



PT. MAJA AGUNG LATEXINDO

MANUFACTURING OF LATEX GLOVES

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

Telp. 62-61 - 859160
62-61 - 859170
Fax. 62-61 - 859180

Page Numbers 1 of 2

"510 (K)" SUMMARY

(1) Name of applicant : Mr. Hansen Laurence
Address : PT. MAJA AGUNG LATEXINDO
Jl. H. Yamin No. 40 - 40 A
Medan 20234
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 ; 62-61-859170

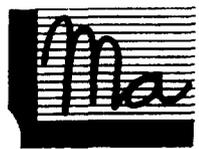
Contact person in U.S.A : Emmy Tjoeng
Fax No. : 562-693-8866

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

(1) Equivalent device legally marketed : Class I Latex Examination Gloves 80 LYY
Powder Free with Protein Claim
meeting ASTM D 3578 - 95

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

K982897



PT. MAJA AGUNG LATEXINDO

MANUFACTURING OF LATEX GLOVES

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

Telp. 62-61 - 859160
62-61 - 859170
Fax. 62-61 - 859180

Page Numbers 2 of 2

(5) Technological characteristic of the gloves.

a. Dimensions

Sizes	Small	Medium	Large
Length (min.)	240 mm	240mm	240 mm
Palm Width thickness	85±10 mm	95±10 mm	111±10 mm
1. Cuff (min)	0.10 mm	0.10 mm	0.10 mm
2. Palm (min)	0.10 mm	0.10 mm	0.10 mm
3. Finger Tip (min)	0.10 mm	0.10 mm	0.10 mm

b. Physical Properties

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

c. Performance Requirement

Characteristic	Related Defects	Inspection Level	AQL
Watertight	Holes	S-4	2.5
Dimensions	Width Length & Thickness	S-2	4
Physical Properties	Before and after ageing	S-2	4

- d. Weight of residual powder in medium size gloves : 0.50 ± 0.20 mg
- e. Total water extractable protein 50 microgram/gram (maximum)
- f. Bio-Compatibility (attached) Annexure XII
- g. Test Results as per ASTM D 3578 – 95 (attached) Annexure V

(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 Standard.
- Meets FAD pin hole requirement.
- Meets labeling claim.

K 982897

MATERIALS USED FOR
THE PRODUCTION OF LATEX EXAMINATION GLOVES
POWDER – FREE WITH PROTEIN CLAIM

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1998

P.T. Maja Agung Latexindo
C/O Ms. Emmy Tjoeng
Official Correspondent
Glove Source, Incorporated
345 Cloverleaf Drive, Suite B
Baldwin Park, California 91706

Re: K982897
Trade Name: Powder-Free Latex Examination Glove with
Protein Content Labeling Claim (50 micrograms or less)
Regulatory Class: I
Product Code: LYY
Dated: November 25, 1998
Received: November 27, 1998

Dear Ms. 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 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 (Pre-market 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 pre-market notification submission does not affect any obligation you might have under sections 531

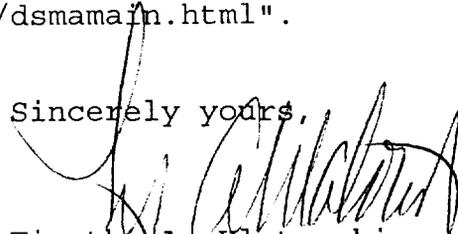
Page 2 - Ms. Tjoeng

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,



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

Enclosure



PT. MAJA AGUNG LATEXINDO

MANUFACTURING OF LATEX GLOVES

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

Telp. 62-61 - 85911
62-61 - 85911
Fax. 62-61 - 85911

K982897

ANNEXURE II

INDICATION FOR USE

Applicant : Mr. Hansen Laurence
Device Name : Latex Patient Examination Gloves Powder Free With Protein
Indication for use : Content Labeling Claim (50 micrograms or less)

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)

Sparita for Chen
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982897

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)