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

OCT 17 2012

Matang Manufacturing Sdn. Bhd
Ms. Leslie Leong
Operation Manager
Lot 10, Kawasan Perindustrian Serkam
Mukim Serkam, Merlimau
Melaka, Malaysia 77300

Re: K122131
Trade/Device Name: Powder Free Nitrile Examination Glove – Blue (Chemotherapy)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: October 4, 2012
Received: October 12, 2012

Dear Ms. Leong:

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

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

3.0 Indication For Use Statement

510(K) Number (if known): K122131

Device Name : Powder Free Nitrile Examination Glove – Blue (Chemotherapy)

Indications For Use : A Powder Free Nitrile Examination Glove – Blue (Chemotherapy) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between the patient and examiner.
In addition, these Chemotherapy gloves were tested for use with the following drug concentrations per ASTM D 6978-05

Permeation Test Results

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3)(Minutes)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	60.3 (60.3, 60.5, 60.6)
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	No breakthrough up to 240 min.
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.
Etoposide (Toposar), 20.0 mg/ml (20,000 pm)	No breakthrough up to 240 min.
Fluorouracil, 50.0 mg/ml (50,000 pm)	No breakthrough up to 240 min.
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.
Mitoxantrone, 2 mg/ml (2,000 ppm)	No breakthrough up to 240 min.
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.
Thiotepa, 10.0 mg/ml (10,000 ppm)	156.0 (163.8, 156.0, 165.0)
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.

Caution : Testing showed the following drugs have low average breakthrough detection time:
* Carmustine – 60.3 min
* Thiotepa – 156.0 min

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth D. Claudia Williams

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

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