HCl	2.0 mg/ml	> 240 mins
Epirubicin HCl (Ellence)	2.0 mg/ml	> 240 mins
Etoposide (Toposar)	20.0 mg/ml	> 240 mins
Fludarabine	25.0 mg/ml	> 240 mins
Fluorouracil	50.0 mg/ml	> 240 mins
Gemcitabine (Gemzar)	38.0 mg/ml	> 240 mins
Idarubicin HCl	1.0 mg/ml	> 240 mins
Ifosfamide	50.0 mg/ml	> 240 mins
Irinotecan	20.0 mg/ml	> 240 mins
Mechlorethamine HCl	1.0 mg/ml	> 240 mins
Melphalan	5.0 mg/ml	> 240 mins
Methotrexate	25.0 mg/ml	> 240 mins
Mitomycin C	0.5 mg/ml	> 240 mins
Mitoxantrone HCl	2.0 mg/ml	> 240 mins
Oxaliplatin	5.0 mg/ml	> 240 mins
Paclitaxel	6.0 mg/ml	> 240 mins
Paraplatin	10.0 mg/ml	> 240 mins
Rituximab	10.0 mg/ml	> 240 mins
Thiotepa	10.0 mg/ml	34.7 mins
Topotecan HCl	1.0 mg/ml	> 240 mins
Trisenox (Arsenic Trioxide)	1.0 mg/ml	> 240 mins
Velcade (Bortezomib)	1.0 mg/ml	> 240 mins
Vincristine Sulfate	1.0 mg/ml	> 240 mins

Tested non-chemotherapy drugs and average breakthrough detection time (minutes) are as follows:

Non-Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Chloroquine	50.0 mg/ml	> 240 mins
Cyclosporin A	100.0 mg/ml	> 240 mins
Retrovir	10.0 mg/ml	> 240 mins

Fentanyl Permeation - Under the testing conditions of ASTM D6978-05(2019), Fentanyl Citrate Injection (100mcg/2mL) was found to have no breakthrough detected up to 240 minutes.
Gastric Acid Permeation - Under the testing conditions of ASTM D6978-05(2019), was found to have no breakthrough detected up to 240 minutes.

CAUTION: Testing showed an average breakthrough time of 13.2 minutes with Carmustine and 34.7 minutes with Thiotepa.

WARNING: Do not 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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