May 1, 2020

YTY Industry (Manjung) Sdn Bhd
Punitha Samy
Senior Manager (YTY Group DCRA & YTY Industry QA)
Lot 1422-1424, Batu 10 Lekir
Sitiawan, Perak 32020
Malaysia

Re: K200453
Trade/Device Name: Non-Sterile, Powder Free Nitrile Examination Gloves, Low Dermatitis Potential, And Tested for use with Chemotherapy Drugs Blue; Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs and Fentanyl Citrate - Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 17, 2020
Received: February 24, 2020

Dear Punitha Samy:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K200453

Device Name

Non-Sterile, Powder Free Nitrile Examination Gloves, Low Dermatitis Potential, And Tested for use with Chemotherapy Drugs Blue

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs:

Blue

Tested Chemotherapy Drug And Concentration	Average Breakthrough Detection Time (minutes)
Carboplatin, 10 mg/ml	> 240 minutes
Carmustine, 3.3 mg/ml	11.3 minutes
Cisplatin (BCNU), 1.0 mg/ml	> 240 minutes
Cyclophosphamide (Cytoxan), 20.0 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
Ifosfamide, 50.0 mg/ml	> 240 minutes
Methotrexate, 25 mg/ml	> 240 minutes
Mitomycin C, 0.5 mg/ml	> 240 minutes
Mitoxantrone, 2 mg/ml	> 240 minutes
Paclitaxel (Taxol), 6.0 mg/ml	> 240 minutes
ThioTEPA, 10.0 mg/ml	7.4 minutes
Vincristine Sulfate, 1.0 mg/ml	> 240 minutes

The following chemotherapy drugs and concentration have extremely low permeation time.
Carmustine (3.3 mg/ml): 11.3 minutes ThioTEPA (10.0 mg/ml): 7.4 minutes

WARNING: NOT TO BE USED WITH CARMUSTINE OR THIOTEPA

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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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
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Indications for Use

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

510(k) Number *(if known)*
K200453

Device Name

Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs and Fentanyl Citrate - Blue

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs and Fentanyl Citrate:

Blue

Tested Chemotherapy Drug And Concentration	Average Breakthrough Detection Time (minutes)
Carboplatin, 10 mg/ml	> 240 minutes
Carmustine, 3.3 mg/ml	30.3 minutes
Cisplatin (BCNU), 1.0 mg/ml	> 240 minutes
Cyclophosphamide (Cytoxan), 20.0 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
Ifosfamide, 50.0 mg/ml	> 240 minutes
Methotrexate, 25 mg/ml	> 240 minutes
Mitomycin C, 0.5 mg/ml	> 240 minutes
Mitoxantrone, 2 mg/ml	> 240 minutes
Paclitaxel (Taxol), 6.0 mg/ml	> 240 minutes
ThioTEPA, 10.0 mg/ml	91.0 minutes
Vincristine Sulfate, 1.0 mg/ml	> 240 minutes
Busulfan, 6 mg/ml	> 240 minutes
Cytarabine, 100 mg/ml	> 240 minutes
Daunorubicin, 5 mg/ml	> 240 minutes
Docetaxel, 10 mg/ml	> 240 minutes
Epirubicin, 2 mg/ml	> 240 minutes
Gemcitabine, 38 mg/ml	> 240 minutes
Irinotecan Hydrochloride, 20 mg/ml	> 240 minutes
Mechlorethamine HCL, 1.0 mg/ml	> 240 minutes
Melphalan, 5 mg/ml	> 240 minutes
Trisenox, 0.1 mg/ml	> 240 minutes
Fentanyl Citrate, 100mcg/2ml	> 240 minutes

The following chemotherapy drugs and concentration have extremely low permeation time.
Carmustine (3.3 mg/ml): 30.3 minutes ThioTEPA (10.0 mg/ml): 91.0 minutes

CAUTION: CARMUSTINE (3.3 MG/ML) AND THIOTEPA (10 MG/ML) HAVE MUCH LOWER PERMEATION TIMES COMPARE TO OTHER CHEMOTHERAPY DRUGS

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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