K092617

SHUN THAI RUBBER GLOVES INDUSTRY PUBLIC COMPANY LIMITED
9 Moo-4 Kached, Muang Rayong, RAYONG 21100, THAILAND
Tel. (+66) 3863 4072-3, (+66) 3863 4816 FAX : (+66) 3863 4001,(+66)3863 4480
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Highly Intend To Reply Your Satisfaction .....

SHUN THAI

510(k) Summary
As Required by 21 Section 807.92 (c)

MAY 20 2010

1. Submitter Name: Shun Thai Rubber Gloves Industry Public Company Limited
2. Address: 9. Moo 4. Kached Muang. Rayong. Thailand 21100
3. Phone: (+66)38 634 4072
4. Fax: (+66)38 634 4001
5. Contact Person: Mr. Hew Seng Yeap (Marketing Director)
6. Official Correspondent: Mr. Kok-Kee Hon
7. Address: 6324 Meetinghouse Way
   Alexandria. VA 22312. USA
8. Phone: 703-941-7656
9. Fax: 703-941-2551
10. Device Trade or Proprietary Name: Royal Guard Nitrile Examination Glove Tested For Use with Chemotherapy Drugs
11. Device Common or Usual Name: Examination Glove
12. Device Classification Name: Nitrile Patient Examination Glove (Powder-Free)
13. Description of the Device: Non Sterile. Powder-Free. Nitrile Examination for Use with Chemotherapy Drugs
14. Intended Use of the Device: This is a disposable device intended for medical application that is worn on the examiner's hand to prevent contamination between examiner and patient and to protect examiner from the following Chemotherapy drugs tested to ASTM **D 6978 with the indicated Breakthrough Detection Times :**

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes.

Nitrile Powder Free Examination Glove	**Blue**	**Green**	**White**
***Carmustine (BCNU)**	**40.00**	**17.00**	**9.00**
Cyclophosphamide (Cytoxan)	> 240	> 240	> 240
Doxorubicin HCl (Adriamycin)	>240	> 240	> 240
Etoposide (Toposar)	>240	> 240	> 240
Fluorouracil	>240	> 240	> 240
Paclitaxel (Taxol)	>240	> 240	> 240
***Thio-Tepa**	**177.00**	**63.00**	**48.00**
Cisplatin	>240	> 240	> 240
Dacarbazine (DTIC)	>240	> 240	> 240

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Nitrile Powder Free Examination Glove (Blue)

***CAUTION: Testing showed average breakthrough time of 40.00minutes with Carmustine.**

Nitrile Powder Free Examination Glove (Green)

*** WARNING: DO NOT USE WITH CARMUTINE.**

Nitrile Powder Free Examination Glove (White)

***CAUTION: Testing showed average breakthrough time of 48.00minutes with Thio-Tepa.**

*** WARNING: DO NOT USE WITH CARMUTINE.**

15. Summary of The Technological Characteristics of the Device: The following technological characteristics of the Device compared to ASTM or Equivalent Standards are summarized below

CHARACTERISTICS	STANDARDS	DEVICE PREFORMANCE
Dimensions	ASTM D 6319-00a (2005)	Meets
Physical Properties	ASTM D 6319-00a (2005)	Meets
Freedom from Holes	ASTM D 6319-00a (2005)	Meets
Powder-Free Residue	ASTM D 6124-06	Meets
Biocompatibility	Primary Skin Irritation in Rabbits	Meets
Biocompatibility	Guinea Pig Sensitization	Meets
Chemotherapy Drug Permation	ASTM D 6978-05	See Breakthrough Time In Section 14

16. 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 above in Section 15.

17. Conclusion

It can be concluded that the Royal Guard Powder-Free Nitrile Examination Glove Tested For Use With Chemotherapy Drugs will perform to the glove performance standards referenced in Section 15 and meets the ASTM standards and FDA requirements. This device is therefore substantially equivalent to currently marketed devices. It is safe and effective as the predicate device 510K 051333 Powder-Free Nitrile Examination Glove.

18. Date Summary Prepared: July 10. 2009

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

Shun Thai Rubber Gloves Industry Public Company Limited
C/O Mr. Kok-Kee Hon
6324 Meeting House Way
Alexandria, Virginia 22312-1718

MAY 20 2010

Re: K092617
Trade/Device Name: Royal Guard
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: May 11, 2010
Received: May 14, 2010

Dear Mr. Hon:

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

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INDICATION FOR USE

Applicant: Shun Thai Rubber Gloves Industry Public Company Limited

510 (K) Number: K 092617

Device Name: Nitrile, Blue, White and Green Examination Gloves, Powder Free and Tested For Use with Chemotherapy Drugs

Indications for Use:

This glove is disposable and intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner, gloves use for protection against chemotherapy drugs as below.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes.

Nitrile Powder Free Examination Glove	**Blue**	**Green**	**White**
***Carmustine (BCNU)**	**40.00**	**17.00**	**9.00**
Cyclophosphamide (Cytoxan)	> 240	> 240	> 240
Doxorubicin HCl (Adriamycin)	>240	> 240	> 240
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Fluorouracil	>240	> 240	> 240
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Nitrile Powder Free Examination Glove(Blue)

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Nitrile Powder Free Examination Glove(Green)

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Nitrile Powder Free Examination Glove(White)

***CAUTION: Testing showed average breakthrough time of 48.00minutes with Thio-Tepa.**

*** WARNING: DO NOT USE WITH CARMUTINE.**

Prescription Use_____ AND/OR Over the-Counter Use _____

(Part 21CFR 801 Subpart D) (21 CFR 801 Subpart C) X

(PLEASE DO NOT INRITE BELOW THIS LINE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K092617