

JUL 12 1999



JANNA TUCKER & ASSOCIATES

198 Avenue De La D'emerald
Sparks, NV 89434-9550
Ph: 775-342-2612
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510(k) SUMMARY

K992031

Submitted By: Janna Tucker & Associates
198 Avenue de la D'emerald
Sparks, NV 89343
Phone: 775-342-2612
FAX: 775-342-2613

Contact Person: Janna P. Tucker, Official Correspondent for
Shanghai Changzheng Latex Factory

Date of Submission: 7 June 1999

Device Name: Patient Examination Glove

Proprietary Name: (Multiple Labels) Exam Gloves, Latex, Powder-Free, with Protein Labeling.

Labels/Labeling: This device will be marketed to healthcare professionals at dentist, and doctor offices, laboratories, clinics and hospitals through its intended use.

Intended 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.

Substantial Equivalence:

This device is equivalent to those in commercial distribution. They are to be worn as a protective device on the examiner's hand or finger.

Both in its intended use and/or physical characteristics, this device is equivalent to devices currently marketed by U.S. companies. It is **substantially equivalent** to the device manufactured by Evergrade Healthcare Products SDN BHD, K973664, Latex Examination Glove, Powder-Free, with Protein Content Labeling Claim.

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Test Results (Means
and/or Results):

This device has met or exceeded the following
standards/tests:

ASTM D 3758-95
ASTM D 5151 FDA Water Leak Test (before & after aging)
Bio-Compatibility
 Dermal Sensitization
 Primary Skin Irritation
Bacteria
Mold

Conclusions:

This device is substantially equivalent to the device approved
as K973664.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Shanghai Changzheng Latex Factory
c/o Janna Tucker & Associates
Ms. Janna P. Tucker
Official Correspondent
198 Avenue De La D'Emerald
Sparks, Nevada 89434-9550

Re: K992031
Trade Name: Latex Examination Glove Powder Free, With
Protein Labeling Claim (50 Micrograms or Less Total
Water Soluble Protein)
Regulatory Class: I
Product Code: LYY
Dated: June 14, 1999
Received: June 16, 1999

Dear Ms. Tucker:

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 (Pre-market 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.

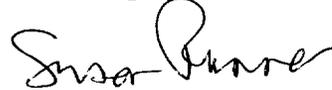
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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,



fas

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

APPLICANT:

SHANGHAI CHANGZHENG LATEX
FACTORY

510(K) NUMBER:

K992031

DEVICE NAME:

Latex Examination Glove, Powder-Free
WITH PROTEIN LABEL IN CLAIM [50 Mcg or less
WATER SOLUBLE PROTEIN PER GM]

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 _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

Chin S. Kim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992031

EXHIBIT B

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