SEP 14 1999

510(K) SUMMARY

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

The assigned 510(k) number is: K992464

1. Submitter's Identification:

Ms. Xinglai Zhou
Shijiazhuang Dilly Plastics Products Co., Ltd.
No. 16, Zhi Nong Road,
Shijaizhuang, Hebei Province
P.R. China

Date Summary Prepared: July 14, 1999

2. Name of the Device:

Shijiazhuang Dilly Plastics Products Co., Ltd.

Synthetic Powdered Vinyl Patient Examination Gloves

3. Predicate Device Information:

Sunmax Enterprise Shanghai Co., Ltd.

Powdered Vinyl Patient Examination Gloves, K#960746

Shanghai Super Gloves Company, Ltd.

Powdered Vinyl Patient Examination Gloves, K#974151

4. Device Description:

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 800.6250, Powdered 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 patient examination glove is a disposable device intended for medical purposes that 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:

Shijiazhuang Dilly Plastics Products Co., Ltd. Synthetic Powdered Vinyl Patient Examination Gloves, is substantially equivalent in safety and effectiveness to the Sunmax Enterprise Shanghai Co., Ltd. Powdered Vinyl Patient Examination Gloves and the Shanghai Super Gloves Company, Ltd. Powder Vinyl Patient Examination Gloves.

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

The standards used for Shijiazhuang Dilly Plastics Products 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.

8. Discussion of Clinical Tests Performed:

Not Applicable – There is no hypoallergenic Claim.

9. Conclusions:

Shijiazhuang Dilly Plastics Co., Ltd. Synthetic Vinyl Patient Examination gloves (Powdered) conform fully to ASTM-D-5250-92 standard 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

SEP 14 1999

Mr. Xinglai Zhou
General Manager
Shijiazhuang Dilly Plastics Products Company, Ltd.
No. 16, Zhi Nong Road
Shijiazhuang, Hebei, China

Re: K992464
Trade Name: Synthetic Powered Vinyl Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: July 10, 1999
Received: July 23, 1999

Dear Mr. Zhou:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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) 594-4690. 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

Attachment A

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510(k) NUMBER (IF KNOWN) : K992464

DEVICE NAME: Shijiazhuang Dilly Plastics Products Co., Ltd.

INDICATIONS FOR USE: Synthetic Powdered Vinyl Patient Examination Gloves—Powdered

A patient examination glove is disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K992464