MAY 18 2005

# C 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: K051153 ." (applicant leave blank)

**Premarket Notification [510(k)] Summary**

**[(a)(1)]. The summary contains on the first page, preferably on your letterhead paper, the submitter's name, address, phone and fax numbers, name of contact person, and date the summary was prepared :**

| | |
|---|---|
| **Submitter's name :** | HEBEI MANFUL IMPORT & EXPORT CO., LTD |
| **Submitter's address :** | NO.58 TONGDA ROAD, JINZHOU CITY, HEBEI PROVINCE, 052260, P.R.CHINA |
| **Phone number :** | (86) 311-4338239 |
| **Fax number :** | (86) 311-4338239 |
| **Name of contact person:** | Ms. Yanchai Zhang |
| **Date the summary was prepared:** | 06 April 2005 |

**[(a)(2)]. The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known**

| | |
|---|---|
| **Device Name**: | Powder Free Vinyl Patient Examination Gloves, white(non-colored) |
| **Proprietary/Trade name**: | Powder Free Vinyl Patient Examination Gloves<br>Other clients private labeling |
| **Common Name:** | Patient examination glove |
| **Classification Name:** | Patient examination glove |
| **Device Classification:** | I |
| **Regulation Number:** | 21 CFR 880.6250 |
| **Panel:** | General Hospital (80) |
| **Product Code:** | LYZ |

**[(a)(3)]. An identification of the legally marketed device to which your firm is claiming substantial equivalence .**

Class I* powder free vinyl patient examination gloves , white(non-colored) that meets all of the requirements of ASTM standard D 5250-00$^{e4}$.

**Predicate device :** FUGUAN (Brand) Powder-Free Vinyl Patient Examination Gloves, Shijiazhuang Fuguan Plastic Products Co., Ltd.. K032908 .

**[(a)(4)] A description of the device**

**Device Description** : powder free vinyl patient examination gloves, white(non-colored) that meets all of the requirements of ASTM standard D 5250-00$^{e4}$.

K051153

**[(a)(5)] The summary describes the intended use of the device**

**Device Intended Use:** powder free vinyl patient examination glove, white(non-colored) 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)(6)] A summary of the technological characteristics of new device compared to the predicate device.**

The powder free vinyl patient examination gloves, non sterile are summarized with the following technological characteristics compared to ASTM or equivalent standard.

| Characteristics | Standard | Device performance |
|---|---|---|
| Dimension | ASTM standard D 5250-00[e4] | Meets |
| Physical Properties | ASTM standard D 5250-00[e4] | Meets |
| Freedom from pinholes | 21 CFR 800.20 | Meets |
| Powder Residual | ASTM standard D 5250-00[e4]<br><br>and D6124-01 | Meets<br><br><2mg/glove |
| Biocompatability | Primary Skin Irritation in rabbits | Passes<br><br>Not a Primary Skin Irritation |
| | Dermal sensitization in the guinea pig | Passes<br><br>Not a Dermal sensitization |

**[(b)(1)] A brief discussion of the nonclinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .**

Powder free vinyl patient examination gloves , white(non-colored) meet requirements per ASTM D5250-00[e4], per ASTM D6124-01, per 21 CFR 800.20 and ISO10993-10.

**[(b)(2)] A brief discussion of the clinical submitted, reference, or relied on in the premarket notification submission for a determination of substantial equivalence .**

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

**[(b)(3)] The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe,as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

It can be concluded that the Powder Free Vinyl Patient Examination Gloves meet the ASTM standard or equivalent standard and FDA requirements for waterleak test on pinhole AQL., meet labeling claims .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Ms. Yanchai Zhang
General Manager Assistant
Hebei Manful Import & Export Company Limited
No. 58 Tongda Road
Jinzhou City, Hebei Province, 052260
P.R. CHINA

Re: K051153
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, White (Non-Colored)
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: April 6, 2005
Received: May 4, 2005

Dear Ms. Zhang:

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.

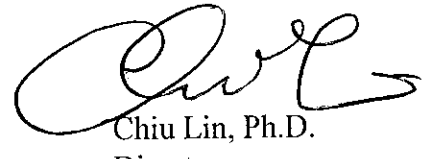
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Applicant: HEBEI MANFUL IMPORT & EXPORT CO., LTD

510(k) Number (if known): K051153

Device Name: Powder Free Vinyl Patient Examination Gloves, White(Non-colored)

INDICATIONS FOR USE

Powder free vinyl 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.

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)

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

510(k) Number: K051153