DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 5, 2013

Hartalega Sdn. Bhd.
Ms. Nurul Aisyah Kong
Quality Assurance Senior Manager
No. 7 Kawasan Persusahaan Suria
45600 Bestari Jaya
SELANGOR Malaysia

Re: K130473
Trade/Device Name: Nitrile Powder Free Examination Glove (Aqua Blue)
Nitrile Powder Free Examination Glove (Aqua Blue)-Extended Cuff
Nitrile Powder Free Examination Glove (Orange)
Nitrile Powder Free Examination Glove (Orange)-Extended Cuff
Nitrile Powder Free Examination Glove (Black)
Nitrile Powder Free Examination Glove (Black)- Extended Cuff
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: April 12, 2013
Received: April 15, 2013

Dear Ms. 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 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. 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 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,

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:

Nitrile Powder Free Examination Glove (ABLU)

*Note:
ABLU = Aqua Blue.

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
2013.06.28 21:08:19 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:

Nitrile Powder Free Examination Glove (ABLU) – Extended Cuff

*Note:
ABLU = Aqua Blue.

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.06.28 21:09:33 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:

Nitrile Powder Free Examination Glove (Orange)

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.06.28 21:10:04 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:

Nitrile Powder Free Examination Glove (Orange) – Extended Cuff

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.06.28 21:10:36 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:

Nitrile Powder Free Examination Glove (Black)

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F Claverie -S
2013.06.28 21:11:06 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____

INDICATION FOR USE

510(k) Number (if known): K130473

Device Name:
Nitrile Powder Free Examination Glove (Black) – Extended Cuff

Indication for Use:

The Nitrile Powder Free Examination Glove is a non - sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F Claverie
2013.06.28 21:11:40 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
510(k) Number: __K130473_____