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

JUN 2 1 1999

K991742

1.0 SMDA 510 (K) SUMMARY

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	April 27, 1999

3.0 Name of Device

Trade Name	:	Non-Sterile Powder Free Polymer Coated Latex Examination Glove (Evergreen & Multiple Private Labels)
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 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 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 EXAM. GLOVES
1. Watertight (1000ml)	GII AQL = 4.0%	Pass GII 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. Thickness (mm) (Single Layer) Finger Palm	 Min 0.08 Min 0.08	 Min 0.10 Min 0.10
5. Physical Properties Before Aging Tensile Strength (Mpa) Ultimate Elongation (%) After Aging Tensile Strength (Mpa) Ultimate Elongation (%)	 Min 14 Min 700 Min 14 Min 500	 23 – 27 830 – 870 23 – 26 820 – 850
6. Powder Content	-	Below 2 mg/glove
7. Protein Content	-	Below 50 microgram/gram

8.0 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.

9.0 The Bio-compatibility Test consists of Primary Dermal Irritation Test and Guinea Pig Sensitization (Buehler) test.
The gloves pass the Bio-compatibility Test.

10.0 Conclusion

We concluded that the Multiple Private Labeled Non-Sterile, Powder Free Polymer Coated 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 1999

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

Re: K991742
Trade Name: Non-Sterile, Powder Free, Polymer Coated Latex Examination Gloves With Protein Content Labeling Claim (50 Micrograms or Less)
Regulatory Class: I
Product Code: LYY
Dated: May 10, 1999
Received: May 21, 1999

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.

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

K991742

INDICATIONS FOR USE STATEMENT

Applicant: YTY INDUSTRY (MANJUNG) SDN BHD

510K Number:

Device Name: Non-Sterile Powder Free Polymer Coated Latex Examination Gloves with Protein Content labeling claim (50 microgram or le (Evergreen & Multiple Private Labeled)

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)

Prescription Use ..... OR Over-The-Counter...X.....
Per 21 CFR 801.109

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991742