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

MAY 2 5 2001

K011376

APPENDIX H

1.0 510 (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	MR. MOH UNG NANG
	Date Summary Prepared	March 15, 2001

3.0 Name of Device

Trade Name	Evergreen or Multiple Private Labels Non-Sterile Powdered Latex Examination Gloves with protein labeling.
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, powdered with absorbable dusting powder, that meets all of the requirements of ASTM Standard D3578-00.

5.0 Description of The Device

Class 1 Latex Patient Examination Glove 80 LYY, powdered with absorbable dusting powder, that meets all of the requirement of ASTM Standard D3578-00 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 Technological Characteristic of Device.

A. DIMENSIONS

DIMENSION	ASTM D3578-00	EVERGREEN/PRIVATE LABEL GLOVE
X-Small Small Medium Large	70 mm ± 10 mm 80 mm ± 10 mm 95 mm ± 10 mm 111 mm ± 10 mm	73 – 78 mm 83 – 88 mm 95 - 100 mm 112 – 115 mm
Length	220 mm small sizes 230 mm med & lg 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. PHYSICAL PROPERTIES

TEST	TENSILE STRENGTH		ULTIMATE ELONGATION	
	ASTM D3578-00	YTY'S Gloves	ASTM D3578-00	YTY'S Gloves
BEFORE AGING	14.0 MPa	23.8 MPa	700 %	820 %
AFTER AGING 7 days at 70^{0}C	14.0 MPa	23.4 MPa	500 %	820 %

Our gloves meets all the specification of the ASTM D3578-00 Standards.

C. WATER TIGHT TEST

FDA water leak test method is used to test 80 pieces of gloves at AQL 2.5. General Inspection I Multiple Sampling Plan. The results are as follows:

Batch	Size	Sample Size	Unit Leak	Disposition
MYJ 12-3	Large	80	0	Accepted
MYJ 12-3	Medium	80	2	Accepted
MYJ 12-3	Small	80	1	Accepted

The test meets the FDA Water Leak Test Requirements.

D. BIOCOMPATIBILITY

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

The gloves pass the Biocompatibility Tests.

E. Water Soluble Protein Test by ASTM D5712-99 standard.

Batch No. Production Date	Protein Content µg/g (against OVBM)
1. 03110202 2. (Nov 6, 2000) Medium	198

Conclusion:

We conclude the Evergreen or Multiple Private Labels Non-Sterile, Powdered Latex Examination Gloves with protein labeling (200 micrograms or less) do Meet the following standards:

- ASTM D3578-00 Standard specification for Rubber Exam Gloves.
- ASTM D5151-99 Test Method for Detection of Holes in Medical Gloves.
- ASTM D6124-97 Standard Test for Residual Powder on Medical Gloves
- ISO 2859
- Bio-Compatibility Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2001

YTY Industry (Manjung) SDN. BHD.
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K011376
Trade/Device Name: Evergreen and Multiple Private Labels Non-Sterile Powdered Latex Patient Examination Gloves, with Protein Labeling (200 Micrograms/g)
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: April 30, 2001
Received: May 4, 2001

Dear Ms. Tucker :

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 legally marketed predicate 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 Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

APPLICANT: **YTY INDUSTRY (MANJUNG) SDN BHD**

510(k) NUMBER: K011376

DEVICE NAME: **POWDERED LATEX EXAM GLOVE WITH PROTEIN LEBELING (Less Than 200μg/g)**

A patient examination gloves 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
K011376