

K974151

ATTACHMENT B

DEC 18 1997

510 (K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K974151

1. Submitter's Identification:

Ms. Lee Hung Yun-Shan  
Shanghai Super Gloves Co., Ltd.  
No. 4, Tingwei Road, Zhuhang Zhen  
Jinshan County, Shanghai, China

Date Summary Prepared: October 30, 1997

2. Name of the Device:

Shanghai Super Gloves Co., Ltd. Vinyl Patient Examination  
Gloves - Powdered

3. Predicate Device Information:

Sunmax Enterprise Shanghai Vinyl Patient Examination Gloves,  
K#960746  
Cheer & Merit Vinyl Patient Examination Gloves, K#941809

4. Device Description:

Classified by FDA's General and Plastic Surgery Device Panel  
as Class I, 21 CFR 880.6250, Vinyl Patient Examination Glove,  
80LYZ, Powdered with Absorbable Dusting Powder, USP, Class III  
and meets all requirements of ASTM Standard D5250-92.

5. Intended Use:

A glove is worn on the hand of healthcare and similar  
personnel to prevent contamination between healthcare  
personnel and the patient's body, fluids, waste or  
environment.

6. Comparison to Predicate Devices:

Shanghai Super Gloves Co., Ltd. Vinyl Patient Examination  
Gloves-Powdered, is substantially equivalent in safety and  
effectiveness to the Sunmax Enterprise Shanghai Vinyl Patient  
Examination Glove and the Cheer & Merit Patient Examination  
Glove.

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7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The standards used for Shanghai Super Gloves Co., Ltd. glove production are based on ASTM-D-5250-92. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 4.0.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level S-4, meeting these requirements. Primary Skin Irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

Shanghai Super Gloves Co., Ltd. operates in compliance with FDA's GMPs.

8. **Discussion of Clinical Tests Performed:**

Not Applicable - There is no hypoallergenic claim.

9. **Conclusions:**

Shanghai Super Gloves Co., Ltd. Vinyl Patient Examination Gloves conform fully to ASTM-D-5250-92 standards as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 18 1997

Shanghai Super Gloves Company, Ltd.  
C/O Ms. Susan D. Goldstein-Falk  
Official Correspondent  
MDI Consultants, Incorporated  
55 Northern Boulevard, Suite 410  
Great Neck, New York 11021

Re: K974151  
Trade Name: Vinyl Patient Examination Gloves (Powdered)  
Regulatory Class: I  
Product Code: LYZ  
Dated: October 30, 1997  
Received: November 4, 1997

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

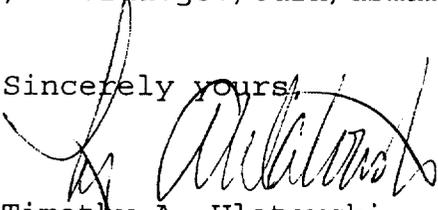
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K974151

Device Name: Shanghai Super Gloves Co., Ltd.  
Vinyl Patient Examination Gloves-Powdered

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.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

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

510(k) Number K974151

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)