



JANNA TUCKER & ASSOCIATES

MAR 13 1998

K973664
510(K) SUMMARY

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Green Valley, AZ 85614
Telephone: (520) 625-2904
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Submitted By: Janna Tucker & Associates
19001 S. Richfield #185
Green Valley, AZ 85614
Phone: 520-625-2904
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Contact Person: Janna P. Tucker, Official Correspondent of Evergrade
Healthcare Products SDN. BHD.

Date of Submission: August 19, 1997

Device Name: Latex Exam Glove, Powder Free with
Protein and Hypoallergenic Labeling

Classification Name: Latex Exam Glove, 80LYY

Proprietary Name: (Various Labels) Latex Exam Glove, Powder Free, with Protein and
Hypoallergenic Labeling

Labels/Labeling: This device will be marketed to healthcare professionals at dentists
and doctor's 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:
The above device is equivalent to those in commercial distribution.
These latex gloves are to be worn as a protective device on the
examiners 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
Sinochem Ningbo, K955918, Latex Exam Gloves, powder-free,
with Protein Labeling and Hypoallergenic Claims.

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Test Results (Means
and/or Results):

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

ASTM D 3578-95, Standard Specification for Rubber Exam Gloves
ASTM D 5712, RRIM Modified Lowry Microassay:
Protein Content, mg/g (against BSA): Internal Surface: 11 +/- 4;
External Surface: 12 +/- 4
FDA Water Leak Test AQL 4.0
Primary Skin Irritation Test
Dermal Sensitization Study
Biocompatibility [Repeated Insult Patch (200 Subjects)]

Conclusions:

This device is substantially equivalent to the Sinochem Ningbo
device approved under 510(k) K955918.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 1998

Evergrade Healthcare Products Sdn Bhd
C/O Janna Tucker & Associates
19001 S. Richfield #185
Green Valley, Arizona 85614

Re: K973664
Trade Name: Latex Examination Glove, Powder-Free,
Hypoallergenic, with Protein Content Labeling Claim
(50 Micro grams or less)
Regulatory Class: I
Product Code: LYY
Dated: February 4, 1998
Received: February 10, 1998

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.

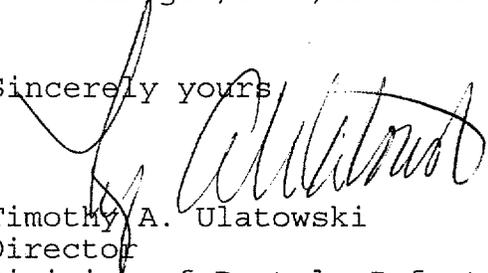
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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. 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) 594-4618. 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,



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: EVERGRADE HEALTHCARE PRODUCTS, SDN. BHD.

510(k) Number (if known): K 973664

Device Name: Latex Exam Glove, Powder Free, with Protein and

Indications For Use: Hypoallergenic Labeling (50µg or less water extractable protein)

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)

Chin S. Lim

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 973664

Prescription Use _____
Per 21 CFR 801.109

OR

Over-The-Counter X

(Optional Format 1-2-96)

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