



YTY INDUSTRY (MANJUNG) SDN. BHD.

(Company No : 380830-P)

Lot 1422-1424, Batu 10 Lekir, 32020 Sitiawan, Perak Darul Ridzuan, Malaysia.

Tel : 05-6792288 (Hunting Line), 6792443 & 6792445 Fax : 05-6791188

K974191

APPENDIX H

DEC 24 1997

1 **510 (K) SUMMARY**

2 **Submitter** YTY Industry (Manjung) Sdn Bhd
Lot 1422-1424, Batu 10 Lekir,
32020 Sitiawan
Perak Darul Ridzuan,
Malaysia.

Tel 605-6792288

Fax 605-6791188

Name of contact Paerson 1. MR. MOH UNG NANG

Date of Summary Prepared September 20, 1997

3 **Name Of Device**

Trade Name Evergreen Non-Sterile Powdered Latex Examination Gloves

Common Name Exam Gloves

Classification Name Patient Examination Glove

4 **Identification of The Legally Marketed Devices**

Class I Latex Patient Examination Glove 80 LYY, powdered with absorbable dusting powder, that meets all of the requirements of ASTM Standard D3578-95

5 **Description Of The Device**

Class I Latex Patient Examination Glove 80 LYL, powdered with absorbable dusting powder, that meets all of the requirement of ASTM Standard D3578-95 and FDA Water Leak Test.

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6.0 The Intended Use Of GLove

A medical glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment.

7.0 Technological Characteristic of Device.

A. Dimensions

DIMENSION	ASTM D 3578-95	EVERGREEN GLOVE
X Small	70 mm +/- 10 mm	73 - 78 mm
Small	80 mm +/- 10 mm	83 - 88 mm
Medium	90 mm +/- 10 mm	93 - 98 mm
Large	100 mm +/- 10 mm	103 - 107 mm
Length	230 mm minimum for all sizes	240 mm minimum for all sizes
Thickness - finger Palm	0.08 mm minimum 0.08 mm minimum	0.10 mm minimum 0.10 mm minimum

B.

TEST	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM D3578-95	YTY'S Gloves	ASTM D 3578-95	YTY'S Gloves
BEFORE AGING	14.0 Mpa.	26.7 Mpa	700%	840%
AFTER AGING 7 days at 70	14.0 Mpa.	21.8 Mpa	500%	820%

Our gloves meets all the specifications of the ASTM D3578-95 Standards.

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C. WATER TIGHT TEST

FDA water leak test method is used to test 80 pieces of gloves at AQL 4.0% General Inspection II multiple sampling plan. The results are as follows:

Batch	Size	Sample Size	Unit Leak	Disposition
70881981	Large	80	1	Accepted
70881962	Medium	80	1	Accepted
70882003	Small	80	0	Accepted

The test meets the FDA Water Leak Test Requirements.

D. BIOCOMPATIBILITY

The test consists of Primary Dermal Irritation Test and Skin Sensitization Study.

The gloves pass the the Biocompatibility Tests.

E. Water Soluble Protein Test by ASTM D5712 standards.

Batch No. Production Date	Protein Content ug/g (against OVBM)
1. R123-5L5M (03/09/97) Medium	209

There is no Label Claim on Protein Level.

Conclusion.

We concluded that Evergreen Non-Strile, Latex Examination Gloves meet:

- ASTM D3578-95 Standard.
- FDA Water Leak Test requirements.
- ASTM D5151-90 Test method for Detection of Holes in Medical Gloves.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1997

Mr. Leonard Frier
President
YTY Industry Sdn. Bhd.
C/O MET Laboratories
914 West Patapsco Avenue
Baltimore, Maryland 21230-3432

Re: K974191
Trade Name: Evergreen Non-Sterile Powdered Latex
Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: December 18, 1997
Received: December 19, 1997

Dear Mr. Frier:

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.

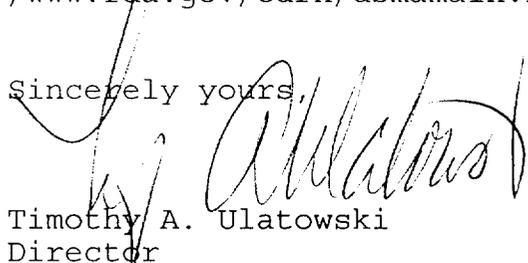
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Applicant : YTY INDUSTRY (MANJUNG) SDN BHD

510K Number : K974191
powdered

Device Name : Evergreen Latex Examination Gloves

Indications For Use :

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

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Concurrence of CDRH Office of Device Evaluation (ODE)

Neowee T. Miller for Chiu S. Lin, Ph.D.

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

510(k) Number K974191

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter ✓