February 24, 2021

GMP Medicare SDN BHD
% David Lim
Executive Director
TG Medical USA (INC)
165 N. Aspen Avenue
Azusa, California 91702

Re: K202003
Trade/Device Name: Nitrile Powder Free Examination Glove, Blue Tested for Use with 32 Chemotherapy Drugs and Fentanyl Permeation Resistance Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: January 15, 2021
Received: January 25, 2021

Dear David Lim:

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,

Ryan Ortega, PhD
Acting 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)*
K202003

Device Name
Nitrile Powder Free Examination Glove, Blue Tested for Use with 32 Chemotherapy Drugs and Fentanyl Permeation Resistance Claim

Indications for Use *(Describe)*
A patient 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.

This glove was tested for use with chemotherapy drugs and Fentanyl Citrate as pet ASTM D6978-05 (Reapproved 2013), Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

No	Test Chemotherapy Drug	Concentration (mg/ml)	Minimum breakthrough Detection Time (min)
1	Amethopterin	25	>240
2	Bleomycin Sulfate	15	>240
3	Busulfan	6	>240
4	Carboplatin	10	>240
5	Carmustine	3.3	11.0
6	Cisplatin	1	>240
7	Cyclophosphamide	20	>240
8	Cytarabine	100	>240
9	Dacarbazine	10	>240
10	Docetaxel	10	>240
11	Doxorubicin HCl	2	>240
12	Ellence	2	>240
13	Etoposide	20	>240
14	Fludarabine	25	>240
15	Fluorouracil	50	>240
16	Gemcitabine	38	>240
17	Idarubicin	1	>240
18	Ifosfamide	50	>240
19	Irinotecan	20	>240
20	Mechlorethamine	1	>240
21	Melphalan	5	>240
22	Methotrexate	25	>240
23	Mitomycin C	0.5	>240
24	Mitoxantrone	2	>240
25	Oxaliplatin	5	>240
26	Paclitaxel	6	>240
27	Rituximab	10	>240
28	Thiotepa	10	39
29	Topotecan	1	>240
30	Trisenox	1	>240
31	Vincristine Sulfate	1	>240
32	Vinorelbine	10	>240
33	Fentanyl Citrate	100 mcg/2ml	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 11 minutes and 39 minutes respectively
Warning: do not use Carmustine.
CAUTION: Testing showed an average breakthrough time of 39 minutes with 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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