April 9, 2022

Riverstone Resources Sdn Bhd
Suresh Kumar
QA Manager
Lot 20852, No.119, Jalan Logam 7
Kamunting Raya Industrial Estate
Taiping, Perak Darul Ridzuan 34600
Malaysia

Re: K220401
Trade/Device Name: Pink Powder Free Nitrile Examination Glove With Bubblegum Scented, Chemotherapy Drugs And Fentanyl Test Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: February 11, 2022
Received: February 11, 2022

Dear Suresh 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220401

Device Name
Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drug and Fentanyl Test Claim

Indications for Use *(Describe)*
Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim 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. It is for over-the-counter use.
In addition, these gloves were tested for use with Chemotherapy drug and Fentanyl test claim in accordance with ASTM D6978-05 standards. Practice for assessment of Medical Glove to Permeation by chemotherapy drug and Fentanyl test claim

Chemotherapy Drugs and Concentration	Minimum Breakthrough Detection Time (Min), ug/cm2/minute
1) Carmustine (BCNU) 3.3mg/ml	13.7 minutes
2) Cyclophosphamide (Cytoxan) (20mg/ml)	>240 minutes
3) Cytarabine HCl (100mg/ml)	>240 minutes
4) Doxorubicin HCl (2.0mg/ml)	>240 minutes
5) Etoposide (20.0mg/ml	>240 minutes
6) Fluorouracil (50.0mg/ml)	>240 minutes
7) Methotrexate (25mg/ml)	>240 minutes
8) Paclitaxel (6.0mg/ml)	>240 minutes
9) ThioTepa (10.0mg/ml)	34.8 minutes
10) Fentanyl Citrate Injection 100mg/2ml	>240 minutes

The Maximum testing time is 240 minutes. Please note that the following drugs have extremely low Permeation time,
Carmustine (BCNU) 3.3mg/ml
ThioTeta (10.0mg/ml)

Warning to do not use with Carmustine and Thio Tepa.

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.

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510(K) Summary

Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim

1.0 Submitter:

Company Name	:	Riverstone Resources Sdn Bhd.
Company Address	:	Lot 20852, No.119, Jalan Logam 7, Kamunting Raya Industrial Estate, 34600, Taiping, Perak Darul Ridzuan, Malaysia.
Contact Person	:	Mr. Suresh Kumar
Telephone	:	+605-8912777
Fax	:	+ 605-8912999
Email	:	qa1@riverstone.com.my

2.0 Preparation Date : 7th April 2022

3.0 Name of the Device

Trade Name / Proprietary Name : Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim

Device Name: Nitrile Patient Examination gloves.

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

Device Class: Class I.

Product Code: LZA, LZC, QDO

4.0 Identification of The Legally Marketed Device:

Reference Device: K991744, SMART SHIELD POWDER FREE COLORED NITRILE EXAMINATION GLOVES WITH BUBBLE GUM SCENT

Predicate Device: K192954 BLUE COLORED, POWDER FREE NITRILE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS AND FENTANYL CITRATE.

5.0 Device Description

The subject device in this 510(k) Notification is Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim. The subject device is a patient examination glove made from nitrile compound, pink 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/Indication for Use

Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim 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. It is for over-the-counter use.

In addition, these gloves were tested for use with Chemotherapy drug and Fentanyl test claim in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drug and Fentanyl test claim

Chemotherapy Drug and Fentanyl Test Claim Concentration	Minimum Breakthrough detection time in Minutes, ug/cm^2/minute
Carmustine (BCNU) 3.3mg/ml	13.7 minutes
Cyclophosphamide (Cytoxan) (20mg/ml)	>240 minutes
Cytarabine HCI (100mg/ml)	>240 minutes
Doxorubicin HCI (2.0mg/ml)	>240 minutes
Etoposide (20.0mg/ml	>240 minutes
Fluorouracil (50.0mg/ml)	>240 minutes
Methotrexate (25mg/ml)	>240 minutes
Paclitaxel (6.0mg/ml)	>240 minutes
ThioTepa (10.0mg/ml)	34.8 minutes
Fentanyl Citrate Injection 100mg/2ml	>240 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.
Carmustine (BCNU) (3.3mg/ml)- Minimum Breakthrough detection time 13.7 ug/cm^2/minute.
Thiotepa (10ug/ml) – Minimum Breakthrough detection time 34.8 ug/cm^2/minute.
Warning to do not use with Carmustine and Thio Tepa

7.0 Specification for Nitrile gloves:

7.1 Dimension and Thickness of Gloves

Dimension	Size S	Size M	Size L	Size XL
Overall Length (mm)	230min	230min	230min	230min
Width (± 5mm)	85	95	105	115
Thickness at Palm (mm)	0.05min	0.05min	0.05min	0.05min
Thickness at Finger Tip (mm)	0.05min	0.05min	0.05min	0.05min

7.2 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

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Comparison of Proposed and Predicate Device

