

EVERRISE GLOVE PRODUCTS CO., LTD

No. 47, Huan Kung Road, Wang Haun Li, Yung Kang City

Tainan Hsien, Taiwan, R.O.C.

TEL: 886-6-2330946, 2332086 FAX: 886-6-2334439

NOV 18 1997

510(K) Summary

K973998

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Date of summary prepared : October 9th, 1997

■ Applicant

Everrise Glove Products Co., Ltd.

No. 47, Huan Kung Road

Wang Haun Li

Yung Kang City

Tainan Hsien

Taiwan, R.O.C.

Tel : 886-6-2330946

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■ Contact Person

Mr. Jason Chang

No. 47, Huan Kung Road

Wang Haun Li

Yung Kang City

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Tel : 886-6-2330946

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E-Mail : everrise@ms14.hinet.net

■ Device Name

Vinyl Patient Examination Gloves,

Powder Free

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■ Device Description

(A) Classified by FDA's General and Plastic Surgery Device Panel as Class I, 21CFR 880.6250

(B) Vinyl Patient Examination Glove, Power Free, 80LYZ

(C) conform to all requirements of ASTM Standard D5250-92 and FDA water leak test.

■ Application

The applicant device is disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

■ Comparison to Predicate Device

Non-Clinical Performance data

Applicant devices comply with ASTM Standard D-5250-92 and FDA 1000ml water leak test for pin-holes.

Test	ASTM D5250-92	Applicant Device
Length (mm)		
Size S	Min. 230mm	240±5mm
M	Min. 230mm	240±5mm
L	Min. 230mm	240±5mm
XL	Min. 230mm	240±5mm
Width (mm)		
Size S	85±5mm	87±3mm
M	95±5mm	97±3mm
L	105±5mm	107±3mm
XL	115±5mm	114±3mm
Thickness (mm)		
Finger	Min. 0.05mm	Min. 0.08mm
Palm	Min. 0.08mm	Min. 0.11mm
Physical Properties		
Before Aging		
Tensile Strength (Mpa)	Min. 9Mpa	Min. 10Mpa
Ultimate Elongation (%)	Min. 300%	Min. 300%

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After Aging		
Tensile Strength (Mpa)	Min. 9Mpa	Min. 9.5Mpa
Ultimate Elongation (%)	Min. 300%	Min. 300%
FDA Water Leak Test		Meets AQL 4.0 with a Inspection Level of S-4

Clinical Performance Data

The results of Modified Draize Test suggest the applicant device did not induce clinically significant irritation nor show any evidence of induced allergic contact dermatitis in human subjects.

■ Conclusion

The applicant devices conform fully to ASTM D5250-92 and applicable 21 CFR requirements, and meets FDA 1000ml Water Leak Test.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jason Chang
General Manager
Everrise Glove Products Company, Ltd.
No. 47, Huan Kung Road
Wang Haun Li, Yung Kang City
Tainan Hsien, Taiwan, R.O.C.

NOV 18 1997

Re: K973998
Trade Name: Vinyl Patient Examination Gloves Powder-Free
Regulatory Class: I
Product Code: LYZ
Dated: October 9, 1997
Received: October 21, 1997

Dear Mr. Chang:

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.

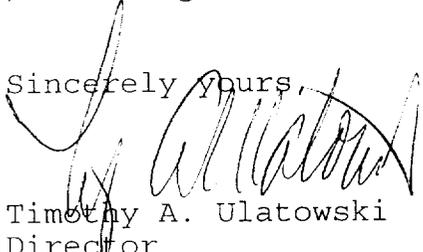
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

510(k) Number (if known): K973998

Device Name: Patient Examination Glove, Powder-Free

Indications For 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

George A. Miller for Charles Lin, PhD

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

510(k) Number K973998

scription Use _____
(per 21 CFR 801.109)

OR

Over-The-Counter Use ✓