



December 22, 2021

Central Medicare Sdn Bhd  
Muhammad Rahman  
Product Assistant Manager  
PT 2609-2620, Batu 8, Jalan Changkat Jong,  
Teluk Intan, Perak 36000  
Malaysia

Re: K211022

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: LZC, LZA, QDO

Dated: November 12, 2021

Received: November 26, 2021

Dear Muhammad Rahman:

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](mailto: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

510(k) Number (if known)

K211022

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.

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

Arsenic Trioxide 1.0 mg/ml >240 mins  
Azacitidine (Vidaza) 25.0 mg/ml > 240 mins  
Bendamustine HCl 5.0 mg/ml > 240 mins  
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 12.7 mins  
Carfilzomib 2.0 mg/ml > 240 mins  
Cetuximab 2.0 mg/ml > 240 mins  
Chloroquine 50.0 mg/ml > 240 mins  
Cisplatin 1.0 mg/ml > 240 mins  
Cladribine 1.0 mg/ml > 240 mins  
Cyclophosphamide (Cytoxan) 20.0 mg/ml > 240 mins  
Cyclosporin A 100.0 mg/ml > 240 mins  
Cytarabine 100.0 mg/ml > 240 mins  
Cytovene (Ganciclovir) 10.0 mg/ml > 240 mins  
Dacarbazine 10.0 mg/ml > 240 mins  
Daunorubicin 5.0 mg/ml > 240 mins  
Decitabine 5.0 mg/ml > 240 mins  
Docetaxel 10.0 mg/ml > 240 mins  
Doxorubicin Hydrochloride 2.0 mg/ml > 240 mins  
Epirubicin (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  
Fulvestrant 50.0 mg/ml > 240 mins  
Gemcitabine (Gemzar) 38.0 mg/ml > 240 mins  
Idarubicin 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  
Mesna 50.0 mg/ml >240 mins  
Methotrexate 25.0 mg/ml > 240 mins  
Mitomycin C 0.5 mg/ml > 240 mins

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Mitoxantrone 2.0 mg/ml > 240 mins  
Oxaliplatin 2.0 mg/ml > 240 mins  
Paclitaxel 6.0 mg/ml > 240 mins  
Paraplatin 10.0 mg/ml > 240 mins  
Pemetrexed 25.0 mg/ml > 240 mins  
Pertuzumab 30.0 mg/ml >240 mins  
Propofol 10.0 mg/ml > 240 mins  
Raltitrexed 0.5 mg/ml > 240 mins  
Retrovir 10.0 mg/ml > 240 mins  
Rituximab 10.0 mg/ml > 240 mins  
Temsirolimus 25.0 mg/ml >240 mins  
Thiotepa 10 mg/ml 35.8 mins  
Topotecan HCl 1.0 mg/ml > 240 mins  
Trastuzumab 21.0 mg/ml >240 mins  
Triclosan 2.0 mg/ml > 240 mins  
Trisenox (Arsenic Trioxide) 1.0 mg/ml > 240 mins  
Velcade (Bortezomib) 1.0 mg/ml > 240 mins  
Vinblastine 1.0 mg/ml > 240 mins  
Vincristine Sulfate 1.0 mg/ml > 240 mins  
Vinorelbine 10.0 mg/ml > 240 mins  
Zoledronic Acid 0.8 mg/ml > 240 mins

CAUTION: Testing showed an average breakthrough time of 35.8 minutes with Thiotepa and 12.7 minutes with Carmustine.

WARNING: Do not use with Carmustine and Thiotepa.

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.

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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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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