

JUN 27 1996

K960746

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: K960746

1. **Submitter's Identification:**

Mr. Ernie Liu
Sunmax Enterprise Shanghai Co., Ltd.
#2 Zhu Hang New Industry Zone Jinshan
County, Shanghai, China

Date Summary Prepared: February 15, 1996

2. **Name of the Device:**

Sunmax Enterprise Shanghai Co., Ltd. Vinyl Patient Examination
Gloves - Powdered

3. **Predicate Device Information:**

Honyee Vinyl Patient Examination Gloves, K#893822
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:**

Sunmax Enterprise Shanghai Co., Ltd. Vinyl Patient Examination Gloves-Powdered, is substantially equivalent in safety and effectiveness to the Honyee 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 Sunmax Enterprise Shanghai 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.

Sunmax Enterprise Shanghai Co., Ltd. operates in compliance with FDA's GMPs.

8. Discussion of Clinical Tests Performed:

Not Applicable - There is no hypoallergenic claim.

9. Conclusions:

Sunmax Enterprise Shanghai 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.

Ernie Liu

ERNIE LIU

FEB. 16, 1996

DATE: _____