



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Cho Sow Fong  
Quality Assurance/ Regulatory Affairs Manager  
PT. Smart Glove Indonesia  
JL Raya Medan-Lubuk Pakam KM19, Tanjong  
Morawa, Deli Serdang  
Sumatera U Indonesia 20362

SEP 07 2010

Re: K101630

Trade/Device Name: Powder Free Nitrile Examination Gloves (6Mil), Tested  
For Use With Chemotherapy Drugs (Blue)  
Sterile, Powder Free Nitrile Examination Gloves, Tested For Use  
Chemotherapy Drugs (Blue)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA

Dated: August 23, 2010

Received: August 26, 2010

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. 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

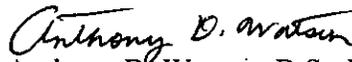
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding 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,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

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

SEP 07 2010

- Device Name:**
1. Powder Free Nitrile Examination Gloves (6Mil), Tested For Use With Chemotherapy Drugs (Blue)
  2. Sterile, Powder Free Nitrile Examination Gloves, Tested For Use With Chemotherapy Drugs (Blue)

**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 device also provides protection against exposure to certain chemotherapy drugs.

Chemotherapy Drugs Permeation (Average Breakthrough detection time in minutes)

	<u>Powder Free Nitrile Examination Gloves (6mil)</u>	<u>Sterile, Powder Free Nitrile Examination Gloves</u>
Carmustine (BCNU) (3.3 mg / ml)	111.9	0.51
Thiotepa (10.0 mg / ml)	162.3	36.5
Fluorouracil (50.0 mg / ml)	> 240	> 240
Etoposide (Toposar) (20.0 mg / ml)	> 240	> 240
Cyclophosphamide (Cytosan) (20.0 mg / ml)	> 240	> 240
Mitomycin C (0.5 mg / ml)	> 240	> 240
Methotrexate (25.0 mg / ml)	> 240	> 240
Paclitaxel (Taxol) (6.0 mg / ml)	> 240	> 240
Doxorubicin Hydrochloride (2.0 mg / ml)	> 240	> 240
Dacarbazine (DTIC) (10.0 mg / ml)	> 240	> 240
Cisplatin (1.0 mg / ml)	> 240	> 240
Mitoxantrone (2.0 mg / ml)	> 240	> 240
Ifosfamide (50.0 mg / ml)	> 240	> 240
Vincristine Sulfate (1.0mg / ml)	> 240	> 240

**Please note that the following drugs have extremely low permeation time of less than 30 minutes / 60 minutes (Carmustine and Thiotepa) for Sterile, Powder Free Nitrile Examination Gloves.**

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)

*Elizabeth P. Clavie - Wells*  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K101630