AUG 3 0 2007

SHANGHAI CHINASTAR CORP

No#283 Che Xin Rd, Che Dun Zhen, Song Jaing County Shanghai, China
C/O: 11F No.201, Nanking East Rd., Sec 3, Taipei, Taiwan, R.O.C
Tel:886-2-2713-6677 Fax:886-2-2546-2480

510(k) Summary

K071072

Prepared: March 28, 2007

Applicant	**Shanghai China Star Corp** No. 283, Che Xing Road, Che Dun Zhen, Song Jiang County: Shanghai, China
Manufacturer	**Shanghai China Star Corp** No. 283, Che Xing Road, Che Dun Zhen, Song Jiang County: Shanghai, China
Submitter	**Romil Rambhia** Official Correspondent for **Shanghai China Star Corp**
Address	**mdi Consultants, Inc.** 55 Northern Blvd., Suite 200 Great Neck, New York 11021 Tel: 516-482-9001 Fax: 516-482-0186 romil@mdiconsultants.com
Trade/proprietary Name	Shanghai China Star Corp Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs.
Common Names	POWDER-FREE Patient Examination Glove
Classification name	Patient Examination Glove
Classification number	21 CFR 880.6250

Device Description:
Shanghai China Star Corp Powder free blue Nitrile Examination Glove is a class I device having product code 80LZA. It is a disposable device powdered with absorbable dusting powder that meets all requirements of ASTM D 631900a-05 and is tested with chemotherapy drugs.

Intended Use:
A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier

Substantial Equivalence Discussion:

A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is substantially equivalent to the predicate devices.

Characteristic and parameters	**Shanghai China Star Corp (New Device)**	**MEDLINE INDUSTRIES, INC (K) 040841**	**ALLEGIANCE HEALTHCARE CORP. (K) 022765**
Product Code	LZA	LZA	LZA
Intended Use	A powder free patient examination glove (Tested for Use with Chemotherapy Drugs) is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. These gloves are not intended to be used as a chemical barrier	Medline Powder-Free Blue Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) 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.	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. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs. The gloves with tested for use with chemotherapy drugs labeling claims.
Width (size medium)	92mm	92mm	N/A
Overall length	240mm	240mm	N/A
Palm thickness	0.17mm	0.17mm	N/A
Finger thickness	0.18mm	0.18mm	N/A
Tensile strength pre aging min	21mpa	21mpa	N/A
Tensile strength after aging min	16mpa	16mpa	N/A
Ultimate elongation pre aging min	500	500	N/A
Ultimate elongation after aging min	500	500	N/A
Meets Biocompatibility standards	Yes	Yes	Yes

Duration of bio-compatibility	Limited	Limited	Limited
Skin irritation test	Passes	Passes	Passes
Dermal sensitization	Passes	Passes	Passes
Residual powder test	Passes	Passes	Passes

N/A is we don't know the specifications.

Summary of Testing:

Test	Results
1. Dermal Sensitization Test	Passes
2. Primary Skin irritation	Passes
3. Permeation testing per ASTM D 6978-05	Passes
4. Iodine Test	Passes
5. Tensile strength	Gloves meets the requirements of ASTM D63 19-00a.
6. Barrier strength	Gloves meets the requirements of ASTM D63 19-00a.

The standards used by Shanghai Chinstar Corp to determine substantial equivalence are based on ASTM D 631900a-2005. All testing meets requirements for physical specifications and dimensions conducted on gloves, Inspection level S-2, AQL 4.0, pinholes at AQL 2.5

There are no special labeling claims and we do not claim our gloves to be hypoallergenic.

Conclusion:

Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs performance was equivalent to any other conventional method evaluated. Our evaluation concluded that our device raises no new issues of Safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shanghai China Star Corporation
C/O Mr. Romil Rambhia
Official Correspondent
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11001

AUG 3 0 2007

Re: K071072
Trade/Device Name: Shanghai China Star Corp Powder Free Blue Nitrile Patient Examination Glove Tested with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 21, 2007
Received: August 22, 2007

Dear Mr. Rambhia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

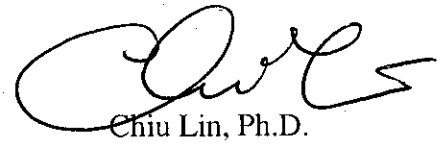
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not Assigned as of now K071072

Applicant: Shanghai China Star Corp

Device Name: Shanghai China Star Corp Powder free Blue Nitrile Patient Examination Glove tested with chemotherapy drugs.

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Prescription Use_____ **AND/OR** **Over-The-Counter Use ✓**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila A Murphy

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071072