April 11, 2022

Central Medicare Sdn Bhd
Fatin Nor Fauzi
Product Process Engineer
PT 2609-2620, Batu 8, Jalan Changkat Jong
Teluk Intan, Perak 36000
Malaysia

Re: K213437
Trade/Device Name: Blue Non Sterile Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs, with Gastric Acid and Fentanyl Permeation Resistance Claims
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO,
Dated: April 4, 2022
Received: April 4, 2022

Dear Fatin Nor Fauzi:

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

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)*

K213437

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

Indications for Use *(Describe)*
Blue Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Gastric Acid and Fentanyl Permeation Resistance Claims is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Tested for Use with Chemotherapy Drugs - Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05 and will be labeled with a statement of compliance and a summary of the testing results.

The following drugs and concentrations have been tested and reached the minimum breakthrough result of >240 minutes:
Arsenic Trioxide 1.0
Azacitidine (Vidaza) 25.0
Bendamustine HCl 5.0
Bleomycin Sulfate 15.0
Busulfan 6.0
Carboplatin 10.0
Carfilzomib 2.0
Cetuximab 2.0
Chloroquine 50.0
Cisplatin 1.0
Cladribine 1.0
Cyclophosphamide (Cytoxan) 20.0
Cyclosporin A 100.0
Cytarabine 100.0
Cytovene (Ganciclovir) 10.0
Dacarbazine 10.0
Daunorubicin 5.0
Decitibine 5.0
Docetaxel 10.0
Doxorubicin Hydrochloride 2.0
Epirubicin (Ellence) 2.0
Etoposide (Toposar) 20.0
Fludarabine 25.0
Fluorouracil 50.0
Fulvestrant 50.0
Gemcitabine (Gemzar) 38.0
Idarubicin 1.0
Ifosfamide 50.0
Irinotecan 20.0
Mechlorethamine HCl 1.0
Melphalan 5.0
Mesna 50.0
Methotrexate 25.0
Mitomycin C 0.5
Mitoxantrone 2.0

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

The following drugs have permeation times lower than 240 minutes: Carmustine: 55.1 minutes and Thiotepa: 199.2 minutes.

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