DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 23, 2015

Hartalega Sdn. Bhd.
Ms. Nurul Aisyah Kong Binti Abdullah
Quality Assurance Senior Manager
No. 7 Kawasan Perusahaan Suria
Bestari Jaya
Selangor Darul Ehsan 45600
MALAYSIA

Re: K150103
Trade/Device Name: Nitrile Powder Free Examination Gloves (Orange) 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: March 18, 2015
Received: March 23, 2015

Dear Ms. Abdullah:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150103

Device Name
Nitrile Powder Free Examination Gloves (Orange) Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
The Nitrile Powder Free Examination Gloves (Orange) Tested for Use with Chemotherapy Drugs is a non-sterile disposable device intended for medical and dental purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. It is also tested to be used against Chemotherapy Drugs. The list of Chemotherapy Drugs tested (with breakthrough times) as per attached table. Please note that Carmustine and Thiotepa have extremely low permeation times of 45.4 minutes and 30.9 minutes, respectively.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Permeation Test Results of Nitrile Powder Free Examination Gloves (Orange) Tested for Use with Chemotherapy Drugs.

Chemotherapy Drugs	Minimum Breakthrough Time (Minutes)
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	**45.4**
Cisplatin 1.0 mg/ml (1,000 ppm)	> 240
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	> 240
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	> 240
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	> 240
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	> 240
Fluorouracil 50.0 mg/ml (50,000 ppm)	> 240
Ifosfamide 50.0 mg/ml (50,000 ppm)	> 240
Methotrexate 25.0 mg/ml (25,000 ppm)	> 240
Mitomycin C 0.5 mg/ml (500 ppm)	> 240
Mitoxantrone 2.0 mg/ml (2,000 ppm)	> 240
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	> 240
Thiotepa 10.0 mg/ml (10,000 ppm)	**30.9**
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	> 240