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

July 25, 2017

Shen Wei USA Inc.
Cheryl Bailey-Kroll
Compliance Manager
33278 Central Ave
Ste 102
Union City, California 94587

Re: K162312
Trade/Device Name: Biodegradable Powder Free Nitrile Exam Gloves With Aloe Vera, Green Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 20, 2017
Received: July 21, 2017

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,

Tara A. Ryan -S

for
Lori Wiggins, MPT, CLT
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)*

K162312

Device Name
Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color

Indications for Use *(Describe)*
The Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510K# K162312 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

Manufacturers:

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

Name:	ZHENJIANG SUHUI LATEX PRODUCTS CO.LTD.
Address:	LIANHE CHUN, YANGZHONG CITY, JIANGSU 212212, CHINA
FDA Est Reg#:	9615498

Name:	NINGXIA MARVISUN RUBBER & PLASTIC PRODUCTS CO., LTD.
Address:	WORKSHOP UNIT 21 & 27, MID. & SML. SZ. ENT. DEVELOPMENT PARK, NINGXIA HIGH-TECH DEVELOPMENT ZONE YINCHUAN, NINGXIA, Area II, CHINA
FDA Est Reg#:	3008932202

Date 510k Summary was prepared 07/20/17

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:	Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color
Device Name:	Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color
Common Name:	Patient Examination Gloves
Classification Name:	Patient examination glove
Device Class:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA

4.0 Predicate Device Information:

The predicate device is K993876, POWDER-FREE NITRILE EXAMINATION GLOVES WITH ALOE VERA GREEN, approved on 2/7/2000. Class I Powder Free Nitrile Examination gloves, 80LZA, which meets all requirements of ASTM D 6319-10 and FDA 21 CFR 800.20.

5.0 Description of the Device:

Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green 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 coated with Aloe Vera, ambidextrous with beaded cuff, green colored, single use disposable devices that comes in six sizes (XS, S, M, L, XL and XXL) supplied in non-sterile state. The gloves are powder free and are manufactured using online chlorination process to avoid sticky surface and obtain good donning properties.

The gloves are made of Nitrile Butadiene 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.

6.0 Intended Use of the Device:

The Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green 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: Glove's shelf life is 3 years.

8.0 Summary of the Technological Characteristics of the Device:

The Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color is summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	ASTM D6319-10	Meets Standard Requirements
Physical Properties (Before/After Aging)	ASTM D6319-10	Meets Standard Requirements
Freedom from pinholes	ASTM D6319-10 / ASTM D5151-11	Meets Standard Requirements
Biocompatibility	ISO 10993-10:2010:	Not a skin irritant under the conditions of study.
	i. Primary Skin Irritation in Rabbits	
	ii. Dermal Sensitization	Not a contact sensitizer under the conditions of the study.

9.0 Discussion of Similarities and Differences

The table below shows similarities and differences between the predicate device and the proposed new device.

Characteristics	Predicate Device	Proposed New Device
Name	K993876, Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color	Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color

Device Description/ Regulation Number	Patient examination glove / 21 CFR 880.6250	Patient examination glove / 21 CFR 880.6250
Product Code	LZA	LZA
Intended use	Intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	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.
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 not intended to be used as a chemical barrier.	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.
Materials	Nitrile	Nitrile
Color / Coating	Green / Aloe Vera	Green / Aloe Vera
Design	Ambidextrous in different sizes per ASTM 6319-00 dimensions' requirement	SAME
Biodegradation Properties	None	Biodegradable, Difference
Performance:		
I. Freedom from Holes	Meets ASTM D6319-00	Meets Standard Requirements
II. Dimension	Meets ASTM D6319-00	Meets Standard Requirements
III. Physical Properties	Meets ASTM D6319-00	Meets Standard Requirements
IV. Powder Residue	Meets < 2mg/glove	Meets Standard Requirements < 2mg/glove
Single Use	Yes	Yes
Biocompatibility Test	i Not a primary skin irritant ii. Not a contact sensitizer	Not a primary skin irritant nor a contact sensitizer under the conditions of study.

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

- The subject device has biodegradation property within landfills tested per ASTM D5526-94 while the predicate device does not have same technological feature. The difference in biodegradation properties does not affect the subject device's safety and effectiveness; subject device met the requirements for Biocompatibility Testing and ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application. The difference in technological feature does not change the performance or affect the intended use of the device.

- Biodegradability is not a medical claim and therefore was not reviewed by FDA.

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

11.0 Conclusion: The conclusion drawn from the non-clinical test demonstrate that the subject device, Biodegradable Powder Free Nitrile Exam Gloves with Aloe Vera, Green Color, is as safe, as effective, and performs as well as the legally marketed device.