November 14, 2023

Kossan International Sdn Bhd
Cho Sow Fong
Senior Manager Regulatory Affairs
Wisma Kossan, Lot 782, Jalan Sungai Putus, Off Batu 3 3/4,
Jalan Kapar
Klang, Selangor 42100
Malaysia

Re: K232461
Trade/Device Name: Powder Free Nitrile Examination Glove, Pink Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate; Powder Free Nitrile Examination Glove, Black Colored, Non-Sterile, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: August 11, 2023
Received: August 15, 2023

Dear Cho Sow Fong:

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.

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
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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.

Submission Number *(if known)*

K232461

Device Name

Powder Free Nitrile Examination Glove, Pink Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Examination Glove, Orange Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Examination Glove, Blue Colored, Non-Sterile, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.
Powder Free Nitrile Examination Glove, Black Colored, Non-Sterile, Low Dermatitis Potential, Tested for Use with Chemotherapy Drugs and Fentanyl Citrate.

Indications for Use *(Describe)*

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

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes			
	Pink	Orange	Blue	Black
Carmustine (BCNU) (3.3 mg/ml)	12.4	11.7	10.1	14.4
Cisplatin (1.0 mg/ml)	>240	>240	>240	>240
Cyclophosphamide (Cytoxan) (20.0 mg/ml)	>240	>240	>240	>240
Cytarabine(100 mg/ml)	>240	Not tested	>240	>240
Dacarbazine (DTIC) (10.0 mg/ml)	>240	>240	>240	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240	>240	>240	>240
Etoposide (20.0 mg/ml)	>240	>240	>240	>240
Fluorouracil (50.0 mg/ml)	>240	>240	>240	>240
Ifosfamide (50.0 mg/ml)	>240	Not Tested	>240	>240
Methotrexate (25.0 mg/ml)	>240	Not Tested	>240	>240
Mitomycin C (0.5 mg/ml)	>240	Not Tested	>240	>240
Mitoxantrone (2.0 mg/ml)	>240	Not Tested	>240	>240
Paclitaxel (Taxol) (6.0 mg/ml)	>240	>240	>240	>240
Thiotepa (10.0 mg/ml)	43.1	43.2	30.2	29.2
Vincristine Sulfate (1.0 mg/ml)	>240	Not Tested	>240	>240

Please note that Carmustine (BCNU) and Thiotepa has low permeation times.

Warning: Do Not Use with Carmustine (BCNU) and Thiotepa

Opioid Drug and Concentration	Minimum Breakthrough Detection Time in Minutes			
	Pink	Orange	Blue	Black
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	>240	>240
Xylazine HCl (100 mg/ml)	Not Tested	>240	>240	>240

Simulated Gastric Acid	Minimum Breakthrough Detection Time in Minutes			
	Pink	Orange	Blue	Black
Simulated Gastric Acid	>240	>240	>240	>240

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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."