K101436

510(k) SUMMARY

NOV 17 2010

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: 08/12/10
Prepared by: Albert Li

2.0 Name of the device:

Glove Proprietary or Trade Name: Blue and Red with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs

Common Name: Exam gloves
Classification Name: Patient examination glove, Specialty Chemotherapy (per 21 CFR 880.6250 product code LZC)
Classification Information: Class I Nitrile patient examination glove 80LZC, powder-free and meeting all the requirements of ASTM D 6319-00a-05 and is tested with chemotherapy drugs according to ASTM D 6978-05.

3.0 Identification of the Legally Marketed Device:

Blue and Red with Pearlescent® Pigment, Powder Free
Nitrile Examination Gloves with Aloe Vera
Regulatory Class I Nitrile patient examination
Product code: 80LZA
510(k): K092411

4.0 Description of the Device:

Blue and Red with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs meets all the requirements of ASTM D 6978-05, ASTM D6319-00a(2005) and FDA 21 CFT 880.6250.

5.0 Intended Use of Device:

Product: Red with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs
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. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows (Fluorouracil, Etoposide, Cyclophosphamide, Carmustine,

Thio-Tepa, Paclitaxel, Doxorubicin Hydrochloride, Dacarbazine, Cisplatin)

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes. The following chemicals have been tested with these gloves.	
Cyclophosphamide	>240
Doxorubicin HCl (Adriamycin)	>240
***Carmustine**	**0.68**
Etoposide	>240
Fluorouracil (Adrucil)	>240
Paclitaxel (Taxol)	>240
***ThioTEPA**	**34.21**
Dacarbazine	>240
Cisplatin	>240

Please note that the following drug have extremely low permeation times of less than 30 minutes, Carmustine has an average breakthrough time of 0.68 minutes.

Please note that the following drug have extremely low permeation times of less than 60 minutes, Thiotepa has an average breakthrough time of 34.21 minutes.

5.1 Intended Use of Device:

Product: Blue with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs
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. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows (Fluorouracil, Etoposide, Cyclophosphamide, Carmustine, Thio-Tepa, Paclitaxel, Doxorubicin Hydrochloride, Dacarbazine, Cisplatin)

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes. The following chemicals have been tested with these gloves.	
Cyclophosphamide	>240
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Paclitaxel (Taxol)	>240
***ThioTEPA**	**27.17**
Dacarbazine	>240
Cisplatin	>240

Please note that the following drugs have extremely low permeation times of less than 30 minutes, Carmustine has an average breakthrough time of 2.10 minutes. Thiotepa has an average breakthrough time of 27.17 minutes.

6.0 Summary of Technological Characteristics for Modified Device:

Blue and Red with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standards	Device Performance
Dimensions	ASTM D 6319-00a05	Meets
Physical Properties	ASTM D 6319-00a05	Meets
Freedom from pinholes	ASTM D 5151-06	Meets (AQL 2.5)
Powder Residual	ASTM D 6124-06	Meets (<2mg/glove)
Biocompatibility	Primary Skin Irritation in Rabbits	Passes (Not a primary skin irritant)
Biocompatibility	Dermal Sensitization	Passes (Not a primary skin irritant)
Resistance to permeation by Chemotherapy Drugs	ASTM D6978-05	Meets

All other characteristics including appearance, thickness, material, physical properties are equivalent to the predicate device. This 510(k) submission is to seek approval for the device to be marketed with the ASTM D6978-05 claim on resistance to permeation by chemotherapy drugs.

7.0 Substantial Equivalence Discussion:

Characteristic and parameters	Shen Wei USA INC. (New Device)	Shen Wei USA INC. K032024	Substantial Equivalence (SE)
Product Code	LZA	LZA	
Indented 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. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows (Fluorouracil, Etoposide, Cyclophosphamide, Carmustine, Thio-	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. (Tested for use with chemotherapy drugs).	SE

	Tepa, Paclitaxel, Doxorubicin Hydrochloride, Dacarbazine, Cisplatin)		
Width (size Medium)	95mm	95mm	SE
Overall Length	240mm	240mm	SE
Palm Thickness	0.19mm	0.19mm	SE
Finger Thickness	0.21mm	0.21mm	
Tensile strength pre-aging min	19 MPa	19 MPa	
Tensile strength after aging min	20 MPa	20 MPa	
Ultimate elongation pre-aging min.	550%	550%	
Ultimate elongation after aging min	550%	550%	
Meets Biocompatibility	YES	YES	SE
Skin irritation test	Passes	Passes	
Dermal sensitization	Passes	Passes	

8.0 Conclusion:

Blue and Red with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs 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.

Albert Li,
Project Manager

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), Incorporated
33278 Central Avenue, Suite 102
Union City, California 94587

NOV 17 2010

Re: K101436
Trade/Device Name: Red & Blue with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Labeling Claims
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA / LZC
Dated: October 18, 2010
Received: October 28, 2010

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.

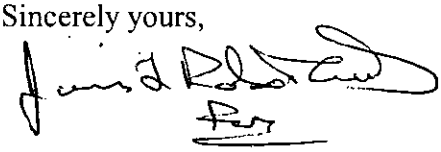
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

K101436

INDICATION FOR USE

NOV 17 2010

Applicant: Shen Wei (USA) Inc.

Device Name: Blue with Pearlescent® Pigment, Powder Free Nitrile Examination Gloves with Aloe Vera, Tested for use with Chemotherapy Drugs

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Elaine S. Maykall for SEC

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
(Optional Format 1-2-96)

Prescription Use _____ **OR** **Over-The Counter** X

Per 21CFR 801.109

510(k) Number: K101436

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INDICATION FOR USE

NOV 1 / 2010

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Concurrence of CDRH Office of Device Evaluation (ODE)

Elaine S. Marshall

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

(Optional Format 3-12-98)

Prescription Use _____ **OR** **Over-The-Counter Use** X

Per 21CFR 801.109

510(k) Number: K101436