October 2, 2023

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

Re: K230681
Trade/Device Name: Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, with 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: August 16, 2023
Received: August 21, 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 (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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230681

Device Name
Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, with Gastric Acid and Fentanyl

Indications for Use *(Describe)*
Blue Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with 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 gastric acid and fentanyl citrate in accordance with ASTM D6978-05.

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

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Arsenic Trioxide	1.0 mg/ml	> 240 minutes
Azacitidine (Vidaza)	25.0 mg/ml	> 240 minutes
Bendamustine HCl	5.0 mg/ml	> 240 minutes
Bleomycin Sulfate	15.0mg/ml	> 240 minutes
Busulfan	6.0 mg/ml	> 240 minutes
Carboplatin	10.0 mg/ml	> 240 minutes
Carmustine (BCNU)	3.3 mg/ml	55.1 minutes
Carfilzomib	2.0 mg/ml	> 240 minutes
Cetuximab	2.0 mg/ml	> 240 minutes
Chloroquine	50.0 mg/ml	> 240 minutes
Cisplatin	1.0 mg/ml	> 240 minutes
Cladribine	1.0 mg/ml	> 240 minutes
Cyclophosphamide (Cytoxan)	20.0 mg/ml	> 240 minutes
Cyclosporin A	100.0 mg/ml	> 240 minutes
Cytarabine	100.0 mg/ml	> 240 minutes
Cytovene (Ganciclovir)	10.0 mg/ml	> 240 minutes
Dacarbazine	10.0 mg/ml	> 240 minutes
Daunorubicin	5.0 mg/ml	> 240 minutes
Decitibine	5.0 mg/ml	> 240 minutes
Docetaxel	10.0 mg/ml	> 240 minutes
Doxorubicin Hydrochloride	2.0 mg/ml	> 240 minutes
Epirubicin (Ellence)	2.0 mg/ml	> 240 minutes
Etoposide (Toposar)	20.0 mg/ml	> 240 minutes
Fludarabine	25.0 mg/ml	> 240 minutes
Fluorouracil	50.0 mg/ml	> 240 minutes
Fulvestrant	50.0 mg/ml	> 240 minutes
Gemcitabine (Gemzar)	38.0 mg/ml	> 240 minutes
Idarubicin	1.0 mg/ml	> 240 minutes
Ifosfamide	50.0 mg/ml	> 240 minutes
Irinotecan	20.0 mg/ml	> 240 minutes
Mechlorethamine HCl	1.0 mg/ml	> 240 minutes
Melphalan	5.0 mg/ml	> 240 minutes
Mesna	50.0 mg/ml	> 240 minutes
Methotrexate	25.0 mg/ml	> 240 minutes
Mitomycin C	0.5 mg/ml	> 240 minutes
Mitoxantrone	2.0 mg/ml	> 240 minutes

Oxaliplatin	2.0 mg/ml	> 240 minutes
Paclitaxel	6.0 mg/ml	> 240 minutes
Paraplatin	10.0 mg/ml	> 240 minutes
Pemetrexed	25.0 mg/ml	> 240 minutes
Pertuzumab	30.0 mg/ml	> 240 minutes
Propofol	10.0 mg/ml	> 240 minutes
Raltitrexed	0.5 mg/ml	> 240 minutes
Retrovir	10.0 mg/ml	> 240 minutes
Rituximab	10.0 mg/ml	> 240 minutes
Temsirolimus	25.0 mg/ml	> 240 minutes
Thiotepa	10.0 mg/ml	98.7 minutes
Topotecan HCl	1.0 mg/ml	> 240 minutes
Trastuzumab	21.0 mg/ml	> 240 minutes
Triclosan	2.0 mg/ml	> 240 minutes
Trisenox (Arsenic Trioxide)	1.0 mg/ml	> 240 minutes
Velcade (Bortezomib)	1.0 mg/ml	> 240 minutes
Vinblastine	1.0 mg/ml	> 240 minutes
Vincristine Sulfate	1.0 mg/ml	> 240 minutes
Vinorelbine	10.0 mg/ml	> 240 minutes
Zoledronic Acid	0.8 mg/ml	> 240 minutes

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

CAUTION: Testing showed breakthrough time of 55.1 minutes with Carmustine and 98.7 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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