



**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

ATTACHMENT N

**1.0 SMDA 510 (K) SUMMARY**

**2.0 Submitter** YTY Industry Sdn Bhd  
 Lot 1422-1424, Batu 10 Lekir  
 32020 Sitiawan  
 Perak Darul Ridzuan  
 MALAYSIA

Tel 605-6792288

Fax 605-6791188

Name of Contact Person 1. MR. MOH UNG NANG

Date of Summary Prepared September 25, 1998

**3.0 Name of Device**

Trade Name : Evergreen Non-Sterile Powder Free Latex Examination Glove - Natural Color  
 Evergreen Non-Sterile Powder Free Latex Examination Glove -Pink  
 Evergreen Non-Sterile Powder Free Latex Examination Glove - Blue

Common Name Exam Glove

Classification Name Patient Examination Glove

**4.0 Identification of The Legally Marketed Devices**

Class 1 Latex Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-95 and FDA requirements.

**5.0 Description of The Device**

Class 1 Latex Patient Examination Glove 80 LYY, powder free that meets all the requirements of ASTM Standard D3578-95 and FDA Water leak test.

**6.0 The Intended Use of Glove**

A medical gloves 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.

16983608

**7. Summary of Performance Data :**

Performance data of gloves based on ASTM D3578-95 and FDA 1000ml watertight test.

TEST	ASTM D3578-95	EVERGREEN POWDER FREE LATEX EXAMINATION GLOVES
1. Watertight (1000ml)	G II AQL=4.0%	Pass G II AQL=4.0%
2. Length (mm)  Size XS S M L XL	Min 230 Min 230 Min 230 Min 230 -	240 mm minimum for all sizes
3. Palm width (mm)  Size XS S M L XL	- 80 + - 10 95 + - 10 111 + - 10	73 - 78 83 - 88 93 - 98 103 - 107
4. Thicknes (mm) (Single Layer)  Finger Palm	min 0.08 min 0.08	0.10 minimum 0.10 minimum
5. Physical Properties.  <b>Before Ageing</b>  Tensile Strength (Mpa) Ultimete Elongation (%)  <b>After Ageing</b>  Tensile Strength (Mpa) Ultimete Elongation (%)	min 14 min 700  min 14 min 500	23.8 - 25.2 810 - 910  19.8 - 20.7 750 - 870
6. Powder Content	-	below 2 mg/ glove
7. Protein content	-	below 50 microgram/ gram

8. The performance data of the glove as shown above meet the ASTM D3578-95 Standard and FDA's requirement.  
Powder content is below 2 mg per glove which meet the FDA Requirements.  
The protein content tested on accelerated aging gloves is < 50 mg/gram.
9. The Biocompatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buchler) test.  
The gloves pass the Biocompatibility Tests.
10. Conclusion

We concluded that the Evergreen non-sterile, powder-free Latex Examination Gloves meet :

- ASTM D3578-95 Standard
- FDA pinhole requirements
- FDA minimum powder residual content.
- Label Claim of maximum 50 micrograms per gram of glove or less for water Extractable Protein.



NOV 5 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

YTY Industry (Manjung) Sdn. Bhd.  
C/O Mr. E. J. Smith  
P.O. Box 4341  
Crofton, Maryland 21114

Re: K983608  
Trade Name: Evergreen Non-sterile, Latex Powder-Free  
Glove with Protein Content Labeling Claim (50  
Micrograms or Less) (Pink, Blue and Natural)  
Regulatory Class: I  
Product Code: LYY  
Dated: September 25, 1998  
Received: October 14, 1998

Dear Mr. Smith:

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 (Premarket 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. 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.

Page 2 - Mr. Smith

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,



f<sub>2</sub> 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): K983608

Device Name: Evergreen Non-Sterile, Powder-Free, Protein Content Labeling Claim (50 microgram or less)  
LATEX Examination Gloves: Natural, Blue and Pink

**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)

Prescription Use \_\_\_\_\_ or Over-the-Counter Use X

Chin S. Lin  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K983608