

K974518
December 12, 1998



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

510 (K) SUMMARY

1.0

2.0

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 Person

1. MR MOH UNG NANG

Date of Summary Prepared

September 25, 1997

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

5.0

Description Of The Device

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

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

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7. Summary of Performance Data :

Performance data of gloves based on ASTM D3578-95 and FDA 1000 ml 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. Before Ageing Tensile Strength (Mpa) Ultimate Elongation (%) After Ageing Tensile Strength (Mpa) Ultimate Elongation (%)	min 14 min 700 min 14 min 500	26.5 810 22.3 750
6. Powder Content	-	below 2 mg / glove
7. Protein Content	-	below 50 microgram / gram

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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 < 50mg/gram.

9. The Biocompatibility Tests 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.



DEC 12 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

YTY Industry (Manjung) SDN. BHD.
G/O Leonard Frier, PE
President
Met Laboratories
914 West Patapsco Avenue
Baltimore, Maryland 21230-3432

Re: K974518
Trade Name: Non-Sterile Powder-Free Latex Examination
Gloves Colored
Regulatory Class: I
Product Code: LYY
Dated: November 26, 1997
Received: December 2, 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.

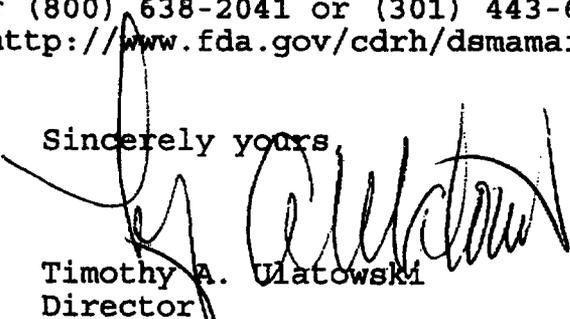
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 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) 594-4692. 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,



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): _____

Device Name: Evergreen Latex Powder-Free Examination Gloves; Natural, Pink, Blue

Indications For Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lin

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

510(k) Number K974518

cription Use _____

21 CFR 801.109)

OR

Over-The-Counter Use α

(Optional Format 1-2-96)

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