April 23, 2025

GMP Medicare Sdn. Bhd.
Ummi Salmah Othman
Regulatory Affairs Assistant Manager
Lot/PT 64593, Jalan Dahlia/KU8,
Kawasan Perindustrian Meru Timur
Klang, Selangor 41050
Malaysia

Re: K250944
Trade/Device Name: Nitrile Powder Free Examination Glove, Blue Tested for Use with 60 Chemotherapy Drugs, Gastric Acid, Xylazine 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: March 24, 2025
Received: March 28, 2025

Dear Ummi Salmah Othman:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250944 ?

Please provide the device trade name(s). ?

Nitrile Powder Free Examination Glove, Blue Tested for Use with 60 Chemotherapy Drugs, Gastric Acid, Xylazine and Fentanyl

Please provide your Indications for Use below. ?

An examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs with Gastric Acid, Xylazine and Fentanyl Citrate in accordance with ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

No	Chemotherapy Drugs	Concentration (mg/ml)	Minimum Breakthrough Detection Time (Min.)
1	Amethopterin	25.0	>240
2	Azacitidine (Vidaza)	25.0	>240
3	Bendamustine HCl	5.0	>240
4	Bleomycin Sulfate	15.0	>240
5	Busulfan	6.0	>240
6	Capecitabine	26.0	>240
7	Carboplatin	10.0	>240
8	Carfilzomib	2.0	>240
9	Carmustine	3.3	11.0
10	Cetuximab (Erbitux)	2.0	>240
11	Chlroquine	50.0	>240
12	Cisplatin	1.0	>240
13	Cladribine	1.0	>240
14	Cyclophosphamide	20.0	>240
15	Cyclosporin A	100.0	>240
16	Cytarabine	100.0	>240
17	Cytovene	10.0	>240
18	Dacarbazine	10.0	>240
19	Dactinomycin	0.5	>240
20	Daunorubin HCl	5.0	>240
21	Decitabine	5.0	>240
22	Docetaxel	10.0	>240
23	Doxorubicin Hydrochloride	2.0	>240
24	Ellence	2.0	>240
25	Eribulin Mesylate	0.5	>240
26	Etoposide	20.0	>240
27	Fludarabine	25.0	>240
28	Fluorouracil	50.0	>240
29	Fulvestrant	50.0	>240
30	Gemcitabine	38.0	>240
31	Idarubicin	1.0	>240

32	Ifosfamide	50.0	>240
33	Irinotecan	20.0	>240
34	Ixabepilone	2.0	>240
35	Leuprolide Acetate	5.0	>240
36	Mechlorethamine	1.0	>240
37	Melphalan	5.0	>240
38	MESNA	100.0	>240
39	Methotrexate	25.0	>240
40	Mitomycin C	0.5	>240
41	Mitoxantrone	2.0	>240
42	Oxaliplatin	5.0	>240
43	Paclitaxel	6.0	>240
44	Pemetrexed	25.0	>240
45	Pertuzumab	30.0	>240
46	Propofol	10.0	>240
47	Raltitrexed	0.5	>240
48	Retrovir	10.0	>240
49	Rituximab	10.0	>240
50	Temsirolimus	25.0	>240
51	Thiotepa	10.0	39.0
52	Topotecan	1.0	>240
53	Trastuzumab	21.0	>240
54	Triclosan	1.0	>240
55	Trisenox	1.0	>240
56	Velcade (Bortezomib)	1.0	>240
57	Vincristine Sulfate	1.0	>240
58	Vinblastine Sulfate	1.0	>240
59	Vinorelbine	10.0	>240
60	Zoledronic Acid	0.8	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 11 minutes and 39 minutes respectively.

Warning: Do not use with Carmustine and Thiotepa

Gastric Acid - Under the testing conditions of ASTM D6978-05, Simulated Gastric Acid was found to have no breakthrough detected up to 240 minutes.

Xylazine - Under the testing conditions of ASTM D6978-05, Xylazine HCl Injection (100 mg/ml) was found to have no breakthrough detected up to 240 minutes.

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

Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)	?