



July 4, 2019

Central Medicare Sdn. Bhd.  
Muhammad Rahman  
Product Assistant Manager  
PT 2609-2620, BT 8, Jalan Changkat Jong  
Teluk Intan, 36000 My

Re: K183149

Trade/Device Name: Blue Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Low Dermatitis and Fentanyl Permeation Resistance Claim

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I

Product Code: LZC, LZA, QDO

Dated: May 30, 2019

Received: June 3, 2019

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,

For Elizabeth Claverie, M.S.  
Assistant Director for THT4B2  
Acting Assistant Director for THT4B1  
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)

K183149

Device Name

Blue Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Low Dermatitis and Fentanyl Permeation Resistance Claim

Indications for Use (Describe)

Blue Non Sterile Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs, with Low Dermatitis and Fentanyl Permeation Resistance Claim is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Low Dermatitis Potential - this product demonstrated reduced potential for sensitizing users to chemical additives.

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.

### Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Tested Chemotherapy Drug	Concentrate(mg/ml)	Minimum Breakthrough Detection Time (minutes)
Bleomycin Sulfate	15	>240
Busulfan	6	>240
Carboplatin	10	>240
*Carmustine	3.3	12.4
Cisplatin	1	>240
Chloroquine	50	>240
Cyclophosphamide	20	>240
Cyclosporin	100	>240
Cytarabine HCl	100	>240
Dacarbazine	10	>240
Daunorubicin HCl	5	>240
Docetaxel	10	>240
Doxorubicin Hydrochloride	2	>240
Epirubicin (Ellence)	2	>240
Etoposide	20	>240
Fludarabine	25	>240
Fluorouracil	50	>240
Gemcitabine	38	>240
Idarubicin	1	>240
Ifosfamide	50	>240
Irinotecan	20	>240
Mechlorethamine HCl	1	>240
Melphalan	5	>240
Methotrexate	25	>240
Mitomycin	0.5	>240
Mitoxantrone	2	>240
Oxaliplatin	5	>240
Paclitaxel	6	>240
Paraplatin	10	>240
Retrovir	10	>240

Rituximab	10	>240
*Thiotepa	10	24.4
Topotecane	1	>240
Trisonex	1	>240
Velcade	1	>240
Vincristine Sulfate	1	>240

\*Please note that the following drugs have extremely low permeation times:  
 Carmustine: 12.4 minutes and Thiotepa: 24.4 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.

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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