Characteristics	Acceptance Criteria	Current Device **Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim, K220401**	Reference Device **Smart Shield Powder Free Colored Nitrile Examination Gloves with Bubble Gum Scent K991744**	Predicate Device **Comfort Rubber Gloves Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate K192954**	Assessment Similarities and Differences
Product Code	LZA.	LZA, LZC and QDO	LZA.	LZA, LZC and QDO	Same
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.	same
Material use	Nitrile compound	Nitrile compound	Nitrile compound	Nitrile compound	same
Colour		Pink	Blue	Blue	Different
Sterility	Non sterile	Non sterile	Non sterile	Non sterile	same
Single used	Single used	Single used	Single used	Single used	same
Non Sterile	Non Sterile	Non Sterile	Non Sterile	Non Sterile	same
Dimensions	Overall Length (mm) Min 230mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10	same
Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10	same

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Characteristics	Acceptance Criteria	Current Device **Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim, K220401**	Reference Device **Smart Shield Powder Free Colored Nitrile Examination Gloves with Bubble Gum Scent K991744**	Predicate Device **Comfort Rubber Gloves Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate K192954**	Assessment Similarities and Differences
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	Meets ASTM D5151-06	same
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	Meets ASTM D6124-06	same
Biocompatibility	ISO 10993-10- Biological Evaluation on Medical Device - -Primary Skin Irritation Test	Passes Under the conditions of this study, the test article was a non-irritant.	Passes Under the conditions of this study, the test article was a non-irritant.	Passes Under the conditions of this study, the test article was a non-irritant.	same
	ISO 10993-10- 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.	same
	ISO 10993-11 – Acute Systemic Test	Not inducing any acute systemic toxicity.	did not provide acute systemic toxicity testing	Not inducing any acute systemic toxicity	Same
Resistance against Chemotherapy Drugs	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-05	1) Carmustine (BCNU) 3.3mg/ml 13.7 minutes 2) Cyclophosphamide (Cytoxan) (20mg/ml) >240 minutes 3) Cytarabine HCI (100mg/ml) >240 minutes 4) Doxorubicin HCI (2.0mg/ml) >240 minutes 5) Etoposide (20.0mg/ml > 240 minutes 6) Fluorouracil (50.0mg/ml) >240 minutes 7) Methotrexate (25mg/ml) >240 minutes	No Chemotherapy was tested	1) Carmustine (BCNU) 3.3mg/ml 10.1 minutes 2) Cyclophosphamide (Cytoxan) (20mg/ml) >240 minutes 3) Cytarabine HCI (100mg/ml) >240 minutes 4) Doxorubicin HCI (2.0mg/ml) >240 minutes 5) Etoposide (20.0mg/ml >240 minutes 6) Fluorouracil (50.0mg/ml) >240 minutes 7) Methotrexate (25mg/ml) >240 minutes	Similar – The Chemotherapy drugs tested have similar breakthrough detection times; the drugs with low permeation times for the 510K is similar than predicate device

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Characteristics	Acceptance Criteria	Current Device **Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim, K220401**	Reference Device **Smart Shield Powder Free Colored Nitrile Examination Gloves with Bubble Gum Scent K991744**	Predicate Device **Comfort Rubber Gloves Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate K192954**	Assessment Similarities and Differences
		8) Paclitaxel (6.0mg/ml) > 240 minutes 9) ThioTepa (10.0mg/ml) 34.8 minutes 10) Fentanyl Citrate Injection, 100mg/2ml >240 minutes		8) Paclitaxel (6.0mg/ml) >240 minutes 9) ThioTepa (10.0mg/ml) 30.2 minutes 10) Fentanyl Citrate Injection, 100mg/2ml >240 minutes	

Performance data of gloves based on ASTM D6319 -10 and FDA 1000ml water leak test					
Characteristics	**Test**	**Test standard**	**Sampling plan / Inspection level / AQL**	**Nitrile Examination Powder Free**	**Result**
Freedom from Pin holes	FDA 1000 ml water leak test	ASTM D5151 -06 (Re-approved 2011)	ISO 2859-1 / G1/AQL 2.5	Meet AQL 2.5	Pass
Dimensions	Length	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	Min 230	Pass
	Width	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	85±5 mm to 115±5 mm (sizes Small to Extra Large)	Pass
	Thickness	ASTM D6319 -10	ISO 2859-1 / S2/AQL 4.0	>0.05mm (Palm, finger)	Pass
Physical properties	Before aging	ASTM D6319 -10 ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength: > 14 Mpa Ultimate Elongation : >500%	Pass
	After Accelerated aging	ASTM D6319 -10 and ASTM D412-06	ISO 2859-1 / S2/AQL 4.0	Tensile strength: > 14 Mpa Ultimate Elongation: > 400%	Pass
Powder-free residue	Powder-free residue	ASTM D6124-06	N=5	Less than 2 mg per glove	Pass

8.0 Summary of Clinical Testing

Clinical testing was not needed for this device under this section

9.0 Conclusion

The Conclusion drawn from the non-Clinical test demonstrates that the subject device in 510(K) Submission, Pink Powder Free Nitrile Examination Glove with Bubblegum Scented, Chemotherapy Drugs and Fentanyl test claim is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K192954.