March 26, 2022

KSG MEDICARE Sdn. Bhd.
% Wava Truscott
President
Truscott MedSci Associates, LLC
180 Burkemeade Ct.
Roswell, Georgia 30075

Re: K220215
Trade/Device Name: Powder Free Nitrile Examination Glove, Non-sterile, Tested for Use with Chemotherapy Drugs, and the Opioid Fentanyl citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ, QDO
Dated: January 23, 2022
Received: January 26, 2022

Dear Wava Truscott:

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,

Clarence W. Murray, III, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220215

Device Name
Powder Free Nitrile Examination Glove, Non-Sterile, Tested for Use with Chemotherapy Drugs, and the Opioid Fentanyl citrate, simulated Gastric Acid, and Fentanyl in Gastric Acid (Blue)

Indications for Use *(Describe)*

Intended for use: A Nitrile powder free examination glove is a disposable device intended for medical purposes, worn on the examiner's hand or finger to prevent contamination between examiner and patient. This specialty glove has also been tested for use with Chemotherapy Drugs and the Opioid Fentanyl citrate, simulated Gastric Acid and Fentanyl in Gastric Acid.

Gloves were tested for Permeation Breakthrough Resistance in accordance with ASTM D6978 testing with the Chemotherapy Drugs listed below		
Chemotherapy Drug	**Concentration Tested**	**Minimum Breakthrough Detection Time**
Carboplatin	10.0mg/ml	No breakthrough up to 240 minutes
Carmustine (BCNU)	3.3mg/ml	23.6 minutes
Cisplatin	10.0mg/ml	No breakthrough up to 240 minutes
Cytarabine HCL	100.0mg/ml	No breakthrough up to 240 minutes
Cyclophosphamide (Cytoxan)	20.0mg/ml	No breakthrough up to 240 minutes
Dacarbazine (DTIC)	10.0mg/ml	No breakthrough up to 240 minutes
Docetaxel	10.0mg/ml	No breakthrough up to 240 minutes
Doxorubicin Hydrochloride	2.0mg/ml	No breakthrough up to 240 minutes
Etoposide (Toposar)	20.0mg/ml	No breakthrough up to 240 minutes
Fluorouracil	50.0mg/ml	No breakthrough up to 240 minutes
Gemcitabine	38.0mg/ml	No breakthrough up to 240 minutes
Ifosfamide	50.0mg/ml	No breakthrough up to 240 minutes
Irinotecan	20.0mg/ml	No breakthrough up to 240 minutes
Mechlorethamine	1.0mg/ml	No breakthrough up to 240 minutes
Melphalan	5.0mg/ml	No breakthrough up to 240 minutes
Methotrexate	25.0mg/ml	No breakthrough up to 240 minutes
Mitomycin C	0.5mg/ml	No breakthrough up to 240 minutes
Mitoxantrone	2.0mg/ml	No breakthrough up to 240 minutes
Paclitaxel (Taxol)	6.0mg/ml	No breakthrough up to 240 minutes
ThioTepa	10.0mg/ml	57.8 minutes
Vincristine Sulfate	1.0mg/ml	No breakthrough up to 240 minutes

Important: Carmustine and ThioTepa have extremely low minimal breakthrough times of 23.6 minutes and 57.8 minutes respectively. **Warning:** Do not use with Carmustine or ThioTepa

Opioid Drug	**Concentration Tested**	**Minimum Breakthrough Detection Time**
Fentanyl citrate (injectable)	100mg/2ml	No breakthrough up to 240 minutes
Gastric Acid (simulated)	0.2%NaCl in 0.7 HCL	No breakthrough up to 240 minutes
Fentanyl in Gastric Acid	50/50 mix	No breakthrough up to 240 minutes

Please Note: Gloves used for protection against possible Chemotherapy Drug exposure should be selected specifically for the type of drugs used. Users should review the drug labeling or material data sheets for the drug being used to determine an adequate level of protection.

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.

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FORM FDA 3881 (6/20) Page 1 of 2 PSC Publishing Services (301) 443-6740 EF