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 17 2003

K031384

APPENDIX-H

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
	Official Correspondence	2. MS. JANNA TUCKER
	Date of Summary Prepared	May 16, 2003

3.0 Name of Device

Trade Name: MULTIPLE PRIVATE LABELS, NON-STERILE, POWDER-FREE POLYURETHANE, WHITE COLOR EXAMINATION GLOVES

Common Name Exam Glove

Classification Name Patient Examination Glove

4.0 Identification of The Legally Marketed Devices

Class 1 Polyurethane Patient Examination Glove 80 LZA, powder free that meets all the requirements of ASTM Standard D6319-00a$^{\varepsilon 3}$.

5.0 Description of The Device

Class 1 Polyurethane Patient Examination Glove 80 LZA, powder free that meets all the requirements of ASTM Standard D6319-00a$^{\varepsilon 3}$ 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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7.0 Summary of Performance Data:

Performance data of gloves based on ASTM D6319-00a^{e3} and FDA 1000ML watertight test.

TEST	ASTM D6319-00a^{e3}	POWDER FREE POLYURETHANE EXAM. GLOVES
1. Watertight (1000ml)	Multiple Normal GI AQL = 2.5	Pass GI AQL = 2.5
2. Length (mm) Size XS S M L XL	 Min 220 Min 220 Min 230 Min 230 -	240 mm minimum for all sizes
3. Palm width (mm) Size XS S M L XL	 70 ± 10 80 ± 10 95 ± 10 110 ± 10 -	 73 – 78 83 – 88 93 – 98 103 – 107
4. Thickness (mm) (Single Layer) Finger Palm	 Min 0.05 Min 0.05	 Min 0.13 Min 0.11
5. Physical Properties Before Aging Tensile Strength (MPa) Ultimate Elongation (%) After Aging Tensile Strength (MPa) Ultimate Elongation (%)	 Min 14 Min 500 Min 14 Min 400	 16-23 600-800 20 – 23 600-720
6. Powder Content	Max 2.0mg/glove	Below 2 mg/glove

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8.0 The performance data of the glove as shown above meet the ASTM D6319-00a$^{\varepsilon 3}$ Standard
Powder content is below 2 mg per glove.

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 Polyurethane White Color Examination Gloves meets:

- ASTM D6319-00a$^{\varepsilon 3}$Standard
- FDA pinhole requirements
- Are below the maximum Powder Residual Content as specified in ASTM D6319-00a$^{\varepsilon 3}$

- We feel this glove is substantially equivalent to the glove approved in K011198.

Revised 6-4-03 JC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2003

YTY Industry (Manjung) Sdn. Bhd.
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D'emarald
Sparks, Nevada 89434-9550

Re: K031384
Trade/Device Name: Multiple Private Labeled, Non-Sterile, Powder-Free Polyurethane White Color, Examination Gloves (Intacta* Polyurthane Gloves)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: June 3, 2003
Received: June 5, 2003

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Applicant: YTY INDUSTRY (MANJUNG) SDN BHD

510K Number: K031384

Device Name: MULTIPLE PRIVATE LABELED, NON-STERILE, POWDER-FREE, POLYURETHANE WHITE COLOR, EXAMINATION GLOVES (INTACTA* POLYURETHANE 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.

Concurrence of CDRH Office of Device Evaluation (ODE)

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

510(k) Number: K031384

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