



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Mr. Cho Sow Fong  
Quality Assurance Manager  
GX Corporation SDN BHD  
Lot 6491-A, Batu 5¾,  
Sementa, Off Jalan Kapar,  
42100 Klang Selangor Darul Ehsan  
MALAYSIA

DEC 28 2009

Re: K091851  
Trade/Device Name: Sterile, Powder Free Nitrile Examination Gloves,  
Blue Tested for with Chemotherapy Drugs  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA, LZC  
Dated: December 15, 2009  
Received: December 17, 2009

Dear Mr. Fong:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, BS, MS, MBA

Director

Division of Anesthesiology, General Hospital,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K091851

Device Name: Sterile, Powder Free Nitrile Examination Gloves, Blue  
Tested For Use With Chemotherapy Drugs.

### Indication For Use:

This glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.  
This glove has been tested for use with specific chemotherapy drugs listed below.

### Chemotherapy Drug Permeation (Breakthrough Detection Time in Minutes)

|   |       |
|---|-------|
| Dacarbazine (DTIC) (10.0 mg/mL)         | > 240 |
| Mitomycin C (5.0 mg/mL)                 | > 240 |
| Carmustine (BCNU) (3.3 mg/mL)           | 3.57  |
| Cyclophosphamide (Cytosan) (20.0 mg/mL) | > 240 |
| Doxorubicin Hydrochloride (2.0 mg/mL)   | > 240 |
| 5-Fluorouracil (50.0 mg/mL)             | > 240 |
| Cisplatin (1.0 mg/mL)                   | > 240 |
| Etoposide (20.0 mg/mL)                  | > 240 |
| Paclitaxel (taxol) (6.0 mg/mL)          | > 240 |
| Thio-Tepa (10.0 mg/mL)                  | 24.39 |
| Vincristine Sulfate (50.0 mg/mL)        | > 240 |
| Methotrexate (25.0 mg/mL)               | > 240 |
| Mitoxantrone (100.0 mg/mL)              | > 240 |
| Ifosfamide (Ifex) (50.0 mg/mL)          | > 240 |

Warning: Do Not Use with Thiotepa and Carmustine

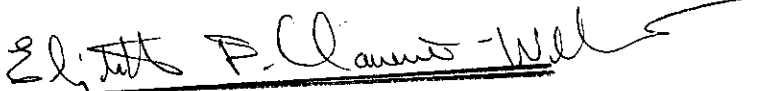
Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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