July 30, 2019

Platinum Glove Industries Sdn Bhd
% Foo Pu
Managing Director
Platinum Glove Industries Sdn. Bhd.
Lot 6491-A, Batu 5 3/4, Sementa, Jalan Kapar
Selangor Darul Ehsan, 42100 My

Re: K182089
Trade/Device Name: Powder Free Blue Nitrile Examination Gloves - Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: June 22, 2018
Received: July 5, 2018

Dear Foo Pu:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*
K182089

Device Name
Powder Free Blue Nitrite Examination Gloves- Tested for Use with Chemotherapy Drugs.

Indications for Use *(Describe)*
A Patient examination glove is a disposable device intended for medical purposes that worn on the examiner's hand or finger to prevent contamination between patient and examiner. Tested for use with chemotherapy drugs as listed below.

Chemotherapy Drug permeation and concentration (Break through Detection Time) in Minutes. The following chemicals have been tested with these gloves.

1. Carmustine (BCNU)3.3 mg/ml(3,300 ppm)	9.0 min
2. Cisplatin 1.0 mg/ml (l,000ppm)	>240 min
3. Cyclophosphamide (Cytoxan) 20mg/ml (20,000ppm)	>240 min
4. Dacarbazine (DTIC)l 0.0 mg/ml (l0,00Oppm)	>240 min
5. Doxorubicin Hydrochloride 2.0 mg/ml (2,000ppm)	>240 min
6. Etoposide (Toposar) 20.0 mg/ml (20,000ppm)	>240 min
7. Fluorouracil 50.0 mg/ml (50,000ppm)	>240 min
8. lfosfamide 50.0 mg/ml (50,000ppm)	>240 min
9. Methotrexate 25 mg/ml (25,000ppm)	>240 min
10. Mitomycin C 0.5 mg/ml (500ppm)	>240 min
11. Mitoxantrone 2.0 mg/ml (2,000ppm)	>240 min
12. Paclitaxel (Taxol) 6.0 mg/ml (6,000ppm)	>240 min
13. Thio-Tepa 10.0 mg/ml (10,000ppm)	16.2min
14. Vincristine Sulfate 1.0 mg/ml (1,000ppm)	>240min

Please Note that Carmustine and Thio-Tepa have low permeation time of less than 240 minutes.

Do not use with Carmustine and Thio-Tepa

Type of Use *(Select* one *or both, as applicable)*

[ ] Prescription Use (Part 21 CFR 801 Subpart D) [X] 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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