



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 24, 2017

Shen Wei Usa Inc.
Cheryl Reep
Compliance Manager
33278 Central Ave. Suite 102
Union City, California 94587

Re: K170290

Trade/Device Name: Powder Free Nitrile Exam Glove with pH Coating, White (Outer)-
Black (Inner) Color, Tested For Use With Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: May 10, 2017
Received: May 10, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Lori A. Wiggins -S

for
Tina Kiang, Ph.D.
Acting Division Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K 170290

Device Name

Powder-Free Nitrile Examination Glove with pH coating, White (Outer)-Black (Inner) Color (Tested For Use With Chemotherapy Drugs)

Indications for Use (Describe)

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination in between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Glove to Permeation by Chemotherapy Drugs:

Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves.

Chemotherapy Drug and Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU), 3.3mg/ml	27.8
Cisplatin, 1.0mg/ml	>240
Cyclophosphamide (Cytosan), 20mg/ml	>240
Cyclosporin A, 100 mg/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	77.9
Vincristine Sulfate, 1.0mg/ml	>240

Please note that the following drug has extremely low permeation times: Carmustine (BCNU): 27.8 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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