K121528

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33278 Central Ave., #102
Union City, CA 94587, USA
T. 510.429.8692
F. 510.487.5347
TOLL FREE.1.888.988.8788

510(k) Summary

SEP 11 2012

1.0 Submitter/ 510(k) Owner:

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

Manufacturer:

Name:	ZHANGJIAGANG JIAMEI RUBBER PRODUCTS CO., LTD
Address:	FENGHUANG TOWN, ZHANGJIAGANG CITY, CHINA 215614
Phone No:	520-845-0023
Fax No:	520-845-0311

Date 510k Summary was prepared: August 7th, 2012

2.0 Contact Person:

Name:	Albert Li
Phone No:	510-429-8692
Fax No:	510-487-5347

3.0 Name of the device:

Trade Name:	Powder-Free Blue Nitrile Examination Gloves Peppermint Scented
Device Name:	Powder-Free Blue Nitrile Examination Gloves Peppermint Scented
Common Name:	Patient Examination Gloves
Classification Name:	Patient examination glove (21 CFR 880.6250, Product Code FMC)
Product Code:	Nitrile -80LZA

4.0 Predicate Device Information:

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The predicate device is K090194, Powder-Free Nitrile Examination Gloves, Black Color, 07/07/2009. Class I Powder Free Nitrile Examination gloves, 80LZA, that meets all requirements of ASTM D 6319-10 and FDA 21 CFR 800.20.

5.0 Description of The Device:

The Powder-Free Blue Nitrile Examination Gloves Peppermint Scented meets all requirements of ASTM D 6319-10 and FDA 21 CFR 800.20. The device is made out of nitrile.

6.0 Labeling and Intended Use of the Device:

Draft labels for Powder-Free Blue Nitrile Examination Gloves Peppermint Scented, can be found in Attachment 3.

The Powder-Free Nitrile Examination Gloves, Peppermint Scented, Blue 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. Indication for Use Statement can be found in Attachment 4.

7.0 Summary of the Technological Characteristics of the Device

The Powder-Free Blue Nitrile Examination Gloves Peppermint Scented, are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	ASTM D6319-10	Meets
Physical Properties	ASTM D6319-10	Meets
Freedom from pinholes	ASTM D6319-10 FDA 21 CFR 800.20	Meets, AQL 2.5
Powder-Free	ASTM D 6124-06	Meets < 2mg/glove
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
	Dermal Sensitization	Passes (Not a contact sensitizer)

The test methods used are the same as those submitted in the original submission.

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned in section 7.0. A summary of the

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non-clinical performance data showing substantial equivalence to predicate device is presented in the table below:

Comparison with Predicate Device

Characteristic and Parameters	**Powder-Free Nitrile Examination Gloves, Blue with Peppermint Scent (New Device)**	**Powder-Free Nitrile Examination Gloves, Black Color (K090194 -Predicate)**	Substantial Equivalence (SE)
Product Code	80 LZA	80 LZA	SE
Color:	Blue	Black	SE
Compound:	Nitrile	Nitrile	SE
Labeling	See Attachment 2 (new)	See Attachment 2 (predicate)	SE
Intended 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.	SE
Width (Medium)	95 mm	95 mm	SE
Length	240 mm	240 mm	SE
Single Palm Thickness	0.09 mm	0.09 mm	SE
Single Finger Thickness	0.10 mm	0.10 mm	SE
Single Cuff Thickness	0.08 mm	0.08 mm	SE
Tensile strength pre-aging (ASTM D412)	25 MPa	25 MPa	SE
Tensile strength after aging (ASTM D412)	25 MPa	25 MPa	SE
Water Leak Testing (ASTM D5151)	Water Leakage checked to AQL 2.5	Water Leakage checked to AQL 2.5	SE
Ultimate elongation pre-aging (ASTM D412)	592%	570%	SE

Ultimate elongation after aging (ASTM D412)	572%	577%	SE
Skin Irritation Test	Pass	Pass	SE
Dermal Sensitization	Pass	Pass	SE
Residual Powder (ASTM D6124)	< 2mg/glove	< 2mg/glove	SE

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves.

10.0 Conclusion:

The Powder-Free Blue Nitrile Examination Gloves Peppermint Scented, will perform according the glove performance standards referenced in section 7.0 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Also, this device is substantial equivalent in safety and performance to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Albert Li
Director of Special Projects & Compliance
Shen Wei USA, Incorporated
33278 Central Avenue, Suite 102
Union City, California 94587

SEP 11 2012

Re: K121528
Trade/Device Name: Powder-Free Nitrile Examination Gloves, Peppermint Scented, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 20, 2012
Received: July 25, 2012

Dear Mr. Li:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

For

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment Two

INDICATION FOR USE

Applicant: Shen Wei (USA) Inc.

Device Name: Powder-Free Nitrile Examination Gloves, Peppermint Scented, Blue Color

Indication 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**.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR **Over-The Counter** ___X___
Per 21CFR 801.109 (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121528