



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2009

Mr. Foo Khon Pu
Chief Executive Officer
GX Corporation SDN BHD
Lot 6487-A, Batu 5 ¾, Semnta, Jalan Kapar
Klang
Selangor Darul Ehsan
MALAYSIA 42100

Re: K090412

Trade/Device Name: Powder Free Nitrile Examination Glove (Pink, Green, Orange, White).
This Product Does Not Contain Thiuram, and/or Carbamate and /or
Thiazole. Low Dermatitis Potential.
Tested For Use With Chemotherapy Drugs.

Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: May 12, 2009
Received: May 14, 2009

Dear Mr. 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. 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.

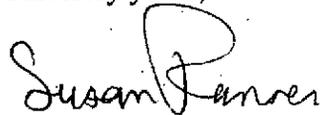
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., MA

Acting 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): K 090412

Device Name: Powder Free Nitrile Examination Glove (Pink, Green, Orange, White).
This Product Does Not Contain Thiuram, and/or Carbamate and/or
Thiazole. Low Dermatitis Potential.
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 is tested for use with Dacarbazine (DTIC), Mitomycin C, Methotrexate, Cyclophosphamide (Cytosan), Mitoxantrone, Doxorubicin Hydrochloride, Ifosfamide (Ifex), 5-Fluorouracil, Cisplatin, Etoposide, Paclitaxel (taxol), Vincristine Sulfate

Warning: Not Recommended For Use With Carmustine and Thio-Tepa

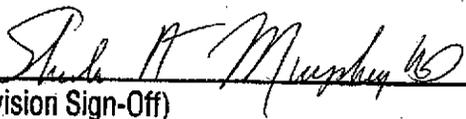
Prescription Use _____
(Part 21 CFR 801 Subpart D)

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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