September 9, 2024

Sri Trang Gloves (Thailand) Public Company Limited
M. Jordan Smith
Executive Director - Regulatory Affairs and Quality Assurance
110 Kanjanavanit Road
Hatyai, Songhkla 90230
Thailand

Re: K240266
Trade/Device Name: Latex Examination Glove Powder Free (Ocean Blue and Natural White)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYY, LZC, OPJ, QDO
Dated: August 4, 2024
Received: August 6, 2024

Dear M. Jordan Smith:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K240266

Device Name
Latex Examination Glove Powder Free (Ocean Blue and Natural White)

Indications for Use *(Describe)*
This device is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

The tested chemotherapy drugs and permeation times are as follows:

Bleomycin Sulfate 15 mg/mL, >240 minutes
Busulfan 6 mg/mL, >240 minutes
Carboplatin (Paraplatin) 10 mg/mL, >240 minutes
Carmustine (BCNU) 3.3 mg/mL, 1.9 minutes
Cisplatin 1.0 mg/mL, >240 minutes
Cyclophosphamide (Cytoxan) 20 mg/mL, >240 minutes
Cytarabine HCl 100 mg/mL, >240 minutes
Dacarbazine (DTIC) 10 mg/mL, >240 minutes
Daunorubicin HCl 5 mg/mL, >240 minutes
Docetaxel 20 mg/mL, >240 minutes
Doxorubicin Hydrochloride 2 mg/mL, >240 minutes
Epirubicin HCl (Ellence) 2 mg/mL, >240 minutes
Etoposide (Toposar) 20 mg/mL, >240 minutes
Fludarabine 25 mg/mL, >240 minutes
Fluorouracil 50 mg/mL, >240 minutes
Gemcitabine 38 mg/mL, >240 minutes
Idarubicin HCl 1 mg/mL, >240 minutes
Ifosfamide 50 mg/mL, >240 minutes
Irinotecan 20 mg/mL, >240 minutes
Mechlorethamine HCl 1 mg/mL, >240 minutes
Melphalan 5 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 mg/mL, >240 minutes
Rituximab 10 mg/mL, >240 minutes
Thiotepa 10 mg/mL, 3.7 minutes
Trisenox 1 mg/mL , >240 minutes
Vincristine Sulfate 1 mg/mL, >240 minutes

Fentanyl tested as follows:
Fentanyl citrate 100 mcg/2mL, >240 minutes

WARNING: Not for use 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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