SEP 30 1998

JANNA TUCKER & ASSOCIATES

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K981876

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

HSING YI PLASTICS PROCESSING CO., LTD
SYNTHETIC VINYL EXAMINATION GLOVE, POWDERED

Submitter: Janna Tucker & Associates
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Contact Person: Janna P. Tucker, President, Janna Tucker & Associates

Date Prepared: May 26, 1998 (Revised July 6, 1998)

Trade Name: (Multiple) Synthetic Vinyl Examination Glove
Common Name: Synthetic Vinyl Exam Glove
Classification Name: Patient Examination Glove, Class I, 80LYZ

Summary of Safety and Effectiveness: Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "... (510(k) Summaries and 510(k) Statements ..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the preparer.

NEW DEVICE NAME: SYNTHETIC VINYL EXAMINATION GLOVE, POWDERED

PREDICATE DEVICE NAME: Synthetic Vinyl Exam Glove

Device Description: The device is powdered synthetic vinyl exam glove. They are non-sterile, single use, disposable gloves.

Intended Use: This synthetic vinyl exam glove is 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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EXHIBIT I

Indications Statement:	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.
Technological Characteristics	This synthetic vinyl exam glove has the same technological characteristics as predicate devices. The device is manufactured in standard sizes.
Performance Data:	The device has met and/or exceeded the requirements of the following standards and laboratory tests: ASTM D5250 Primary Skin Irritation Study Dermal Sensitization Study FDA Surgical Glove Bio-Burden Test FDA Water Leak, before & after aging All tests were performed in a certified testing laboratory.
Conclusions:	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the device is substantially equivalent to other like devices under the Federal Food, Drug, and Cosmetic Act.

JANNA P. TUCKER, President
Janna Tucker & Associates
Official Correspondent for
Hsing Yi Plastics Processing Co., Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

Hsing Yi Plastic Processing Company, Limited
C/O Ms. Janna P. Tucker
President
Janna Tucker & Associates
198 Avenue de la D'Emerald
Sparks, Neveda 89434

Re: K981876
Trade Name: Synthetic Vinyl Examination Glove, Powdered
Regulatory Class: I
Product Code: LYZ
Dated: September 22, 1998
Received: September 18, 1998

Dear Ms. Tucker:

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 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). 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 requirements, 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

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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE

APPLICANT: HSING YI PLASTICS PROCESSING CO., LTD.

510(K) NUMBER: K981876

DEVICE NAME: **Synthetic Vinyl Examination Glove, Powdered**

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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981876

Prescription Use____ OR Over-The-Counter Use✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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EXHIBIT B
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