



Food and Drug Administration  
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December 24, 2015

Riverstone Resources Sdn. Bhd.  
Mr. Suresh Kumar  
Quality Assurance Manager  
Lot 55 & 56, No 13, Jalan Jasmin 2  
Kawasan Perindustrian Bukit Beruntung  
Selangor 48300  
MALAYSIA

Re: K152542

Trade/Device Name: Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis  
Potential Claim and with 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: Undated

Received: November 30, 2015

Dear Mr. Kumar:

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 and Part 809); 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 and Part 809), 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,  
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Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)  
K152542

Device Name  
Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with tested for use with Chemotherapy Drugs

Indications for Use (Describe)

The Nitrile Powder Free Examination Glove (Blue) with Low Dermatitis Potential Claim is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner In addition these gloves was tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards, Practice for assessment of medical glove to Permeation by chemotherapy Drugs.

Chemotherapy Drugs and Concentration	Minimum Breakthrough Detection time in minutes,0.01ug/cm2/minute
1)Carmustine (BCNU)(3.3mg/ml)	20.1 Minutes
2)Cyclophosphamide (20mg/ml)	> 240 Minutes
3)Cisplatin (1.0mg/ml)(1000ppm)	> 240 Minutes
4)Doxorubicin Hydrochloride (2 mg/ml)	> 240 Minutes
5) Etoposide (20mg/ml)	> 240 Minutes
6) Fluorouracil (50mg/ml)	> 240 Minutes
7)Methorexate (25mg/ml)	> 240 Minutes
8)Paclitaxel (6mg/ml)	> 240 Minutes
9)Thiotepa (10mg/ml)	50.6 minutes

The Maximum testing time is 240 minutes . Please note that the following drugs have low permeation time

- 1) Carmustine (BCNU)(3.3mg/ml) with Permeation time of 20.1 minutes
- 2) Thiotepa (10mg/ml) with Permeation time of 50.6 Minutes

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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## Appendix 2

### **510(K) Summary Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and with Tested for use with Chemotherapy Drugs**

#### **1.0 Submitter :**

Company Name : Riverstone Resources Sdn Bhd.

Company Address : Lot 55 & 56, No 13, Jalan Jasmin 2  
Kawasan Perindustrian Bukit Beruntung,  
48300, Bukit Beruntung,  
Selangor, Malaysia.

Contact Person : Mr Suresh Kumar

Telephone No : 603-60283033

Email : qa1@riverstone.com.my

**2.0 Preparation Date** : 14<sup>th</sup> December 2015

#### **3.0 Name of the Device**

Trade Name / Proprietary Name : Powder Free Nitrile Examination Glove (Blue)  
With Low Dermatitis Potential Claim and with  
tested for Use with Chemotherapy drugs.

Device Name : Nitrile Patient Examination gloves.

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

Device Class : Class I.

Product Code : LZA , LZC.

**4.0) Identification of The Legally Marketed Device :**

Class I patient Examination glove with claiming, this product contain Low Dermatitis Potential Claim and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Predicate Device: K050122, Powder Free Nitrile Examination (Blue) (This Product does not contain Thiuram and/or Carbamate and/or Thiazole) and K141623,EMG Blue Nitrile examination Gloves Powder Free with tested for use with Chemotherapy Drugs labeling claim

**5.0 Device Description**

The subject device in this 510(k) Notification is Blue Nitrile Examination gloves, with claiming, this product contain Low Dermatitis Potential Claim and tested for use with Chemotherapy drugs. The subject device is a patient examination glove made from nitrile compound, Blue color, powder free and non sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

**6.0 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 .In addition these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 standards ,Practice for assessment of Medical Glove to Permeation by chemotherapy Drugs . It is for over-the-counter use.

**6.0 Specification for Nitrile gloves:**

**6.1 Dimension and Thickness of Gloves**

<b>Dimension</b>	<b>Size S</b>	<b>Size M</b>	<b>Size L</b>	<b>Size XL</b>
Overall Length (mm)	270min	270min	270min	270min
Width (± 5mm)	85	95	105	115
Thickness at Palm (mm)	0.10min	0.10min	0.10min	0.10min
Thickness at Finger Tip (mm)	0.10min	0.10min	0.10min	0.10min

## Appendix 2

### 6.1.2 Gloves Physical Properties and Holes

Measurement	Before Ageing	After Aging at 70°C for 168 hrs @ 100°C for 22 hrs
Tensile Strength (MPa)	14min	14 Min
Ultimate Elongation (%)	500min	400min
Pin-hole Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

Gloves meet all the specification listed in ASTM D 6319-10

Characteristics	Acceptance Criteria	Powder Free Nitrile Examination Gloves(Blue) with Low Dermatitis Potential Claim and with tested for use with chemotherapy drugs,K152542	Powder Free Nitrile Examination Gloves (This Product does not contain Thiuram and/or Carbamate and/or Thiazole) ,K050122	EMG Blue Nitrile Examination glove Powder free with tested for use with Chemotherapy Drugs labeling Claim,K141623
Product Code	LZA, LZC	LZA, LZC	LZA	LZA ,LZC
Intended use	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. The device is for over-the-counter use.	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. The device is for over-the-counter use.	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. The device is for over-the-counter use.	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. The device is for over-the-counter use.
Material use	Nitrile compound	Nitrile compound	Nitrile compound	Nitrile compound
Colour	Blue	Blue	Blue	Blue
Sterility	Non sterile	Non sterile	Non sterile	Non sterile
Single used	Single used	Single used	Single used	Single used
Non Sterile	Non Sterile	Non Sterile	Non Sterile	Non Sterile

