DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 9, 2017

Hartalega Sdn. Bhd.
Nurul Kong
Quality Assurance Senior Manager
No. 7 Kawasan Perusahaan Suria
Bestari Jaya, 45600 MY

Re: K162818
Trade/Device Name: Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZC
Dated: December 9, 2016
Received: December 13, 2016

Dear Nurul Kong:

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" (21 CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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)*
K162818

Device Name
Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (Blue)

Indications for Use *(Describe)*
The Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (Blue) is a non- sterile disposable device intended for medical purpose that is worn on 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.

The list of Chemotherapy Drugs tested (with breakthrough times) is as per below:

Carmustine (BCNU) (3.3 mg/ml)	10.1 minutes
Cisplatin (1.0 mg/ml)	> 240 minutes
Cyclophosphamide (Cytoxan) (20 mg/ml)	> 240 minutes
Dacarbazine (DTIC) (10.0 mg/ml)	> 240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml)	> 240 minutes
Etoposide (Toposar) (20.0 mg/ml)	> 240 minutes
Fluorouracil (50.0 mg/ml)	> 240 minutes
Methotrexate (25 mg/ml)	> 240 minutes
Mitomycin C (0.5 mg/ml)	> 240 minutes
Paclitaxel (Taxol) (6.0 mg/ml)	> 240 minutes
Thiotepa (10.0 mg/ml)	20.3 minutes
Vincristine Sulfate (1.0 mg/ml)	> 240 minutes

* Please note that the following drugs have extremely low permeation times of 10.1 minutes with Carmustine (3.3 mg/ml) and 20.3 minutes with Thiotepa (10.0 mg/ml).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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