



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-002

November 30, 2012

Mr. Eddy Rosyadie  
Quality Assurance Manager  
Top Glove Sdn. Bhd  
Lot 4968, Jalan Teratai, Batu 6, Off Jalan Meru  
Klang, Selangor Darul Ehsan  
Malaysia 41050

Re: K122999

Trade/Device Name: Blue Powder Free Nitrile Examination Gloves  
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: October 19, 2012

Received: October 22, 2012

Dear Mr. Rosyadie:

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. 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.

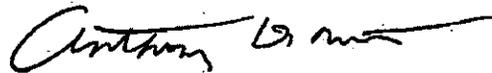
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

510 (k) Number (if known) : K122999

Device Name : **Blue Powder Free Nitrile Examination Gloves  
Tested For Use With Chemotherapy Drugs**

Indication For Use:

**Blue Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs**  
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.

In addition, these gloves were tested for use with Chemotherapy drugs in accordance  
with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation  
by Chemotherapy Drugs:

	<u>Chemotherapy Drug and Concentration</u>	<u>Minimum Breakthrough Detection time in Minutes, 0.01 ug/cm2/minute</u>
1	Cisplatin, 1.0 mg/ml (1,000ppm)	>240
2	Cyclophosphamide (Cytosan), 20.0mg/ml (20,000ppm)	>240
3	Dacarbazine (DTIC), 10.0 mg/ml (10,000ppm)	>240
4	Doxorubicin Hydrochloride, 2.0mg/ml (2,000ppm)	>240
5	Etoposide (Toposar), 20.0 mg/ml (20,000)ppm	>240
6	Fluorouracil, 50.0 mg/ml (50,000ppm)	>240
7	Paclitaxel (Taxol), 6.0 mg/ml (6,000ppm)	>240
8	Carmustine (BCNU) 3.3mg/ml (3,300ppm)	0.9
9	Thiotepa, 10.0mg/ml ( 10,000ppm)	0.05

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time of less than 30 minutes

**Carmustine (BCNU) 3.3mg/ml (3,300ppm)**  
**Thiotepa, 10.0mg/ml ( 10,000ppm)**

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

AND/OR

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

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

**Maria Cruz-fisher**

Digitally signed by Maria Cruz-fisher  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,  
ou=People, cn=Marla Cruz-fisher,  
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Date: 2012.11.30 10:48:43 -0500

**(Division Sign-Off)**  
**Division of Anesthesiology, General Hospital**  
**Infection Control, Dental Devices**

**510(k) Number:** \_\_\_\_\_