

JUN 6 2002

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

K021220

**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  
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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: I**

Product code: 80LZA

**4.0 Specification:** Nitrile patient examination glove , Powder Free Glove , Blue color ,Non sterile

Class I 80LZA meets all of the requirements of ASTM standard D6319-00a<sup>e1</sup>

**5.0 Device Description:** Nitrile Patient Examination glove , Powder free Glove, Blue color  
non sterile  
Glove were tested for permeation with Chemotherapy Drugs

**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:** Halogenation / Siliconization and extensive washing in water.  
Outer surface : Free from glove powder

**8.0 Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler) : Consumer Product Testing Co.**  
Experiment reference number : T99-0171-1

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

510 (k) SUMMARY

**9.0 QUALITY CHARACTERISTICS**

Dimensions	Meet ASTM D 6319-00a <sup>e1</sup>
Physical Properties	Meet ASTM D 6319-00a <sup>e1</sup>
Residue Powder	Meet ASTM D 6319-00a <sup>e1</sup>
Freedom from pinholes	Meet ASTM D 6319-00a <sup>e1</sup> Meet ASTM D 5151

**10. Conclusion:** Siam Sempermed Nitrile patient examination glove , Powder Free Glove , Blue color , non sterile

meet the ASTM standard or equivalent standard  
meet pinhole FDA requirements  
meet labeling claims (see 5.0 and 6.0 above)



Dr. POONSUK CHERDKIATGUMCHAI  
Chief Quality Officer  
Nov 12,2001



JUN 6 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Siam Sempermed Corporation Limited  
C/O Mr. John V. Calhoun  
Sempermed USA, Incorporated  
30798 US Highway 19 North  
Palm Harbor, Florida 34684

Re: K021220

Trade/Device Name: Nitrile Patient Examination Glove Powder-Free (Blue Color)  
Tested for Use with Chemotherapy Drugs  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: I  
Product Code: LZA  
Dated: March 18, 2002  
Received: March 22, 2002

Dear Mr. Calhoun:

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.

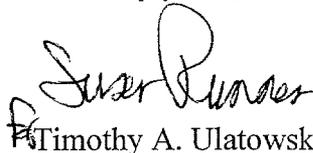
Page 2 – Mr. Calhoun

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

## INDICATIONS FOR USE

Applicant: Siam Sempermed Corp., Ltd.

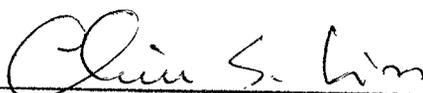
510(k) Number: K 021220

Device Name: Nitrile Patient Examination Glove Powder-Free (Blue Color)  
Tested for Use with Chemotherapy Drugs

### 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)

Gloves to be used for protection against chemotherapy drug exposure during use with chemotherapy drug preparation and administration to patients. Chemotherapy drugs tested are: Amethopterin Hydrate, Cisplatin, Cyclophosphamide, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, 5-Flourouracil, Paclitaxel, and Vincristine Sulfate.



(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K 021220

(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)