



Food and Drug Administration
10903 New Hampshire Avenue
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September 22, 2015

Terang Nusa, Sdn. Bhd.
Mr. Robert Hill
Regulatory Director
1, Jalan 8
Pengkalan Chepa 2 Industrial Zone
16100 Kota Bharu
MALAYSIA

Re: K150973
Trade/Device Name: NUZONE X2G Polychloroprene Synthetic Green Surgical Gloves
Powder Free, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: July 1, 2015
Received: July 5, 2015

Dear Mr. Hill:

This letter corrects our substantially equivalent letter of August 4, 2015.

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

Indications for Use

510(k) Number (if known)
K150973

Device Name
NUZONE X2G
Polychloroprene Synthetic Green Surgical Gloves Powder Free, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe)

This Surgeons glove is a device made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

These gloves are tested for use with Chemotherapy Drugs.
Testing based on ASTM D6978-05

| DRUG | Minimum Breakthrough Detection Time (Specimen 1/2/3) Minutes |
|---|--|
| Carmustine (BCNU), 3.3 mg/ml (3,300ppm)..... | 30.6 (30.6, 30.6, 30.8) |
| Cisplatin, 1.0 mg/ml (1,000ppm)..... | Up to 240 |
| Cyclophosphamide (Cytosan), 20 mg/ml (20,000ppm)..... | Up to 240 |
| Dacarbazine (DTIC), 10.0 mg/ml (10,000ppm)..... | Up to 240 |
| Doxorubicin Hydrochloride, 2.0 mg/ml (2,000ppm)..... | Up to 240 |
| Etoposide (Toposar), 20.0 mg/ml (20,000ppm)..... | Up to 240 |
| Paclitaxel (Taxol), 6.0 mg/ml (6,000ppm)..... | Up to 240 |
| Fluorouracil, 50.0 mg/ml (50,000ppm)..... | Up to 240 |
| Thiotepa, 10.0 mg/ml (10,000ppm)..... | 31.2 (31.2, 60.8, 61.3) |
| Vincristine Sulfate, 1.0 mg/ml (1,000ppm)..... | Up to 240 |

Please note that the following drugs have low permeation times:

Carmustine (BCNU) 30.6
Thiotepa 31.2

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.

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