K102006-11

Appendix 2

510(k) Summary
Latex Examination Gloves Powder Free

JUL 16 2010

1.0 Submitter:

Company Name: Riverstone Resources Sdn. Bhd.

Company Address: Lot 55, 56, No. 15 Jalan Jasmin 2
Kawasan Perindustrian Bukit Beruntung,
48300 Bukit Beruntung
Selangor, Malaysia.

Contact Person: Ms. Chong Chu Mee

Telephone No: +603-60283033

Fax No: + 603-60283022

2.0 Name of the Device

Trade Name/ Proprietary Name: RS Care Latex Examination Gloves Powder Free

Device Name: Latex Patient Examination gloves

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

Device Class: Class I

Product Code : Latex – LYY

3.0 Identification of The Legally Marketed Device:

Class I patient Examination gloves, Powder Free, LYY which meets all the requirement of ASTM D 3578-05 and FDA 21 CFR 880.6250.

4.0 Description of Device

Latex Examination gloves powder free as described in this 510(k) Notification is substantially equivalent to the current class I patient examination gloves with product Code LYY (21CFR 880.6250). It meets all the specifications in ASTM D 3578-05, Standard Specification for Latex Examination Gloves. They are made from natural latex compound and powder free.

5.0 Intended use of the Device

Latex Examination gloves powder free is a disposable device intended for medical purpose is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.

6.0 Summary of the Technological Characteristics of the Devices

The powder-free latex examination gloves possess the following technological characteristics compared to ASTM or Equivalent standards:

Characteristics	Standards	Device Performance
Dimension	ASTM D 3578-05	Meets
Physical Properties	ASTM D 3578-05	Meets
Freedom from pinholes	ASTM D 3578-05	Meets
Powder-Free	ASTM D 3578-05	Meets
Protein Content	ASTM D 3578-05	Meets
Biocompatibility	Primary Skin Irritation Test Consumer Product Safety Commission, Title 16, Chapter II, Part 1500	Passes
	Dermal Sensitization Assay ASTM-F 720-81(Reapproved 2007)^{E1}	Passes

7.0 Conclusion

It can be concluded that latex examination gloves powder free shall perform according to the glove performance standards references in section 6.0 above and meet ASTM D 3578-05 standard and FDA requirements and the labeling claims for the product.

Prepared by,

Chong Chu Mee
Technical Manager
Date: 22th Feb 2010.

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

JUL 16 2010

Mr. Chong Chu Mee
Technical Manager
Riverstone Resources SDN. BHD.
Lot 55 & 56, Number 15, Jalan Jasmin 2
Kawasan Perindustrian Bukit 48300 Bukit Beruntung
Selangor, Malaysia

Re: K100611
Trade/Device Name: RS Care Latex Medical Examination Gloves Powder Free (Non-Sterile)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: June 12, 2010
Received: June 22, 2010

Dear Mr. Chu Mee:

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

Applicant: Riverstone Resources Sdn. Bhd.

510(k) Number (if known): K100611

Device Name: RS Care Latex Medical Examination Gloves Powder Free (Non-Sterile)

Indications for Use:

A powder-free patient examination gloves 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 _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K100611