FEB 7 2000

K994255

PT. MAJA AGUNG LATEXINDO

MANUFACTURING OF LATEX GLOVES

Jln. Utama No. 98 PUJI MULIO
SUNGGAL - DELI SERDANG
SUMATERA UTARA - INDONESIA

Telp. 62-61 - 859
62-61 - 859
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"510 (K)" SUMMARY

(1) Name of applicant : Mr. Hansen Laurence
Address : PT.Maja Agung Latexindo
Jl.H. M. Yamin No. 40 - 40 A
Medan
Indonesia
Phone No. 62 - 61 - 328888; 62 - 61 - 859170
Fax No . 62 - 61 - 520588; 62 - 61 - 520588

The contact persons within the firm as well as in U.S.A are given below:
Contact person in firm : Mr. Hansen Laurence
Fax No.: 62 - 61 - 520588 62-61-8459180

Contact person in U.S.A : Emmy Tjoeng
Fax No.: 626-913-1498

(2) Device details
Trade Name : Private lebel-Latex Examination Gloves Pre - Powdered
Classification Name : Patient Examination Gloves
Product Code : Latex 80 LYY

(3) Equivalent device legally marketed : Class I Latex Examination Gloves 80 LYY Pre-Powdered 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 that require a sterile procedure.

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(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 ageing	After ageing at 100°C 22 hrs.
Tensile Strength	:	21 Mpa (min.)	16 Mpa (min.)
Ultimate Elongation	:	700 % (min.)	600 % (min.)

c. Performance Requirement

Characteristic	Related Defects	Inspection Level	AQL
Visible defects	Stains, Lumps, Holes etc.	S-4	2.5
Watertight	Holes	S-4	1.5
Dimensions	Width Length & Thickness	S-2	4
Physical Properties	Before and after ageing	S-2	4
Sterility	Fails sterility		Not Acceptable

(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
Gloves meet or exceed the ASTM D 3578 Standard.
Meets FDA pin hole requirement.
Meets labeling claim.
Meets the sterility assurance level.

ANNEXURE XI

MATERIALS USED FOR THE PRODUCTION OF LATEX EXAMINATION GLOVES - PRE-POWDERED

	Dry Weight
60 %Concentrated Natural Rubber Latex	- 100
Zinc diethyl dithiocarbamate	- 0.50
Zinc dibutyl dithiocarbamate	- 0.30
Zinc oxide	- 0.75
Sulphur	- 0.80
KOH Solution	- 0.10
Titanium dioxide	- 0.60
BHT	- 1.50

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 7 2000

PT. Maja Agung Latexindo
c/o Mr. Emmy Tjoeng
Official Correspondent for
PT. Maja Agung Latexindo
Shamrock Marketing Company, Incorporated
889 South Azusa Avenue
City of Industry, California 91748

Re: K994255
Trade Name: Latex Examination Gloves Pre-powdered Sterile
Regulatory Class: I
Product Code: LYY
Dated: December 15, 1999
Received: December 17, 1999

Dear Mr. Tjoeng:

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

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ANNEXURE II K994255

INDICATION FOR USE

PT. Maja Agung Latexindo

Applicant : Mr. Hansen Laurence
Device Name : Latex Examination Gloves Pre-Powdered Sterile
Indication for use :

A latex 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 that require a sterile procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Chin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994255