K122396

JAN 31 2013

Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Wealth On (Jiangsu) Co., Ltd
Dongyuan Village, Hengji Town, Jianhu County
Yancheng, Jiangsu Province, China
Tel: 86- 21-33517339
Submitter's FDA Registration Number: 3009307502

US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
5 Carey Street
Pennington, NJ 08534
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Date of Summary: June, 2012

Device Name:	
Proprietary Name:	Powdered Vinyl Patient Examination Glove, Clear (non-colored) (or other clients private labeling)
Common Name:	Patient examination glove
Classification Name:	Patient examination glove
Device Classification:	I
Regulation Number:	21 CFR 880.6250
Panel: General	Hospital
Product Code:	LYZ

Predicate Device Information:

(1) K081657, "Powdered Vinyl Patient Examination Gloves, Light Yellow", manufactured by *"Jiangsu Cureguard Glove Co., Ltd."*
(2) K110219, "Powder Free Vinyl Patient Examination Gloves", manufactured by *"Wealth on (Jiangsu) Co., Ltd. (our own company)."*

Device description:

Powdered vinyl patient examination gloves, clear (non-colored) are made of polyvinyl chloride, and are non sterile that meets all of the requirements of ASTM standard D

5250-06, except for sterility requirements. The powder is made from cornstarch. The gloves are color free.

Indications for Use:
The powdered vinyl patient examination glove, clear (non-colored), is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The powder is made from cornstarch. It is color free and is sold as non sterile.

Comparison to Predicate Devices
The powdered vinyl patient examination gloves, clear (non-colored), non sterile are compared with the following Predicate Devices in terms of in terms of these three areas: Indications for Use/Design/Material, Performance, and Labeling.

(1) K081657, "Powdered Vinyl Patient Examination Gloves, Light Yellow", manufactured by *"Jiangsu Cureguard Glove Co., Ltd."*
(2) K110219, "Powder Free Vinyl Patient Examination Gloves", manufactured by *"Wealth on (Jiangsu) Co., Ltd. (our own company)."*

Substantial equivalence is established with respect to intended use, Labeling, performance, design, materials, and other applicable characteristics. Side-by-side comparison tables that include the following four areas are provided below:

A: Indication for Use
B: Labeling (labels, instructions for use, promotional material) for the legally marketed device to which substantial equivalence is claimed.
C: Performance data supporting substantial equivalence
D: Design and materials

A: Indications for Use:

The following table shows similarities and differences in indications for use between our device and the predicate devices.

Table 5.1: Comparison of Indications for Use

Description	Our Device	Predicate Device 1 (K081657)	Predicate Device 2 (K110219)
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The powder is made from cornstarch.	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The powder is Powder free

Our device and K081657, K110219 are almost identical in terms of indications for use. The only difference is that our device uses cornstarch as the powder source, while the

powder source for K081657 is not specified. This minor difference is not significant enough to alter how and when the gloves should be used.

Our device and K110219 are also almost identical in terms of indications for use. The only difference is that K110219 is powder free while this device is powdered with cornstarch as the powder source. This minor difference is not significant enough to alter how and when the gloves should be used.

B: Labeling:

The labels for both our device and predicate device are provided in Section 13 of this submission (Sec13.1 and 13.2 for our device, Sec13.3 for the predicate device K081657, and Sec 11.4 for K110219).

The following table shows similarities and differences of key elements of the labeling between our device and the predicate devices.

Table 5.2: Comparison of Key Elements in Labeling

Description	Our Device	Predicate Device 1 (K081657)	Predicate Device 2 (K110219)
Product Name	Yes (Powered Vinyl Examination Gloves)	Yes (Cureguard Gloves Vinyl Powdered)	Yes (Power Free Vinyl Examination Gloves)
Manufacturer Name and Address	Yes	No	Yes
Product Model, Size, and Lot Number	Yes	Yes	Yes
Quantity/Box	Yes	Yes	Yes
Color Statement	Yes	Yes	Yes
Storage Recommendation	Yes	No	Yes
Single Use Statement	Yes	Yes	Yes
Sterility Statement	Yes	Yes	Yes

The label for this device under submission is identical to K110219, except for this device is labeled as Powdered, while K110219 is labeled as powder free.

The label for this device under submission is very similar to K081657. Actually it contains all the information the K081657 label has, and more.

C: Performance:

The following table shows similarities and differences of the performance between our device and the predicate devices. Tests were conducted following the recommended procedures outlined in the respective consensus standards, and results for powdered Vinyl Patient Examination Gloves, Clear (non-colored) (or other clients private labeling), manufactured by *"Wealth On (Jiangsu) Gloves Co., Ltd"* met all relevant requirements in the test standards, and are comparable to the predicate device.

