



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

December 21, 2015

LPL (Hui Zhou) Glove Co., Ltd.  
% Rhonda Alexander, M.S., M.P.A.  
Senior Regulatory Specialist  
Registrar Corp  
144 Research Drive  
Hampton, Virginia 23666

Re: K150934

Trade/Device Name: Powder Free Vinyl Patient Examination Glove (Non-Sterile)  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LYZ  
Dated: November 25, 2015  
Received: November 27, 2015

Dear Rhonda Alexander:

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Division Director  
Division of Anesthesiology,  
General Hospital, Respiratory, Infection  
Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150934

Device Name

Powder Free Vinyl Patient Examination Glove (Non-Sterile)

Indications for Use (Describe)

A patient examination glove 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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



# LPL (HUI ZHOU) GLOVE CO., LTD

## 来百利（惠州）手套有限公司

地址：中国广东省惠州市博罗县  
罗阳镇大小塘村

电话：0086-752-6863391

传真：0086-752-6863392/3393

网页：[www.lplglove.com](http://www.lplglove.com)

邮箱：[Info@lplglove.com](mailto:Info@lplglove.com)

Address : Daxiaotang village, Luoyang Town, Boluo County,  
Huizhou City, Guangdong Province, 516120 China.

Tel : 0086-752-6863391

Fax : 0086-752-6863392/3393

Website : [www.lplglove.com](http://www.lplglove.com)

Email : [Info@lplglove.com](mailto:Info@lplglove.com)

---

### 510(k) Summary (21 CFR 807.92)

#### I. SUBMITTER

LPL (HUI ZHOU) GLOVE CO., LTD

Daxiaotang Village, LuoYang Town, Boluo County

Huizhou City, Guangdong Province

516120 China

Tel: 00867526863391

Fax: 00867526863392

Email: [info@lplglove.com](mailto:info@lplglove.com)

Website: [www.lplglove.com](http://www.lplglove.com)

Contact Person: Lee Hong Chong, Quality Assurance

Date Prepared: December 8, 2015

#### II. DEVICE

Name of Device: Powder Free Vinyl Patient Examination Glove (Non-Sterile)

Classification Name: Patient Examination Glove

Regulatory Class: Class I

Product Code: LYZ

Regulation Number: 21 CFR 880.6250

Panel: General Hospital

#### III. PREDICATE DEVICE

Name of Device: Powder Free Non-Sterile Vinyl Examination Glove

Manufacturer: Jianguo Sunshine Plastic Products Co., Ltd.

K Number: K100978

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

There have been no previous submissions.

#### IV. DEVICE DESCRIPTION

Powder Free Vinyl Patient Examination Glove (Non-Sterile) is a patient examination glove available in S, M, L, XL. The glove is provided non-sterile and meets the entire requirement of ASTM standard D 5250-06.

**V. INDICATIONS FOR USE**

A patient examination glove 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.

**VI. SUMMARY OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The Powder Free Vinyl Patient Examination Glove (Non-Sterile) is compared with the following Predicate Devices in terms of intended use, design, material, specification, and performance.

- (1) K100978: Powder –Free Non-Sterile Vinyl Examination Glove, manufactured by Jiangsu Sunshine Plastic Products Co., Ltd

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

Table 5.1 Comparison of Intended Use, Design, and Material

Description	Subject Device Vinyl Patient Examination Glove (Non-Sterile) K150934	Predicate Device K100978 Powder –Free Non-Sterile Vinyl Examination Glove
Indications for use	A patient examination glove 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 patient examination glove 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.
Material	Poly vinyl Chloride (PVC)	Poly vinyl Chloride (PVC)
Size	S, M, L, XL	S, M, L, XL
Single use	Yes	Yes
Sterile	Non-sterile	Non-sterile
Color	Clear	Clear

The Powder Free Vinyl Patient Examination Glove (Non-Sterile) is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Subject device K150934	Predicate device K100978
Dimension	Length : ≥230mm Meets ASTM D5250-06	Meets ASTM D 5250-06
	Width: S size=85mm±5mm M size=95mm±5mm L size=105mm±5mm XL size=115mm±5mm	

	Finger thickness $\geq$ 0.05mm	
	Palm thickness $\geq$ 0.08mm	
Physical Properties	Tensile strength $\geq$ 11MPa Elongation $\geq$ 300% Meets ASTM D 5250-06	Meets ASTM D 5250-06
Freedom from pinholes	No leaks; meets ASTM D5250-06 (AQL requirement: 2.5 with an accept/reject criteria of 2/3, sample size of 32)	Meets 21 CFR 800.20

Powder Residual	Powder residue $\leq$ 1.1  Meets ASTM D5250-06 and D6124-06	Meets ASTM D 5250-06
Cytotoxicity (ISO 10993-5: 2009)	Under the conditions of the study, not cytotoxic	N/A
Biocompatibility (ISO 10993-10: 2010)	Primary Dermal Irritation in rabbits-under the conditions of the study, not an irritant  Dermal Sensitization in the guinea pig-under conditions of the study, not a sensitizer	Passes  Passes

Summary of Similarities and Differences

The device is similar in design and appearance, and has the same intended use and performance characteristics to the predicate device. The device has a different type of plasticizers from the predicate device and the plasticizer content is non phthalate. The differences between the subject devices and the predicate do not raise new questions of safety and effectiveness.

**VII. PERFORMANCE DATA/TESTING**

The subject device meets the requirements per ASTM D5250-06 and ASTM D6124-06 and ASTM 5151-06.

**Biocompatibility Testing**

The subject device is considered to be a surface device for intact skin, with limited duration (<24hours). The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Skin sensitization

The device passed all biocompatibility testing.

## VIII. CONCLUSIONS

The data in this submission indicate that both subject devices met the same performance standard as the predicate. The intended use of the predicate device and the subject devices are the same. Additionally, the subject devices successfully passed biocompatibility testing, as did the predicate device.

The intended use of the subject device is the same as the predicate device and is substantially equivalent to it. The differences between the subject and predicate do not raise questions that negatively impact a finding of substantial equivalence.

The Powder Free Vinyl Patient Examination Glove (Non-Sterile) is substantially equivalent to the predicate device: Powder Free Non-Sterile Vinyl Examination Glove. Based on the nonclinical tests performed, the subject device performs as safely and as effectively as the legally marketed predicate device, Jiangsu Sunshine Plastic Products Co., Ltd. Powder Free Non-Sterile Vinyl Examination Glove cleared under K100978, Class I (21 CFR 880.6250, Product code LYZ).