June 24, 2026

SW Technologies, Inc.
Michael Van Sunder
Vice President of Commercial Development
33278 Central Ave.
Suite 102
Union City, California 94587

Re: K252117
Trade/Device Name: Biodegradable Powder Free Nitrile Examination Glove, Blue Color, 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, OPJ, QDO
Dated: June 24, 2026
Received: June 24, 2026

Dear Michael Van Sunder:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252117

Device Name
Biodegradable Powder Free Nitrile Examination Glove, Blue Color, Tested for use with Chemotherapy drugs, Fentanyl Citrate , Simulated Gastric Acid and Fentanyl Citrate-Simulated Gastric Acid Solution

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

Chemotherapy Drug and Concentration	Breakthrough times in minutes per ASTM D6978-05 (2019)
Carmustine (BCNU), 3.3mg/ml	86.3
Cisplatin, 1.0mg/ml	>240
Cyclophosphamide (Cytoxan), 20mg/ml	>240
Dacarbazine (DTIC) 10g mg/ml	>240
Doxorubicin Hydrochloride, 2.0 mg/ml	>240
Etoposide (Toposar), 20mg/ml	>240
Fluorouracil 50mg/ml	>240
Paclitaxel (Taxol), 6.0mg/ml	>240
Thiotepa, 10mg/ml	89.3
Bleomycin Sulfate,15 mg/ml (15,000 ppm)	>240
Busulfan,6 mg/ml (6,000 ppm)	>240
Carboplatin,10 mg/ml (10,000 ppm)	>240
Cytarabine,100 mg/ml (100,000 ppm)	>240
Daunorubicin HCI,5 mg/ml (5,000 ppm)	>240
Docetaxel HCI,10 mg/ml (10,000 ppm)	>240
Epirubicin HCI (Ellence),2 mg/ml (2,000 ppm)	>240
Fludarabine Phosphate,25 mg/ml (25,000 ppm)	>240
Gemcitabine HCI,38 mg/ml (38,000 ppm)	>240
Idarubicin HCI,1 mg/ml (1,000 ppm)	>240
Mechlorethamine HCI,1 mg/ml (1,000 ppm)	>240
Melphalan HCI,5 mg/ml (5,000 ppm)	>240
Methotrexate,25 mg/ml (25,000 ppm)	>240
Mitomycin C,0.5 mg/ml (500 ppm)	>240
Mitoxantrone HCI,2 mg/ml (2,000 ppm)	>240
Oxaliplatin,2 mg/ml (2,000 ppm)	>240
Rituximab,10 mg/ml (10,000 ppm)	>240
Trisenox (Arsenic Trioxide), 1 mg/ml (1,000 ppm)	>240
Vincristine Sulfate,1 mg/ml (1,000 ppm)	>240
Vinorelbine,10 mg/ml (10,000 ppm)	>240
Ifosfamide (50.0 mg/ml)	>240
lrinotecan (20.0 mg/ml)	>240
Fentanyl Citrate 100mcg/2ml	>240
Simulated Gastric Acid	>240
Fentanyl-Simulated Gastric Acid Solution 50/50	>240

Caution: Please note low permeation times for Carmustine at 86.3 minutes and Thiotepa at 89.3 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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