JUL 27 2007

SHANGHAI MOTEX HEATHCARE CO., LTD.

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" 510(k) SUMMARY "

The assigned 510(k) number is : K063757

Submitter's Name: *SHANGHAI MOTEX HEALTHCARE CO., LTD.*
No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China

Date summary prepared: November 26, 2006

Device Name:

- Classification name: *Surgeon's Gloves*
- Classification number: *KGO, Class I*
- *Regulation Number:* *878.4460*
- Proprietary name: *Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves*
- Predicate Device: *K050071, MEDISPO powdered surgeon's gloves and MEDISPO-PF powder-free surgeon's gloves*
- Official Correspondent: *Dr. Jen, Ke-Min*

  E-mail: ceirs.jen@msa.hint.net (Tel) 886-3-5208829; (Fax) 886-3-5209783

  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC

- **Intended Use:**

Motex Powder-Free Surgical Gloves are sterile disposable devices made of natural rubber latex (that may bear a trace amount of glove powder) and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

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Motex Powdered Latex Surgical Gloves are sterile disposable devices made of natural rubber latex that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants..

- **Technological Characteristics:**

The Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves characteristics are summarized below compared to ASTM and ISO standards to the predicate device:

Characteristic	*Standard*
Dimensions	*meets ASTM D 3577-06,*
Physical Properties	*meets ASTM D 3577-06,*
Freedom from Holes	*meets ASTM D 3577-06,*
Biocompatibility	*meets ISO10993-5/-10*
Sterilization Validation	*meets ISO11137*

- **Clinical Data:**

Not applicable.

- **Conclusions:**

The Motex Powder-Free Surgical Gloves & Powdered Latex Surgical Gloves and predicate devices also meet the technological characteristics of ASTM D 3577-06, ISO10993-5/-10, and ISO11137 standards. Besides, for Powder-Free SURGICAL GLOVES contain no more than 2mg powder and no more than 50ug/dm2 extractable protein, and for Powdered Latex SURGICAL GLOVES contain no more than 120mg powder and no more than 120ug/dm2 extractable protein claim.

Thus the new devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shanghai Motex Healthcare Company Limited
C/O Dr. Jen Ke-Min
Official Correspondent
ROC Chinese-European Industrial
No. 58, Fu Chiun Street
Hsin Chu City, Taiwan 30067
CHINA

Re: K063757
Trade/Device Name: Motex Powder-Free Surgical Gloves and Powdered Latex Surgical Gloves
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: June 15, 2007
Received: June 29, 2007

Dear Dr. Jen:

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 (240) 276-0115. 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/industry/support/index.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): **K063757**

Device Name: *Motex Powder-Free Surgical Gloves and Powdered Latex Surgical Gloves*

Indications for Use:

Motex Powder-Free Surgical Gloves are sterile disposable devices made of natural rubber latex (that may bear a trace amount of glove powder) and is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

Motex Powdered Latex Surgical Gloves are sterile disposable devices made of natural rubber latex that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants.

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)

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

510(k) Number: K063757