

**510(k) SUMMARY**

**01.11.1997**

**NOV 20 1998**

*K981975*

**1.0 APPLICANT:**

Dr. POONSUK CHERDKIATGUMCHAI  
SIAM SEMPERMED CORPORATION. Ltd.  
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PATHONG HATYAI SONGKHLA  
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**2.0 CONTACT PERSON**

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MR DON MORRIS  
SATARI CORP.,Ltd  
30798 US Hwy 19 N  
Palm Harbor  
USA FL 34684  
TEL: 813 787 7250 OR 800 366 9545  
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**3.0 Device Class: I**

**Product code: 80LYY**

**4.0 Specification:** Latex patient examination glove powderfree -Class I 80LYY  
meets all of the requirements of ASTM standard D3578-95

**5.0 Device Description:** Latex Patient Examination glove Powderfree (blue color) Polymer coated

**6.0 Intended use:** A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner.

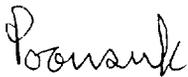
**7.0 Surface treatment:** Polymer coated, Halogenation/Siliconization and extensive washing in water  
**Outer surface:** Free from glove powder

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**9.0 QUALITY CHARACTERISTICS**

DESCRIPTION	ASTM standard	SPECIFICATION
<b>DIMENSION</b> Overall length	<b>S-2 AQL 4.0</b> 230 min.	<b>S-2 AQL 4.0</b> 240+/-10 mm
Width (double wall)	S 80 +/- 10 mm M 95 +/- 10 mm L 111 +/- 10 mm	SS < 80 mm S 83 +/- 5 mm M 94 +/- 5 mm L 105 +/- 4 mm XL 110 +/- 5 mm
Thickness, mm Finger palm	0.08 mm MIN. 0.08 mm MIN.	0.08 mm MIN. 0.08 mm MIN.
<b>PHYSICAL PROPERTIES</b> Before and aging Tensile strength Elongation at break	<b>S-2 AQL 4.0</b>  According to ASTM D3578-95	<b>S-2 AQL 4.0</b>  14 Mpa MIN 700% MIN.
After aging Tensile strength Elongation at break		14 Mpa MIN. 500% MIN.
<b>WATER EXTRACTABLE PROTEIN</b>	N/A	<b>S-2 AQL 4.0</b>
<b>POWDER LEVEL</b>	N/A	2 mg MAX.
<b>FREEDOM FROM HOLE</b>	<b>S-4 AQL 4.0</b>	<b>II AQL 1.5</b>

**9.0 Conclusion:** Siam Sempermed Latex Patient Examination Glove Powderfree (blue color) polymer coated meet the ASTM standard or equivalent standard  
 meet pinhole FDA requirements  
 meet labeling claims (see 5.0 and 6.0 above)



Dr. POONSUK CHERDKIATGUMCHAI  
 Corporate Officer (quality)



NOV 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SIAM SEMPERMED CORPORATION, Limited  
C/O Mr. Don Morris  
SATARI Corporation, Limited  
30798 US Highway 19N  
Palm Harbor, Florida 34684

Re: K981975  
Trade Name: Latex Patient Examination Glove Powder-Free  
(Blue Color) Polymer Coated  
Regulatory Class: I  
Product Code: LYY  
Dated: October 20, 1998  
Received: October 21, 1998

Dear Mr. Morris:

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.

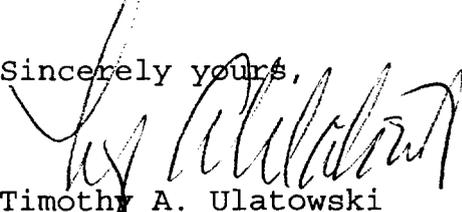
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 pre-market 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.

Page 2 - Mr. Morris

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

510(k) NUMBER (IF KNOWN): K981975

DEVICE NAME: LATEX PATIENT EXAMINATION GLOVE -POWDER FREE  
POLYMER COATED - BLUE

INDICATIONS FOR USE:

A MEDICAL GLOVE IS WORN ON THE HAND OF HEALTH CARE AND  
SIMILAR PERSONNEL TO PREVENT CONTAMINATION BETWEEN HEALTH  
CARE PERSONNEL AND THE PATIENT.

(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)

*Oliver S. Lim*

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

510(k) Number K 981975