November 2, 2018

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

Re: K180786
Trade/Device Name: Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs Aqua Blue (ABLU), Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs Violet Blue (VBLU) - Extended Cuff
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: October 11, 2018
Received: October 15, 2018

Dear Nurual 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180786

Device Name
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs - Violet Blue (VBLU)- Extended Cuff

Indications for Use *(Describe)*
The Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs - Violet Blue (VBLU)- Extended Cuff is a sterile disposable device intended for medical 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) is as below:

Carmustine (3.3 mg/ml)	20.3 minutes
Cisplatin (1.0 mg/ml)	> 240 minutes
Cyclophosphamide (20 mg/ml)	> 240 minutes
Dacarbazine (10.0 mg/ml)	> 240 minutes
Doxorubicin Hydrochloride (2.0mg/ml)	> 240 minutes
Etoposide (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 (6.0 mg/ml)	> 240 minutes
Thiotepa (10.0 mg/ml)	100.6 minutes
Vincristine Sulfate (1.0 mg/ml)	> 240 minutes

Please note that Carmustine and Thiotepa have extremely low permeation times of 20.3 minutes and 100.6 minutes.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180786

Device Name
Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs - Aqua Blue (ABLU)

Indications for Use *(Describe)*
The Sterile Nitrile Powder Free Examination Glove Tested for Use with Chemotherapy Drugs - Aqua Blue (ABLU) is a sterile disposable device intended for medical 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) is as below:

Carmustine (3.3 mg/ml)	43.8 minutes
Cisplatin (1.0 mg/ml)	> 240 minutes
Cyclophosphamide (20 mg/ml)	> 240 minutes
Dacarbazine (10.0 mg/ml)	> 240 minutes
Doxorubicin Hydrochloride (2.0mg/ml)	> 240 minutes
Etoposide (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 (6.0 mg/ml)	> 240 minutes
Thiotepa (10.0 mg/ml)	97.8 minutes
Vincristine Sulfate (1.0 mg/ml)	> 240 minutes

Please note that Carmustine and Thiotepa have extremely low permeation times of 43.8 minutes and 97.8 minutes.

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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