PT. MAJA AGUNG LATEXINDO

MANUFACTURE OF LATEX GLOVES

K013996

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

Telp. 62-61 - 8459160
62-61 - 8459170
Fax. 62-61 - 8459180

FEB 2 6 2002

"510 (K)" SUMMARY

(1) Name of applicant : Mr. Hansen Laurence
Address : PT. MAJA AGUNG LATEXINDO
Jl. Utama No. 98 Puji Mulio
Sunggal –Deli Serdang
North Sumatra - Indonesia
Phone No. : 62-61-845-9170
Fax No. : 62-61-845-9180

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. : 62-61-845-9180

Contact person in U.S.A : Emmy Tjoeng
Fax No. : 909-591-8878

(2) Device details
Trade Name : Latex Powder free Sterile Examination Gloves

Classification Name : Latex Powder free Sterile Examination Gloves

(3) Product Code : Latex 80 LYY

(4) Equivalent device legally marketed : Class I Latex Examination Gloves 80 LYY
Pre – Powdered meeting ASTM D 3578 – 01
Sterilized by gamma radiation

(5) Intended use : A latex 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.

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(6) 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	75±5 mm	80±10 mm	00±10 mm	105±10 mm	115±5 mm
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 70°C 168 hrs.
Tensile Strength :	14 Mpa	14 Mpa
Ultimate Elongation :	650 % (min.)	600 % (min.)

c. Performance requirement

Characteristic	Related Defects	Inspection Level	AQL
Sterility	Fails sterility	*A*	N/A
Freedom from holes	Holes	1	2.5
Dimensions & Thickness	Width Length	S-2	4
Physical Properties after ageing	Before and	S-2	4
Powder Free Residue	Exceeds Maximum Limit	N=5	N/A
Protein Content	Exceeds Recommended Maximum Limit	N=3	N/A
Powder Amount	Exceeds Recommended Maximum Limit	N=2	N/A

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

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

(9) Non-clinical data
We certify that the gloves meet or exceed the ASTM D 3578 – 01 Standard.
Meets FDA pinhole requirement.
Meets labeling claim.
Meets the sterility assurance level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

PT. Maja Agung Latexindo
C/O Ms. Emmy T. Joeng
Shamrock Marketing Company, Incorporated
5445 Daniel Street
Chino, California 91710

Re: K013996
Trade/Device Name: Latex Powderfree Sterile Examiantion Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: November 29, 2001
Received: December 3, 2001

Dear Ms. Joeng:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

INDICATION FOR USE

Applicant : Mr. Hansen Laurence
Device Name : Latex Powderfree Sterile Examination Gloves
Indication for use :

A sterile latex powderfree 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.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013996