

K011749

AUG 22 2001

**Siam Sempermed Corp., Ltd.**   
110 Moo 8 Kanjanavanit Rd., Hat Yai, Songkhla, Thailand 90230  
Tel: 66 074 291 648 to 9 Fax: 66 074 291 650

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**510 (k) SUMMARY**  
21062001

**1.0 APPLICANT:**

Dr. POONSUK CHERDKIATGUMCHAI  
SIAM SEMPERMED CORPORATION., Ltd.  
110 MOO 8 KANJANAVANIT ROAD  
PATHONG HATYAI SONGKHLA  
THAILAND 90230  
TEL: 66 074 291 648 OR 291 649  
FAX: 66 074 291 650

**2.0 CONTACT PERSON**

Dr. POONSUK CHERDKIATGUMCHAI  
SIAM SEMPERMED CORPORATION., Ltd.  
110 MOO 8 KANJANAVANIT ROAD  
PATHONG HATYAI SONGKHLA  
THAILAND 90230  
TEL: 66 074 291 648 OR 291 649  
FAX: 66 074 291 650

MR WILLIAM HARRIS  
SEMPERMED USA Inc.  
30798 US Hwy. 19 N  
Palm Harbor,  
USA FL 34684  
TEL: 727 787 7250  
FAX: 727 787 7558

**3.0 Device Class: J**

Product code: 80LYY

**4.0 Specification:** Latex patient examination glove, Powder Glove (Single side polymer coated) -Class I 80LYY meets all of the requirements of ASTM standard D3578-00

**5.0 Device Description:** Latex Patient Examination glove, Powder Glove (Single side polymer coated), non sterile 200 micrograms or less of total water extractable protein per gram

**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 Outer Surface :** Free from talc (Magnesium silicate)

**8.0 Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler) :** Consumer Product Testing Co. Experiment reference number : T95-0189-1

**Conclusion :** According to Federal Hazardous Substances Act Regulation, (16 CFR 1500.41), and under the conditions of this test, This test article is not a primary dermal irritant

: This test article is not a sensitizer in guinea.pigs, under condition of this test.

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Corp., Ltd.

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**9.0 QUALITY CHARACTERISTICS**

Dimensions	Meet ASTM D 3578-00
Physical Properties	Meet ASTM D 3578-00
Protein content	Recommended 200 ug/dm <sup>2</sup> in ASTM D 3578-00
Freedom from pinholes	Meet ASTM D 3578-00 Meet ASTM D 5151

**10. Conclusion:** Siam Sempermed Latex Patient Examination Glove ,Powder Glove , 200 micrograms or less of total water extractable protein per gram  
meet the ASTM standard or equivalent standard  
meet pinhole FDA requirements  
meet labeling claims (see 5.0 and 6.0 above)

*P. Cherdkiatgumchai*

Dr. POONSUK CHERDKIATGUMCHAI  
Chief Quality Officer  
21062001



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 22 2001

Ms. Katie Levinson  
Product Manager  
Sempermed USA, Incorporated  
30798 US Highway 19 North  
Palm Harbor, Florida 34684

Re: K011749  
Trade/Device Name: Latex Powdered Patient Examination  
Glove, 200 Micrograms or Less  
Regulation Number: 880.6250  
Regulatory Class: I  
Product Code: LYY  
Dated: May 24, 2001  
Received: May 31, 2001

Dear Ms. Levinson:

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.

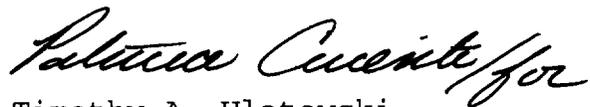
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

**INDICATION FOR USE**

Applicant: Siam Sempermed Corp. Ltd.

510(k) Number (if known): K011749

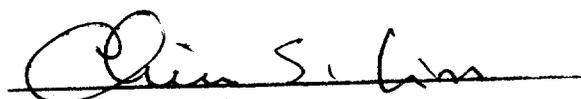
Device Name: Latex Powdered Examination Glove with a Protein Content Labeling Claim of 200 micrograms or less of water extractable protein per glove

**Indications For Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner.  
(21CFR 880.6250)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K011749