K011412

MAY 31 2001

510(k) SUMMARY

Submitted For:	HEYUAN HONGLI INDUSTRIES, INC. No. 2, Mingzhu Industrial Heyuan, Guang Dong China Phone: 867623213796
Submitted by:	TUCKER & ASSOCIATES Official Correspondent and United States Agent for Heyuan Hongli Industries, Inc. JANNA P. TUCKER, President – CEO 198 Avenue de la D'emerald Sparks, NV 89434 Phone: 775-342-2612 Fax: 775-342-2613 E-mail: Tuckerjan@aol.com
Date of Submission:	
Device Name:	POWDER-FREE VINYL EXAM GLOVE Class I Device, 80LYZ
Proprietary Name:	(Multiple Labels) Powder-Free Vinyl Exam Glove
Labels/Labeling:	This device will be marketed to healthcare professionals at Dentist and Doctor Offices, Laboratories, Clinics and Hospitals through its intended use.
Intended 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.
Substantial Equivalence:	This device is equivalent to those in commercial distribution. They are to be worn as a protective device on the examiner's hand or finger, also protecting the patient. Both in its intended use and/or physical characteristics, this Device is equivalent to devices currently marketed by U.S. Companies. It is **substantially equivalent** to the devices Manufactured by Shanghai Champion Plastic Products Company, Limited (K994136) and Copioumed International , (K972624).

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Test Results (Means And/or Results):	This device has met or exceeded the following Standards/Tests: ASTM D 5250-00 ASTM D 5151-00 ASTM D 6124 BIO-BURDEN Bio-Compatibility: Dermal Sensitization Primary Skin Irritation
Conclusion:	This device is substantially equivalent to the devices Approved as K972624 and K994136.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2001

Heyuan Hongli Industries, Incorporated
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K011412
Trade/Device Name: Powder-Free Vinyl Examination Gloves
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYZ
Dated: May 4, 2001
Received: May 8, 2001

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,

Susan Runner

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: **HEYUAN HONGLI INDUSTRIES, INC.**

510(k) NUMBER: K011412

DEVICE NAME: **POWDER-FREE VINYL EXAM GLOVES**

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)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011412

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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