PT. TATA RUBBERINDO INDUSTRIES

11 th. Floor WISMA ARGO MANUNGGAI
Jl. Jend. Gatot Subroto Kav. 22
Jakarta - 12930

Factory : Jl. Raya Serang Km. 13.8
Phone : ( 021 ) 5962435 (Hunting)
Fax. : ( 021 ) 5962436
Cikupa - Tangerang

K991158



## "510 (K)" SUMMARY (K991158)

(1) Name of applicant : Mr. Andy Tanaka
Address : PT. Tata Rubberindo Industries
Jl. Raya Serang Km. 13.8
Cikupa - Tangerang
Jakarta – Indonesia
Phone No. 62-21- 5962435
Fax No . 62-21- 5962436

The contact persons within the firm as well as in U.S.A are given below:
Contact person in firm : Mr. Andy Tanaka
Fax No . 62-21- 5962436

Contact person in U.S.A : Cindy Tung
Fax No. : 626-913-1498

(2) Device details
Trade Name : Latex Examination Gloves - Powder Free
Classification Name : Patient Examination Gloves
Product Code : Latex 80 LYY

(3) Equivalent device legally marketed : Class I Latex Examination Gloves 80 LYY Powder – Free meeting ASTM D 3578-95

(4) Intended use : A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between and patient examiners.

(5) Technological characteristic of the gloves.

a. Dimensions

| Sizes | XS | S | M | L | XL |
|---|---|---|---|---|---|
| Length | 240 mm | 240 mm | 240 mm | 240 mm | 240 mm |
| Width | 80 < mm | 80±10 mm | 95±10 mm | 111±10 mm | >111mm |
| Thickness | | | | | |
| 1. Cuff (min) | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm |
| 2. Palm (min) | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm |
| 3. Finger Tip (min) | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm | 0.10 mm |

b. Physical Properties

| | Before aging | After aging at 70°C 168 hrs. |
|---|---|---|
| Tensile Strength : | 21 Mpa | 16 Mpa |
| Ultimate Elongation : | 700 % (min.) | 600 % (min.) |

(6) Performance data is the same as mentioned immediately above.

(7) Clinical date is not needed for gloves or for most devices cleared by the 510 (K) process.

(8) Non-clinical data
We certify that these gloves meet ASTM D 3578 Standard.
Meets FDA pinhole requirement.
Meets labeling claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 1999

PT. Tata Rubberindo Industries
C/O Mr. Andy Tanaka
Jl. Raya Serang Km. 13.8
Cikupa – Tangerang
INDONESIA

Re: K991158
Trade Name: Latex Examination Gloves – Powder Free
Regulatory Class: I
Product Code: LYY
Dated: May 12, 1999
Received. My 14, 1999

Dear Mr. Tanaka:

This letter corrects our substantially equivalent letter of May 28, 1999 regarding the address.

We have reviewed your Section 510(k) notification of intent to market the device ific 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 yoto 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely,

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

Enclosure

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**ANNEXURE II**

K991158

## INDICATION FOR USE

Applicant : Mr. Andy Tanaka
Device Name : Latex Patient Examination Gloves Powder Free
Indication for use :

A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiners.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chiu S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991158

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

(Optional Format 1-2-96)

[redacted]