AUG 2 0 2004

K041276

ATTACHMENT X

510(K) SUMMARY

I. INFORMATION

SUMMITTER'S
Name: SHANGHAI MOTEX HEALTHCARE CO., LTD.

Address: Shanghai Motex Heathcare Co., Ltd.
No. 359, Jiasong Zhong Road
Huaxin, Qingpu
Shanghai, China 201708

Contact Person: Tony T. K. Cheng

Phone: 86-21-59799888 Fax: 86-21-59799728

Date of Preparation: July 14, 2004

NAME OF DEVICE

Trade or Proprietary Name: 1) Prodermic Green Powder-Free Nitrile Examination Glove
2) Multiple or Customer's Trade Names

Common or Usual Name: Non-Sterile Nitrile Power-Free Patient Examination Glove

Classification Name: Patient Examination Glove, Powder-Free (per 21 CFR 880.6250)

IDENTIFICATION OF THE LEGALLY MARKETED DEVICE

Class I Patient Examination Glove, 80LZA, powder-free, that meets all requirements of ASTM D6319-00ae3 and FDA 21 CFR 800.20.

PREDICATE DEVICE

Pro-Blue Powder-Free Medical Examination Glove, K030207

5. DESCRIPTION OF DEVICE

a. Basis of scientific concepts for the device:

Nitrile rubber is impermeable to water and body fluids under normal conditions of use. Its elastomeric properties enable it to conform to hand, allow flexible manipulations for medical procedures.

b. Physical and performance characteristics such as design, material, and physical properties:

Nitrile rubber is known to form a superior barrier to bloodborne pathogens and body fluids. As specified in ASTM D6319-00ae3 nitrile gloves also have good physical properties for medical examination procedures.

6. INTENDED USE OF THE DEVICE

This is a disposable device, intended for medical purpose, that is worn on the examiner's hand to prevent contamination between patient and examiner. Powder-free examination gloves are suitable in situations where powder is not desirable.

EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

The proposed device is substantially equivalent to the predicate device K030207 except for the following:

a) Color additive is different: green for the proposed device and blue for the predicate device.

b) The accelerators/sulfur mixture used in the predicate device has been replaced by a synthetic polymer with reactive functional groups to achieve balanced physical properties.

II. SUMMARY OF PERFORMANCE DATA:

1. DISCUSSION OF NON-CLINICAL TESTS

CHARACTER -ISTICS	STANDARDS	DEVICE PERFORMANCE THIS SUBMISSION	DEVICE PERFORMANCE PREDICATE K030207
Freedom From Holes	ASTM D6319-00ae3 ASTM D5151-99 FDA 21 CFR 800.20	Meets	Meets
Powder-Free Residual	ASTM D6124-01	Meets, Less than 2 mg/glove	Meets, Less than 2 mg/glove
Physical Properties	ASTM D6319-00ae3	Meets	Meets
Dimensions	ASTM D6319-00ae3	Meets	Meets

2. DISCUSSION OF ANIMAL CLINICAL TESTS

CHARATERISTICS	STANDARDS/METHODS	DEVICE PERFORMANCE
Primary Skin Irritation	ISO 10993 Biological Evaluation of Medical Devices, Part 10	Passes
Dermal Sensitization	Guinea Pig Sensitization Buehler Method	Passes

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND PERFORMANCE =/> PREDICATE PRODUCT

The data summaries indicate that the proposed device meets the established performance standards for non-sterile powder-free patient nitrile examination gloves, and that the proposed device is substantially equivalent to predicate K030207.

Pursuant to 21 C.F. R. 807.87(j), I, Tony T.K. Cheng certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Managing Director for the Shanghai Motex Healthcare Co., Ltd.,

and in the reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Tony T.K. Cheng, Managing Director

7/14/2004
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

Shanghai Motex Healthcare Company Limited
C/O Dr. Wunan Huang
At Tech, Incorporated
150J West Phillips Road
Greer, South Carolina 29650

Re: K041276
Trade/Device Name: Green Nitrile Powder-Free Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 30, 2004
Received: August 2, 2004

Dear Dr. Huang:

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.

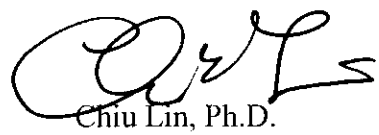
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): **K041276**

Device Name: **Green Nitrile Powder-Free Examination Gloves**

Indications For Use: **This green powder-free nitrile examination glove is a disposable device made of nitrile rubber that may bear trace amount of powder and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants (21 CFR 880.6250).**

Prescription Use _____ AND/OR Over-The-Counter Use __x_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Luby

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

510(k) Number: K041276