



Food and Drug Administration
10903 New Hampshire Avenue
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August 24, 2015

Hartalega NGC Sdn Bhd
Nurul Aisyah Kong
Senior Manager-quality Assurance
C-G-9, Jalan Dataran SD1
Dataran SD PJU 9
Bandar Sri Damansara
Kuala Lumpur 52200
Malaysia

Re: K151343

Trade/Device Name: Nitrile Powder Free Examination Gloves Tested for Use with
Chemotherapy Drugs (Blue, Orange, White)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: July 15, 2015

Received: July 20, 2015

Dear Ms. Aisyah 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 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 Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151343

Device Name

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (Blue)

Indications for Use (Describe)

The Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (Blue) is non – 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) are;

Chemotherapy Drugs	Concentration (mg/ml)	Breakthrough time (minutes)
Carmustine	3.3	0.1
Cisplatin	1.0	>240
Cyclophosphamide (Cytosan)	20.0	>240
Dacarbazine	10.0	>240
Doxorubixin Hydrochloride	2.0	>240
Etoposide	20.0	>240
Fluoroucil	50.0	>240
Methotrexate	25.0	>240
Mitomycin	0.5	>240
Paclitaxel	6.0	>240
Thiotepa	10.0	20.4
Vincristine Sulfate	1.0	>240

Please note the following drugs Carmustine and Thiotepa have extremely low permeation times of 0.1 and 20.4 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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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Indications for Use

510(k) Number (if known)

K151343

Device Name

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

Indications for Use (Describe)

The Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (Orange) is non – 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) are;

Chemotherapy Drugs	Concentration (mg/ml)	Breakthrough time (minutes)
Carmustine	3.3	20.3
Cisplatin	1.0	>240
Cyclophosphamide (Cytosan)	20.0	>240
Dacarbazine	10.0	>240
Doxorubixin Hydrochloride	2.0	>240
Etoposide	20.0	>240
Fluoroucil	50.0	>240
Methotrexate	25.0	>240
Mitomycin	0.5	>240
Paclitaxel	6.0	>240
Thiotepa	10.0	50.6
Vincristine Sulfate	1.0	>240

Please note the following drugs Carmustine and Thiotepa have extremely low permeation times of 20.3 and 50.6 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)

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Indications for Use

510(k) Number (if known)

K151343

Device Name

Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (White)

Indications for Use (Describe)

The Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (White) is non – 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) are;

Chemotherapy Drugs	Concentration (mg/ml)	Breakthrough time (minutes)
Carmustine	3.3	20.4
Cisplatin	1.0	>240
Cyclophosphamide (Cytosan)	20.0	>240
Dacarbazine	10.0	>240
Doxorubixin Hydrochloride	2.0	>240
Etoposide	20.0	>240
Fluoroucil	50.0	>240
Methotrexate	25.0	>240
Mitomycin	0.5	>240
Paclitaxel	6.0	>240
Thiotepa	10.0	71.0
Vincristine Sulfate	1.0	>240

Please note the following drugs Carmustine and Thiotepa have extremely low permeation times of 20.4 and 71.0 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)

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