

OCT 1 0 2003

K032201

PERUSAHAAN PELINDUNG GETAH (M) SDN BHD

(Company No. 169997-P)
Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat,
Senawang Industrial Estate, 70450 Seremban,
Negeri Sembilan Darul Khusus, Malaysia.
Tel: 606-6772781 Fax: 606-6772780



Amended: October 2, 2003
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510(K) SUMMARY

Applicant: PERUSAHAAN PELINDUNG GETAH (M) SDN BHD

Address Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat
Senawang Industrial Estate, 70450 Seremban,
Negeri Sembilan, Malaysia.

Phone No. 60-6-6772781 Fax No. 60-6-6772780

Contact Person Peter Yew Nieng Choon

Date of Summary October 2, 2003

Device Information

Trade Name RUBBERCARE

Common Name Powdered Latex Exam Gloves

Classification Name Patient Examination Glove, powdered

Claim of Equivalence

The device is a class I latex patient examination gloves 80LYY powdered with absorbable dusting powder, that meets all the requirements of ASTM standard D 3578-01a⁶².

Device Description

It is made from natural rubber latex using USP cornstarch as donning powder. The manufacturing process includes pre and post leaching stages to remove residual chemicals and water-soluble proteins. The extent of protein removal is within the limit of the ASTM D3578-01a⁶² recommended limits for both powder and water-soluble protein.

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Intended Use of Device

The device is intended as a protective device to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Technological Characteristics

Following is a table showing the measured parameters of the gloves (e.g. lengths, thickness, widths, physical properties, protein contents, etc) as compared to ASTM. Also data that meets FDA biocompatibility, pinhole, and any other requirements, and any other parameter on which we want to make a labeling claim.

Parameter	ASTM Specifications	Measured Values
Length (sizes M, L), mm	230 min.	240 – 245
Thickness (palm), mm	0.08 min.	0.14 – 0.16
Thickness (finger), mm	0.08 min.	0.16 – 0.20
Width (size M), mm	95 ± 10	94 – 98
Tensile Strength, Before Aging, Mpa	18 min.	20 – 29
Tensile Strength, After Aging, Mpa	14 min.	20 – 26
Ultimate Elongation, Before Aging, %	650 min.	750 – 900
Ultimate Elongation, After Aging, %	500 min.	750 – 950
Water Extractable Protein, µg/gram	200µg/dm ² (recommended)	100µg/gram and below
Water Leak Test, Before Aging, AQL	2.5	1.5 and below
Water Leak Test, After Aging, AQL	n.a.	2.5 and below
Residual Powder, mg/dm ²	10	9 – 10
Skin Irritation Test	n.a	Passed*
Dermal Sensitization Test	n.a	Passed*

* Please refers to attachment H (page 19)

Conclusions

Based on the test data given above, we certify that our gloves:

- meet or exceed the ASTM standard D3578-01a^{e2}
- meet the FDA pinhole requirements; and
- meet our labeling claim on protein content.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Mr. Peter Yew Nieng Choon
Managing Director
Perusahaan Pelindung Getah (M) SDN BHD
Lot 110, Lorong Senawang 4/3, Off Jalan Senawang Empat
Senawang Industrial Estate, 70450 Seremban,
Negeri Sembilan, Darul Khusus,
MALAYSIA

Re: K032201

Trade/Device Name: Rubbercare Powdered Latex Examination Gloves (containing 100
Micrograms or Less of Total Water Extractable Protein Per gram)
Regulation Number: Patient Examination Glove
Regulation Name: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: October 2, 2003
Received: October 6, 2003

Dear Mr. Nieng Choon:

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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

PERUSAHAAN PELINDUNG GETAH (M) SDN BHD

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INDICATIONS FOR USE

Applicant: PERUSAHAAN PELINDUNG GETAH (M) SDN BHD
510(k) No. K032201
Device Name: RubberCare Powdered Latex Examination Gloves (containing 100 micrograms or less of total water extractable protein per gram)

Indications for Use

The RubberCare powdered 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 examiner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dr. Prof. Dr. Chuan-Lian

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

510(k) Number: K032201

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)