DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 17, 2016

Shen Wei (USA), Inc.
% Ms. Cheryl Bailey-Kroll
Compliance Manager
33278 Central Ave.
Suite 102
Union City, California 94587

Re: K161074
Trade/Device Name: Powder Free Nitrile Examination Gloves Flock-Lined, Black Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: October 12, 2016
Received: October 18, 2016

Dear Cheryl Bailey-Kroll,

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 yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161074

Device Name
Powder-Free Nitrile Examination Glove Flock-Lined, Black Color

Indications for Use *(Describe)*
Powder-Free Nitrile Examination Glove Flock-Lined, Black Color is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.

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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Attachment One

Shen Wei USA Inc.
33278 Central Ave. Suite 102
Union City, CA 94587

510(k) Summary

1.0 Submitter:

Name:	Shen Wei USA Inc.
Address:	33278 Central Ave. Suite 102 Union City, CA. 94587
FDA Est Reg#:	2939388
Phone No:	510-429-8692
Fax No:	510-487-5347

Manufacturer:

Name:	ZHANGJIAGANG DAYU RUBBER PRODUCTS CO., LTD
Address:	XIZHANG TOWN ZHANGJIAGANG CITY, CHINA 215614
FDA Est Reg#:	1000254914
Phone No:	520-845-0023
Fax No:	520-845-0311

Date 510k Summary was prepared: October 10, 2016

2.0 Contact Person:

Name:	Cheryl Reep
Phone No:	510-429-8692
Fax No:	510-487-5347
Email:	Creep@shenweiusa.com

3.0 Name of the device:

Trade Name:	Powder Free Nitrile Examination Gloves Flock-Lined, Black Color
Device Name:	Powder Free Nitrile Examination Gloves Flock-Lined, Black Color
Common Name:	Patient Examination Gloves
Classification Name:	Patient examination glove
Device Class:	Class 1
Regulation Number:	21 CFR 880.6250
Product Code:	80 LZA

4.0 Predicate Device Information:

Device Name: Non Sterile, Powder Free Nitrile Examination Glove, Blue with Polymer Coating
Company Name: Siam Sempermed Corp. Ltd.
510K Number: K070639

5.0 Description of the Device:

Powder Free Nitrile Examination Gloves Flock-Lined, Black Color Non-Sterile, is a disposable device intended for

medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only. The gloves are lined with cotton flock, ambidextrous with beaded cuff, black colored, single use disposable devices that comes is six sizes (XS, S, M, L, and XL) supplied in non-sterile state.

The gloves are made of synthetic rubber, designed and manufactured in accordance with ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application. Its physical and performance characteristics meet all requirements of ASTM D6319-10. Powder was not used for this glove's manufacturing process.

6.0 Labeling and Intended Use of the Device:

The Powder Free Nitrile Examination Gloves Flock-Lined, Black Color is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.

7.0 Shelf Life or Expiration Data: Not Applicable

8.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves Flock-Lined, Black Color is summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	ASTM D6319-10	Meets
Physical Properties (Before/After Aging)	ASTM D6319-10	Meets
Freedom from pinholes	ASTM D6319-10 / ASTM D5151-11	Meets
Powder Residual	ASTM D6319-10	Meets <2mg/glove
Biocompatibility	ISO 10993-10:2010: i. Primary Skin Irritation in Rabbits	i. Not a primary skin irritant
	ii. Dermal Sensitization	ii. Not a contact sensitizer

9.0 Device Interior Lining and Manufacturing Process:

The Powder Free Nitrile Examination Gloves Flock-Lined, Black Color is sprayed with a white cotton flock on the interior of the glove to help facilitate donning.

10.0 Substantial Equivalence Based On Assessment of Non-Clinical Performance Data

Comparison to Predicate- The subject device Powder Free Nitrile Examination Gloves Flock-Lined, Black Color compares favorably to the predicate device, Non Sterile, Powder Free Nitrile Examination Glove, Blue with Polymer Coating, as indicated in the tabulated summary below:

Substantial Equivalence Comparison Table

Characteristics	Predicate Device	Proposed New Device	Comments
Name	Non Sterile, Powder Free Nitrile Examination Glove, Blue with Polymer Coating	Powder Free Nitrile Examination Gloves Flock-Lined, Black Color	N/A
510K Number	K070639	K161074	N/A
Company	Siam Sempermed Corp. Ltd.	Shen Wei USA Inc.	N/A

Device Description/ Regulation Number	Patient examination glove / 21 CFR 880.6250	Patient examination glove / 21 CFR 880.6250	Substantially Equivalent
Product Code	LZA	LZA	Substantially Equivalent
Intended use	Intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is for over-the counter use.	Intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.	Substantially Equivalent
Instruction for Use	A disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.	A disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only.	Substantially Equivalent
Non-Sterile	Non-Sterile	Non-Sterile	Substantially Equivalent
Materials	Nitrile	Nitrile	Substantially Equivalent
Color	Blue	Black	Difference
Design	Ambidextrous in different sizes per ASTM 6319-10-dimension requirement	Ambidextrous in different sizes per ASTM 6319-10-dimension requirement	Substantially Equivalent
Lining / Coating	Polymer Coating	Flock Lining	Difference
Single Patient Use	Single Patient Use	Single Patient Use	Substantially Equivalent
Performance:	Meets ASTM D6319-10	Meets ASTM D6319-10	Substantially Equivalent
I. Freedom from Holes			
II. Dimension			
III. Physical Properties			
IV. Powder Residue			
Single Use	Yes	Yes	Substantially Equivalent
Biocompatibility Test	Passes: i. Primary Skin Irritation Test ii. Dermal Sensitization Test	Passes: i. Not a primary skin irritant ii. Not a contact sensitizer	Substantially Equivalent

Summary of Difference and Comparison of Safety and Effectiveness- The subject device differs from the predicate in that:

1) The subject device is color Black while the predicate device is color Blue. Difference in color does not affect subject device's safety and effectiveness; subject device was tested and met requirements for Biocompatibility and ASTM standards.
2) The subject device is manufactured with the inner surface coated or lined with flock to facilitate donning. The predicate device is manufactured with the inner surface coated with polymer to assist in donning. Though the materials of construction differ, the subject device's material is functionally equivalent to those of the cited predicate.

11. Summary of Clinical Testing: Not applicable. No clinical testing was performed.

12. Conclusion: The conclusion drawn from the nonclinical test demonstrate that the subject device, Powder Free Nitrile Examination Gloves Flock-Lined, Black Color, is as safe, as effective, and performs as well as the legally marketed device.