DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 11, 2015

Siam Sempermed Corp., LTD
c/o John Calhoun
Manager of Regulatory Affairs
Sempermed USA, Inc.
13900 49th Street North
Clearwater, Florida 33762

Re: K142685
Trade/Device Name: Non-Sterile, Powder Free Nitrile Examination Gloves with Polymer Coating, Aloe, Vitamin E, White and Pink
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: January 9, 2015
Received: January 12, 2015

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. 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142685

Device Name
Non-sterile, Powder free Nitrile Examination Glove with Polymer Coating, Aloe, Vitamin E, White and Pink

Indications for Use *(Describe)*
This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ATTACHMENT 5

K142685

510 (k) Summary

1.0 Submitter

Company name: Siam Sempermed Corp., Ltd

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Songkhla. Thailand 90110

Phone: (+66) 74 344 663

Fax: (+66) 74 344 677

Contact Person: Mr. Anan Pruksanusak (Managing Director)

2.0 Official Correspondent

Company name: Sempermed USA Inc.

Address: 13900 49th Street North
Clearwater, USA , FL 33762

Phone: 727-787-7250

Fax: 727-787-7558

Contact person: John V. Calhoun

3.0 Preparation Date: September 11, 2014

4.0 Identification of Legally Marketed Predicate Device

Trade/Proprietary Name: *Nitrile Examination Gloves with Aloe & Vitamin E, Powder-free*

Device Description: *Non-sterile, Powder-free Nitrile Examination Glove with Polymer Coating, Aloe and Vitamin E, Blue*

510(k): K121549

Device name: Examination glove

Device Classification Name: Patient Examination Gloves (21 CFR 880.6250)

Device Class: Class 1

Product Code: LZA

Classification Panel: General Hospital (Part 880)

5.0 Device description

The subject device is a patient examination glove made of a synthetic nitrile latex compound. It is non-sterile, powder-free, with a polymer inner coating, and coating of aloe and Vitamin E (per 21 CFR 880.6250, Class I). The device can be either white or pink in color. The device is ambidextrous and can be worn on either the left or right hand. The device meets ASTM D6319-10: Standard Specification for Nitrile Examination Gloves for Medical Application.

The subject device is substantially equivalent to legally marketed Nitrile Examination Gloves identified as Product Code LZA.

6.0 Intended Use of Device

Non-sterile, Powder free Nitrile Examination Glove with Polymer Coating, Aloe, Vitamin E, White and Pink is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

7.0 Summary of Technological Characteristics of Device and Comparison to Legally Marketed Predicate Device

Non-sterile, Powder free Nitrile Examination Glove with Polymer Coating, Aloe, Vitamin E, White and Pink is substantially equivalent to the predicate device, which differs only by color. A side-by side comparison of the predicate device with the subject device is presented in Table 1 on the following pages.

Table 1. Side-by-side Comparison of Predicate Device with Subject Device

Characteristics	Acceptance Criteria/Standards	**Predicate: K121549** Non-Sterile, Powder-free Nitrile Examination Glove with Polymer Coating. Aloe and Vitamin E, Blue	**Subject device (K142685)** Non-Sterile, Powder-free Nitrile Examination Glove with Polymer Coating. Aloe and Vitamin E, White and Pink
Indications for Use	Medical Glove Guidance Manual	This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	This is a medical device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner
Device Design	-	A protective garment that covers the hand and wrist with openings for fingers and thumb	A protective garment that covers the hand and wrist with openings for fingers and thumb
Material	ASTM D6319-10	Nitrile Synthetic latex	Nitrile Synthetic latex
Single Use	Medical Glove Guidance Manual	Single use	Single use
Ambidextrous	Medical Glove Guidance Manual	Ambidextrous	Ambidextrous
Sterility	Not applicable	Not applicable	Not applicable
Dimensions	ASTM D6319-10 -*Overall Length:* 220 mm min (XS, S) 230 mm min (M, L, XL) -*Width (+/- 10 mm)* Size XS:70 mm Size S: 80 mm Size M: 95 mm Size L: 110 mm Size XL: 120 mm -*Thickness:* Finger: 0.05 mm min Palm: 0.05 mm min	Meets ASTM D6319-10 -*Overall Length:* 220 mm min (XS, S) 230 mm min (M, L, XL) -*Width (+/- 10 mm)* Size XS:70 mm Size S: 80 mm Size M: 95 mm Size L: 110 mm Size XL: 120 mm -*Thickness:* Finger: 0.05 mm min Palm: 0.05 mm min	Meets ASTM D6319-10 -*Overall Length:* 220 mm min (XS, S) 230 mm min (M, L, XL) -*Width (+/- 10 mm)* Size XS:70 mm Size S: 80 mm Size M: 95 mm Size L: 110 mm Size XL: 120 mm -*Thickness:* Finger: 0.05 mm min Palm: 0.05 mm min
Physical Properties	ASTM D6319-10 (aging= 70 +/- 2°C for 166 +/- 2 hrs; 100 +/- 2° C for 22 +/- 0.3 hrs) -*Tensile Strength:* 14 MPa min (before aging) 14 MPa min (after aging) -*Ultimate Elongation*: 500% min (before aging) 400% min (after aging)	Meets ASTM D6319-10 (aging= 70 +/- 2°C for 166 +/- 2 hrs; 100 +/- 2° C for 22 +/- 0.3 hrs) -*Tensile Strength:* 14 MPa min (before aging) 14 MPa min (after aging) -*Ultimate Elongation*: 500% min (before aging) 400% min (after aging)	Meets ASTM D6319-10 (aging= 70 +/- 2°C for 166 +/- 2 hrs; 100 +/- 2° C for 22 +/- 0.3 hrs) -*Tensile Strength:* 14 MPa min (before aging) 14 MPa min (after aging) -*Ultimate Elongation*: 500% min (before aging) 400% min (after aging)
Freedom from Pinholes	ASTM D5151-06	Meets AQL 2.5, Inspection Level G-1	Meets AQL 2.5, Inspection Level G-1
Residual Powder	ASTM D6124-06	≤2.0 mg/pc	≤2.0 mg/pc

Color	-	Lavender Blue	White and Pink
Labeling	Medical Glove Guidance Manual	Includes English, French, and Spanish languages	Draft includes English only and lacks other minor elements pending completion of FINAL design; brand name(s) pending
Biocompatibility	Primary Dermal Irritation in Rabbits and Guinea Pig Closed Patch Sensitization Test (ISO 10993-10)	Under the conditions of these studies, the test article was a non-irritant and non-sensitizer	Under the conditions of these studies, the test article was a non-irritant and non-sensitizer

8.0. Conclusion:

The physical performance of the subject device (*Nitrile Examination Gloves with Aloe & Vitamin E, Powder-free*) is substantially equivalent to predicate K121549 and will perform according to the glove performance and biocompatibility standards referenced. Both are manufactured from the same nitrile synthetic latex material using the same production process. Only the colors differ. Based on the intended use, physical properties, and technological characteristics, the subject device is safe and effective as a legally marketed device.