K101822

510 (k) SUMMARY APPENDIX M

(As Required by 21 section 807.92 (c))

NOV 19 2010

1. **Submitted For :**
   SGMP Company Limited
   181 Moo 6, Tambol Kampaengphet ,
   Rattaphum , Songkhla 90180 Thailand,

2. **Submitted By :**
   Tucker & Associates
   Official Correspondent for SGMP Company Limited
   Janna P.Tucker , President – CEO
   198 , Avenue de la D'emerald , Sparks,
   NV 89434-9550
   Phone No : 775-342-2612
   Fax No : 775-342-2613
   Email : Tuckerjan@aol.com

3. **Device Trade or Proprietary Name :**
   Non-sterile , Powder-free Blue Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs.

4. **Device Common Name :**
   Examination Gloves

5. **Device Classification Name :**
   Patient Examination Gloves (per 21CFR 880.6250)

6. **Device Description :**
   Non-sterile , Powder-free Blue Nitrile Examination Gloves , Tested for use with Chemotherapy Drugs.

7. **Intended Use of Device :**
   A disposable medical glove to be worn on the hand of the healthcare and similar personnel to prevent contamination between healthcare personnel and patient.

ATCH 2
APPENDIX M revised 10-12-10, Janna Tucker
Now shows Equivalence to K082957

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The Non-sterile Powder Free Blue Nitrile Examination Gloves Tested for use with Chemotherapy Drugs , 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.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes
The following chemical have been tested with these gloves.

Test Chemotherapy Drug	Average Breakthrough Detection Time (Minutes)
***Carmustine (BCNU)**	**0.49 minutes**
Cisplatin	>240 minutes
Cyclophosphamide (Cytoxan)	>240 minutes
Doxorubicin Hydrochloride	>240 minutes
Etoposide (Toposar)	>240 minutes
Flurouracil	>240 minutes
Paclitaxel (Taxol)	>240 minutes
***Thiotepa**	**2.61 minutes**
Vincristine Sulfate	>240 minutes
Dacarbazine (DTIC)	>240 minutes
Methotrexate	>240 minutes

*Please note that Carmustine (BCNU) and Thiotepa have extremely low permeation times of 0.49 and 2.61 minute only.

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8. Substantial Equivalence Discussion :

Characteristic and Parameter	SGMP Company Limited Non-sterile , Powder-free Blue Nitrile Examination Gloves. Tested for use with Chemotherapy Drugs	Siam Sempermed Corp.Ltd. Non-sterile , Powder-free Nitrile Examination Glove , Blue with Polymer Coating, Tested for use with Chemotherapy Drugs 510 K # K082957	Substantial Equivalence (SE)
Devise Class	1	1	SE
Product Code	LZA	LZA	SE
Glove Color	Blue	Blue	SE
Dimensions	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Physical Properties	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Freedom From Pinholes	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Powder-free Residue	Meets ASTM D6124-06	Meets ASTM D6124-06	SE

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Biocompatibility Test	Passes Primary Skin Irritation in Rabbits	Passes Primary Skin Irritation in Rabbits	SE
	Passes Guinea Pig Maximization	Passes Guinea Pig Sensitization	SE
Chemotherapy Drugs Tests	Meets ASTM D6978-05 Cisplatin > 240 mins Cyclophosphamide > 240 mins Doxorubicin Hydrochloride > 240 mins Etoposide > 240 mins Flurouracil > 240 mins Paclitaxel > 240 mins Vencristine Sulfate > 240 mins Dacarbazine > 240 mins Methotrexate > 240 mins	Meets ASTM D6978-05 Cisplatin > 240 mins Cyclophosphamide > 240 mins Doxorubicin Hydrochloride > 240 mins Etoposide > 240 mins Flurouracil > 240 mins Paclitaxel > 240 mins Vencristine Sulfate > 240 mins Dacarbazine > 240 mins Methotrexate > 240 mins	SE

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CONCLUSION:

The data presented indicates the Powder-Free, Blue Nitrile Examination Gloves, Tested for Use With Chemotherapy Drugs Labeling Claim, (Non-Sterile), K101822 is equivalent to K082957, Non-Sterile, Powder-free Nitrile Examination Gloves, Blue with Polymer Coating, Tested for use with Chemotherapy Drugs.

It should be noted that testing for use with two chemotherapy drugs had extremely low permeation times as follows: CARMUSTINE (BCNU) @ 0.49 minutes, and THIOTEPA @ 2.61 minutes. Therefore, these gloves are not approved for use when using those chemo drugs.

These gloves do meet the following recognized standards unless otherwise noted:

ASTM D6319-00a00A(2005), Standard Specification for Nitrile Gloves

ISO 2859-1, Standard for Water Leak Test and/or ASTM D5151-06, Test Method for Detection of Holes in Medical Gloves

ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.

Biocompatibility Testing on White Rabbits and Guinea Pigs

Labeling meets FDA requirement

Substantially equivalent to Siam Sempermed Corp. Ltd. K082957

ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

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

SGMP Company, Limited
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434

NOV 19 2010

Re: K101822
Trade/Device Name: Non-Sterile, Powder Free Blue Nitrile Examination Gloves
Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA/LZC
Dated: October 22, 2010
Received: October 21, 2010

Dear Ms. Tucker:

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

INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

NOV-1-9-20

510K NUMBER : K101822

Device Name : Non-Sterile, Powder Free Blue Nitrile Examination Gloves , Tested for use with Chemotherapy Drugs.

Indication For Use :

The Non-sterile Powder Free Blue Nitrile Examination Gloves Tested for use with Chemotherapy Drugs , 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.

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*Please note that Carmustine (BCNU) and Thiotepa have extremely low permeation times of 0.49 and 2.61 minute only.

Prescription Use ..... **AND / OR** **Over-The-Counter.....✓**
(Part 21 CFR 801.Subpart D) **21 CFR 801 Subpart C**

Attch 1
IFU Revised
10-12-10
J. Ricker

Elaine S. Manwell
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH , Office of Device Evaluation (ODE)

510(k) Number: K101822