JUL 29 1999

EXHIBIT #1

SHANGHAI CHINASTAR CORP.

NO. 283, CHE XIN ROAD, CHE DUN ZHEN, SONG JIANG COUNTY, SHANGHAI, CHINA
C/O: 11F, 201, NANKING E. RD., SEC 3, TAIPEI, TAIWAN, R.O.C.
TEL/FAX: 886-2-27171298

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: K992206

1. Submitter's Identification:

Mr. LEE HUNG TE CHIH
SHANGHAI CHINASTAR CORP.
No. 1, Rong Xing Road, Che Dun Zhen, Song Jiang County
Shanghai, China

Date Summary Prepared: 25 May 1999

2. Name of the Device:

SHANGHAI CHINASTAR CORP.
Powder-free Vinyl Patient Examination Gloves

3. Predicate Device Information:

Shanghai Huamao Gloves Co., Ltd. #K984460

4. Device Description:

Classified by FDA's General and Plastic Surgery Device Panel as Class I, 21 CFR 880.6250, Powder-free Vinyl Patient Examination Glove, 80LYZ 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.

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6. Comparison to Predicate devices:

SHANGHAI CHINASTAR CORP. Powder-free Vinyl Patient Examination Gloves, is substantially equivalent in safety and effectiveness to the Shanghai Super Gloves Co., Ltd. Powder-free vinyl patient examination Gloves.

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

The standards used for SHANGHAI CHINASTAR CORP. 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.

A USP Iodine Test for Starch at finished inspection is conducted to insure that our gloves meet our "powder-free" claim. We adhere to all USP Iodine Test methodology and testing "powder-residue by weight" and are contracting with a laboratory to conduct particulate testing for added assurance. Final release testing consists of a light transmission test using a spectrophotometer.

8. Discussion of Clinical Tests Performed:

Not Applicable – There is not hypoallergenic claim.

9. Conclusions:

SHANGHAI CHINASTAR CORP. Vinyl Patient Examination Gloves conform fully to ASTM D-5250-92 standards as well as applicable 21 CFR references, and meets pinhole FDA requirements, bio-compatibility 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

JUL 29 1999

Shanghai Chinastar Corporation
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K992206
Trade Name: Powder-Free Vinyl Patient Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: June 28, 1999
Received: June 30, 1999

Dear Ms. Goldstein-Falk:

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 A

510(k) Number (if known): K992206

Device Name: SHANGHAI CHINASTAR CORP.
Powder-Free Vinyl Patient Examination Gloves

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)

Prescription Use ____ **OR** **Over-The-Counter Use** X
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992206