Table 5.3: Comparison of Physical, Biocompatibility and Performance Testing

Description	Our Device	Predicate Device 1 (K081657)	Predicate Device 2 (K110219)
Dimension	Meets ASTM D5250-06	Meets ASTM D5250-06	Meets ASTM D5250-06
Physical Property	Meets ASTM D5250-06	Meets ASTM D5250-06	Meets ASTM D5250-06
Free of Pinhole	Meets ASTM D5151-06	Meets ASTM D5151-06	Meets ASTM D5151-06
Residue Powder	Meets ASTM D6124-06 < 10 mg/dm^2	Meets ASTM D6124-06 < 10 mg/dm^2	No Powder, Meets ASTM D6124-06. < 2 mg/glove
Primary Skin Irritation (ISO 10993-10)	No skin irritation	No skin irritation	No skin irritation
Dermal sensitization (ISO 10993-10)	No dermal sensitization	No dermal sensitization	No dermal sensitization

More details of non-clinical tests are summarized in *Sections 15 & 18.*

Our device and K081657 both meet dimensional, physical, and performance requirements set forth in ASTM D5250-06, and the biocompatibility requirements.

Our device and K110219 also both meet dimensional, physical, and performance requirements set forth in ASTM D5250-06, and the biocompatibility requirements. The only difference is that this device under submission is powdered with amount < 10 mg/dm^2, while K110219 is powder free, with amount < 2 mg/glove.

In conclusion, the powdered vinyl patient examination gloves, clear (non-colored), non sterile, manufactured by "Wealth On (Jiangsu) Gloves Co., Ltd." meet requirements per ASTM D5250-06, ASTM D6124-06, ASTM D 5151-06, and ISO 10993-10. It is safe and

effective, and its performance meets the acceptance criteria pre-defined in the test standards and its intended uses. The test results are also comparable to the predicate device.

D: Design and Material

The following table shows similarities and differences in design and material between our device and the predicate devices.

Table 5.4: Comparison of Indications for Use, Design, and Material

Description	Our Device	Predicate Device 1 (K081657)	Predicate Device 2 (K110219)
Basic Design	A garment covering the hand and waist area. Gloves have separate sheaths or openings for each finger and the thumb.	Same	Same
Materials	Poly Vinyl Chloride	Same	Same
Powder	Yes/ Cornstarch	Yes/ Information on types of powder not available	No
Size	XS, S, M, L, XL	Information not available	XS, S, M, L, XL
Single Use	Yes	Yes	Yes
Color	Colorless	Light Yellow	Colorless
Sterile	Non sterile	Non sterile	Non sterile

Our device and K081657 share the similar basic design and uses the same material. The only difference is that our device is color free while the predicate device has light yellow color. Free of pigment makes our device safer and more biocompatible.

Our device and K110219 also share the similar basic design and uses the same material. The only difference is that this device is powdered while K110219 is powder free. Cornstarch is used as the source of powder which has long been established as safe and biocompatible.

A brief discussion of the non-clinical testing data that was submitted, referenced or relied on to demonstrate that the Subject Device is safe and effective, and whose performance meets the requirements of its user-defined acceptance criteria and intended uses:

Powdered vinyl patient examination glove meet requirements per ASTM D5250-06, ASTM D6124-06, ASTM D 5151-06, and ISO 10993-10. It is safe and effective, and its performance meets the requirements of its pre-defined acceptance criteria and intended uses.

A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence.

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

Substantial Equivalent Conclusions

Based on the comparison of intended use, design, materials, and performance, our powdered patient vinyl examination gloves, clear (non-colored) are substantial equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 31, 2013

Wealth On (Jiangsu) Company, Limited
C/O Mr. Charles Shen
Manton Business and Technology Services
5 Carey Street
PENNINGTON NJ 08534

Re: K122396
Trade/Device Name: Powdered Vinyl Patient Examination Gloves, Clear (non-colored) (or other clients private labeling)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: December 30, 2012
Received: January 8, 2013

Dear Mr. Shen:

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.

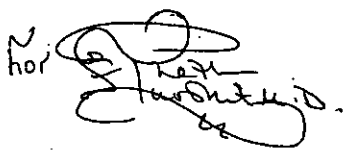
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Enclosure

Section 4: Indications for Use

510(k) Number (if known): K122396

Device Name: Powdered Vinyl Patient Examination Gloves, Clear (non-colored) (or other clients private labeling)

Indications for Use:

The powdered vinyl patient examination glove, clear (non-colored) is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The powder is made from cornstarch. It is color free and is sold as non sterile.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A. Murphey

Digitally signed by Sheila A. Murphey
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sheila A. Murphey, 0.9.2342.19200300.100.1.1=1300369048
Date: 2013.01.28 13:46:56 -05'00'

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

510(k) Number: K122396