SHANGHAI FOREMOST PLASTIC INDUSTRIAL CO., LTD.
Yan Li River Bridge East, Che Xing Highway, Che Dun Town,
Songjiang County, Shanghai 201611, PRC
TEL: 86-21-5760-0245 FAX: 86-21-5760-1003

K971415 MAY 23 1997

510 (k) SUMMARY

Date of summary prepared: March 25, 1997

1. Applicant:

Shanghai Foremost Plastic Industrial Co., Ltd.
Yan Li River Bridge East
Che Xing Highway, Che Dun Town
Songjiang County, Shanghai 201611
People's Republic of China
Tel:#: 86-21-5760-2752, Fax#: 86-21-5760-1003

2. Contact Person:

Dr. Tiang S. Chang
1016 Seward Avenue
Westfield, N. J. 07090
Tel#: 908 233-3571 Fax#: 908 233-0925 e-mail: tschang@earthlink.net

3. Name of Device

Vinyl Patient Examination gloves, Powder-free

4. Device Description:

Classified by FDA's General and Plastic Surgery Device Panel as Class I, 21 CFR 880.6250, Vinyl Patient Examination Glove, Powder-free, 80LYZ, conform to all requirements of ASTM Standard D5250-92 and FDA water leak test.

5. Intended Use

The applicant device is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

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6. Comparison to Predicate Device

Non-Clinical Performance data

Applicant devices comply with ASTM Standard D-5250-92 and FDA 1000 ml water leak test for pin-holes.

Test		ASTM D5250-92	Applicant Device
Length (mm)			
Size	S	Min. 230 mm	240 ± 5 mm
	M	Min. 230 mm	240 ± 5 mm
	L	Min. 230 mm	240 ± 5 mm
	XL	Min. 230 mm	240 ± 5 mm
Width (mm)			
Size	S	85 ± 5 mm	87 ± 3 mm
	M	95 ± 5 mm	98 ± 3 mm
	L	105 ± 5 mm	106 ± 3 mm
	XL	115 ± 5 mm	114 ± 3 mm
Thickness (mm)			
Finger		Min. 0.05 mm	Min. 0.08 mm
Palm		Min. 0.08 mm	Min. 0.11 mm
Physical Properties			
Before Aging			
Tensile Strength (MPa)		Min. 9 MPa	Min. 10 MPa
Ultimate Elongation (%)		Min. 300%	Min. 300%
After Aging			
Tensile Strength (MPa)		Min. 9 MPa	Min. 9.5 MPa
Ultimate Elongation (%)		Min. 300%	Min. 300%
FDA Water Leak Test			Meets AQL 4.0 with a Inspection Level of S-4

Clinical Performance Data

The results of Modified Draize Test suggest the applicant device did not induce clinically significant irritation nor show any evidence of induced allergic contact dermatitis in human subjects.

7. Conclusions

The applicant devices conform fully to ASTM D5250-92 and applicable 21 CFR requirements, and meets FDA 1000 ml Water Leak Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1997

Shanghai Foremost Plastic Industrial Co, Ltd.
C/O Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meetling, Pennsylvania 19462-1298

Re: K971415
Trade Name: Vinyl Patient Examination Glove, Powder-Free
Regulatory Class: I
Product Code: LYZ
Dated: April 16, 1997
Received: April 17, 1997

Dear Mr. Mosenkis:

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) 594-4692. 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" (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 1b

510(k) Number (if known): K971415

Device Name: Patient Examination Glove, Powder-Free

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.

(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 K971415

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

(Optional Format 1-2-96)