March 15, 2023

Kossan International Sdn Bhd3
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: K223375
Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue 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, OPJ, QDO
Dated: January 31, 2023
Received: February 2, 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 (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,

Bifeng Qian -S

Bifeng Qian, M.D., Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223375

Device Name
Powder Free Nitrile Patient Examination Glove, Blue 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
Bendamustine HCI (Treanda) (5 mg/ml)	>240
Bleomycin Sulfate (15 mg/ml)	>240
Busulfan (6 mg/ml)	>240
Carboplatin (10 mg/ml)	>240
Carfilzomib (2 mg/ml)	>240
Carmustine (BCNU) (3.3 mg/ml)	26.2
Cetuximab (Erbitux) (2 mg/ml)	>240
Cisplatin (1 mg/ml)	>240
Cladribine (1 mg/ml)	>240
Cyclosporin A (100 mg/ml)	>240
Cyclophosphamide (Cytoxan) (20 mg/ml)	>240
Cytarabine (100 mg/ml)	>240
Cytovene (Ganciclovir) (10 mg/ml)	>240
Dacarbazine (DTIC) (10 mg/ml)	>240
Daunorubicin HCI (5 mg/ml)	>240
Decitabine (5 mg/ml)	>240
Docetaxel (Taxotere) (20 mg/ml)	>240
Doxorubicin Hydrochloride (2 mg/ml)	>240
Epirubicin HCI (Ellence) (2 mg/ml)	>240
Etoposide (20 mg/ml)	>240
Fludarabine (25 mg/ml)	>240
Fluorouracil (50 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Idarubicin HCI (1 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mechlorethamine HCI (1 mg/ml)	>240
Melphalan (5 mg/ml)	>240
Methotrexate (25 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Mitoxantrone (2 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Paclitaxel (Taxol) (6 mg/ml)	>240
Pemetrexed (25 mg/ml)	>240
Raltitrexed (0.5 mg/ml)	>240

Retrovir (Zidovudine) (10 mg/ml)	>240
Rituximab (10 mg/ml)	>240
Thiotepa (10 mg/ml)	59.1
Topotecan (1 mg/ml)	>240
Trisenox (Arsenic Trioxide) (1 mg/ml)	>240
Velcade (Bortezomib) (1 mg/ml)	>240
Vidaza (Azacytidine) (25 mg/ml)	>240
Vinblastine (1 mg/ml)	>240
Vincristine Sulfate (1 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240
Zoledronic Acid (1 mg/25ml)	>240

Please note that Carmustine (BCNU) and Thiotepa has low permeation times of 26.2 and 59.1 minutes respectively.
Warning: Do Not Use with Carmustine (BCNU)
Caution: Thiotepa has low permeation times of 59.1 minutes

Opioid and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

Simulated Gastric Acid Fluid	Minimum Breakthrough Detection Time in Minutes
Simulated Gastric Acid Fluid	>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.

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