K122363

510 (k) Summary

As Required by 21 section 807.92 (c)

SEP 10 2012

1. **Submitter Name:** Siam Sempermed Corp., Ltd
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5. **Contract Person:** Mr. Anan Pruksanusak (Chief Operations Officer)
6. **Date summary prepared:** April 07, 2012
7. **Official Correspondent:** Sempermed USA Inc.
8. **Address:** 13900 49th Street North Clearwater, USA , FL 33762
9. **Phone:** 727 787 7250
10. **Fax:** 727 787 7558
11. **Contact person:** Mr. William E. Harris
12. **Device Trade or Proprietary Name:** Non sterile, Powder free Nitrile Examination Glove, Blue.
13. **Device Common or usual name:** Examination glove
14. **Device Classification Name:** Nitrile Patient Examination Glove (Powder free, Blue color)
15. **Description of the Device:**
    Non sterile, Powder free Nitrile Examination Glove, Blue.
16. **Intended use of the device:**
    A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
17. **Summary of The Technological Characteristics of The devices:**
    Non-sterile, Powder free Nitrile Examination Glove, Blue is summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions: overall length; width, palm and finger thickness	ASTM D 6319-10	Meets
Tensile strength: before and after aging	ASTM D 6319-10	Meets
Ultimate elongation: before and after aging	ASTM D 6319-10	Meets
Freedom from holes: pinholes AQL 2.5	ASTM D 6319-10	Meets
Powder Free Residue	ASTM D 6319-10	Meets
Biocompatability	Primary Skin Irritation in Rabbits Guinea Pig Sensitization	Passes Passes
Dimensions: overall length; width, palm and finger thickness	ASTM D 6319-10	Meets

18. Substantial Equivalents Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above.

19. Conclusion

It can be concluded that the Non sterile, Powder free Nitrile Examination Glove, Blue will perform according to the glove performance standards referenced in section 17 above and meet ASTM standards, and FDA requirements. Consequently, this device is substantially equivalent to currently marketed devices. This device is safe and effective as the predicate device *Siam Sempermed Corp., Ltd Nitrile, Examination Glove, Blue, Powder free.* Indeed, it is equivalent. This is better expressed in the tabulated comparison as below.

A technical comparison process flow chart is offered on the following page.

FDA file reference number of predicate device	510k number : K083755 (Non-Strile, Powder Free Nitrile Examination Glove, with Polymer Coating, Tested for use with Chemotherapy Drugs
TECHNOLOGICAL CHARACTERISTICS	See additional details in main submission, Section 4, Subpart H
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Not applicable
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Not applicable
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Not applicable
Dimensional standards	Identical
Physical properties	Identical
Thermal safety	Not applicable
Radiation safety	Not applicable
Production process	Similar; new device is online chlorinated. See following page for more information
Labeling	Similar: new device lacks a chemotherapy labeling claim and associated statements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 10 2012

Siam Sempermed Corporation, Limited
C/O Mr. William E. Harris
President and Chief Executive Officer
Sempermed USA, Incorporated
13900 49TH Street North
Clearwater, Florida 33762

Re: K122363
Trade/Device Name: Non-Sterile, Powder-Free Nitrile Examination Glove, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: August 6, 2012
Received: August 6, 2012

Dear Mr. Harris:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122363

Device Name: Non-sterile, Powder-free Nitrile Examination Glove, Blue

Indications For Use: A powder-free examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K122363