**Appendix 2**

Dimensions	Overall Length (mm) Min 270mm Width ( $\pm$ 5mm) <b>Size S = 85mm</b> <b>Size M = 95mm</b> <b>Size L = 105mm</b> <b>Size XL = 115mm</b> Thickness at Palm (mm) Min; 0.10 mm Thickness at Finger Tip (mm) Min 0.10 mm	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Physical properties	<b>Before Ageing</b> Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min <b>After Aging at 70°C for 168 hrs @ 100°C for 22 hrs</b> Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	Meets ASTM D5151-06
Residual Powder	$\leq$ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	Meets ASTM D6124-06

**Appendix 2**

Biological Evaluation on Medical Device - -Primary Skin Irritation Test		Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.
Biological Evaluation on Medical Device - -Dermal Sensitization Assay		Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.
Resistance against Chemotherapy Drugs		<p>1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 20.1 min.</p> <p>2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : &gt;240 min.</p> <p>3) Cisplatin (1mg/ml or 1000ppm), Breakthrough time : &gt; 240 min</p> <p>4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : &gt;240 min.</p> <p>5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : &gt;240 min.</p> <p>6) Flourouracil (50mg/ml or 50,000), Breakthrough time : &gt;240 min.</p> <p>7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : &gt; 240 min.</p>		<p>1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 4.5min.</p> <p>2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : &gt;240 min.</p> <p>3) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : &gt;240 min</p> <p>4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : &gt;240 min.</p> <p>5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : &gt;240 min.</p> <p>6) Flourouracil (50mg/ml or 50,000), Breakthrough time : &gt;240 min.</p> <p>7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : &gt; 240 min.</p>

**Appendix 2**

		8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min.  9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 50.6 min.		8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min.  9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 6.88 min.
Low Dermatitis Potential Claim	1)Modified Draize 95 test	No Clinical evidence presence of residual chemical additives that may induce Type IV allergy in human subject	No Clinical evidence presence of residual chemical additives that may induce Type IV allergy in human subject	

**Resistance against Chemotherapy Drugs**

<b>Chemotherapy Drug and concentration</b>	<b>Minimum Breakthrough detection time in Minutes,0.01µg/cm<sup>2</sup>/minute</b>
<b>1)Carmustine (BCNU) (3.3mg/ml)</b>	<b>20.1 minutes</b>
<b>2)Cyclophosphamide (20mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>3)Cisplatin (1mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>4)Doxorubicin Hydrochloride (2 mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>5)Etoposide (20mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>6)Fluorouracil (50mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>7)Methorexate (25mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>8) Paclitaxel (6mg/ml)</b>	<b>&gt; 240 minutes</b>
<b>9) Thiotepa (10mg/ml)</b>	<b>50.6 minutes</b>

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.

Carmustine (BCNU) (3.3mg/ml)

Thiotepa (10mg/ml)

**7.0) Substantial Equivalent Based on Assessment of Non-Clinical Performance data**

Testing was performed per ASTM D6319-10 , ASTM D5151-06, ASTM D6124-06,ISO 10993-10:2010 and 16 CFR Part 1500.41. The glove meet standards requirement referenced in section 6.0 above. Biocompatibility test indicates the gloves are not a contact skin sensitizer and not a primary skin irritant

**8.0) Substantial Equivalent Based on Assessment of Clinical Performance Data**

Powder Free Nitrile Examination Glove (Blue) With Low Dermatitis Potential Claim and tested for Use with Chemotherapy drugs were tested in accordance with Modified Draize -95 test , per FDA’s guidance document “Guidance for Industry and FDA Reviewer/Staffs: Premarket Notification [510k] Submissions for testing for skin sensitization to chemical in natural Rubber Products”.

The study was conducted in two stages. In the first, a population of 30 human subjects was tested to evaluate the product for the potential to cause irritation or sensitization. The second stage was initiated on a further number of subjects to a total of a minimum 205 individuals after the first stage has shown that the test product does not indicate a potential for inducing dermal irritation and does not shown sensitization capability

The study completed on 205 non sensitized adult human subjects, who reasonably reflect the general user population in the US, gave all negative results. There was no clinical evidence of the presence of residual chemical additives at the level that may induce type IV allergy in the un-sensitized general user population in the tested article.

**9.0 Conclusion**

Based on intended uses, technological characteristics and Non-Clinical performance data, Powder Free Nitrile Examination Glove (Blue) with Low Dermatitis Potential Claim and with tested for Use with Chemotherapy drugs is substantially equivalent to the predicate device (K050122) and (K141623)