K113233

MAR 2 9 2012

510(k) SUMMARY

1.0 Submitter

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

Date of Summary Prepared: 12/29/2010

Name and Location of Actual Manufacturers:

Name	**Zhenjiang Kangda Emulsion Co., Ltd.**
Address	**Lianhe Town, Yangzhong City, Zhenjiang**
Country	**China**
Phone No.	**(511)551-1390**
Fax No.	**(511)832-2861**

Name:	**Zhengjiagang Dayu Rubber Products CO., LTD.**
Address	**Xizhang Town, Zhangjiagang City, Jiangsu**
Country	**China**
Phone No.	**520-945-0023**
Fax No.	**520-845-0311**

2.0 Contact Person:

Name:	Mr. Albert T Li
Phone No.	(510)429-8692
Fax No.	(510)487-5347

3.0 Device Identification:

Glove Proprietary or Trade Name: Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less)
Common Name: Surgical Gloves
Classification Name: Surgeon's gloves - 21 CFR 878.4460
Predicate Device: K063757 Motex Powder-Free Surgical Gloves and Powdered Latex surgical Gloves

4.0 Identification of the Legally Marketed Device or Predicate Devices:

Class 1 Powder Free, Powdered natural rubber latex Surgeon's gloves, 79KG0, this surgical glove described in this 510(k) is substantially equivalent to K063757.

5.0 Description of the Device:

The Surgical Glove is made of all natural rubber, sterile, and powdered with USP absorbable dusting powder and contains less than 50 micrograms or less of protein content.

6.0 Intended Use of Device:

A powdered surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

A powder-free surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

7.0 Summary of Technological Characteristics for Modified Device:

The Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less) are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	ASTM D 3577-09e1	Meets
Physical Properties	ASTM D 3577-09e1	Meets
Freedom from pinholes	ASTM D 3577-09e1	Meets
Powder Residual	ASTM D 6124-06	Meets
Protein Level	ASTM D 5712-10	Meets
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
Biocompatibility	Dermal Sensitization	Passes (Not a primary skin irritant)
Sterilization Validation	ISO 11137-2:2006	Meets

8.0 Sterility:

Name of Sterilization Company: Yangzhou Irradiation Processing Center
Address: No. 568, yangzijiang North Road, Yangzhou, China
Phone Number: 086-514-87300601

The Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less) are sterilized using 25 Kilograys of Gamma Radiation and have a Sterility Assurance Level (SAL) of 10-6.

The sterilization cycle has been validated according to ISO 11137-2:2006 method.

9.0 Packaging and Labeling:

The Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less) are packaged in sterilization pouches that are paper bags or paper/plastic bags and sealed and packaged into an outer carton. The entire carton is then sterilized by Gamma radiation specified in section 9.0. View **Attachment 3** for labeling details.

10.0 Conclusion:

The Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less) will perform according to the glove performance standards reference in section 7 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices such as K063757.

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
Project Manager
Shen Wei (USA) Inc.
33278 Central Ave. Suite 102
Union City, California 94587

MAR 2 9 2012

Re: K113233
Trade/Device Name: Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less)
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: March 13, 2012
Received: March 15, 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment Two

INDICATION FOR USE

Applicant: Shen Wei (USA) Inc.

Device Name: Powdered Latex Surgical Gloves Sterile; Powder Free Latex Surgical Gloves, Sterile with Protein Content Labeling Claim (50 micrograms or less)

Indication For Use:

A powdered surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

A powder-free surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Elizabeth F. Claxton Wilson

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

510(k) Number: K113233