



January 28, 2022

Shen Wei USA Inc.
Cheryl Reep
Compliance Director
33278 Central Ave Ste 102
Union City, California 94587

Re: K213142

Trade/Device Name: Biodegradable Powder Free Flock-Lined Nitrile Examination Glove, Black and Gray Colors, Tested for use with Chemotherapy drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl Citrate Simulated Gastric Acid Solution

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I, reserved

Product Code: LZA, LZC, QDO

Dated: December 20, 2021

Received: January 5, 2022

Dear Cheryl Reep:

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, 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

510(k) Number (if known)

K213142

Device Name

Biodegradable Powder Free Flock-Lined Nitrile Examination Glove, Black and Gray Colors, Tested for use with Chemotherapy drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl Citrate-Simulated Gastric Acid Solution

Indications for Use (Describe)

Biodegradable Powder Free Flock-Lined Nitrile Examination Glove, Black and Gray Colors, Tested for use with Chemotherapy drugs, Fentanyl Citrate, Simulated Gastric Acid and Fentanyl Citrate-Simulated Gastric Acid Solution is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

Breakthrough times per ASTM D6978-05 (2019)

Chemotherapy Drug and Concentration	Black Color	Gray Color
Carmustine (BCNU), 3.3mg/ml	84.3mins	54mins
Cisplatin, 1.0mg/ml	>240mins	>240mins
Cyclophosphamide (Cytoxan), 20mg/ml	>240mins	>240mins
Dacarbazine (DTIC), 10mg/ml	>240mins	>240mins
Doxorubicin Hydrochloride, 2.0mg/ml	>240mins	>240mins
Etoposide (Toposar), 20mg/ml	>240mins	>240mins
Fluorouracil, 50mg/ml	>240mins	>240mins
Paclitaxel (Taxol), 6.0mg/ml	>240mins	>240mins
Thiotepa, 10mg/ml	116.2mins	109.4mins
Fentanyl Citrate, 100mcg/2ml	>240mins	>240mins
Simulated Gastric Acid	>240mins	>240mins
Fentanyl-Simulated Gastric Acid Solution 50/50	>240mins	>240mins

CAUTION: Testing showed an average breakthrough time for Carmustine at 84.3minutes and 54minutes, Thiotepa at 116.2 minutes and 109.4 minutes.

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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