April 9, 2020

Riverstone Resources SDN BHD
Suresh Kumar
Official Correspondent
Lot 55, No 13 Jalan Jasmin 2 Kawasan Perindustrian
Bukit Beruntung, 48300 My

Re: K200326
Trade/Device Name: Powder Free Nitrile Examination Glove (Aqua Green)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: February 2, 2020
Received: February 10, 2020

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,

FDA Elizabeth F. Claverie -S

CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200326

Device Name
Powder Free Nitrile Examination Glove (Aqua Green)

Indications for Use *(Describe)*

The Powder Free Nitrile Examination Glove (Aqua Green) is a disposable device intended for Medical purpose that is worn on the examiner's hands or finger to prevent contamination patient and examiner.

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

K200326

Powder Free Nitrile Examination Glove (Aqua Green)

Preparation Date: April 8th, 2020

1. Submitter:
Company Name: Riverstone Resource Sdn Bhd.
Company Address: Lot 55,No 13, Jalan Jalan Jasmin 2 Kawasan Perindustrian Bukit Beruntung 48300. Selangor Malaysia.

Contact Person: Mr Suresh Kumar
Telephone No: 603-60283033
Email: qa1@riverstone.com.my

2. Name of the Device
Trade Name / Proprietary Name: Powder Free Nitrile Examination Glove (Aqua Green)
Device Name: Nitrile Patient Examination gloves.
Device Classification Name: Patient Examination gloves (21 CFR 880.6250).
Device Class: Class I.
Product Code: LZA

3. Identification of The Legally Marketed Device:
Predicate Device: K141579
Device Name: Emg Black Nitrile Medical Examination Glove Powder Free
Device Classification Name: Patient Examination gloves (21 CFR 880.6250).
Device Class: Class I.
Product Code: LZA

4. Device Description

The subject device in this 510(k) Notification is Powder Free Nitrile Examination Glove (Aqua Green). The subject device is a patient examination glove made from nitrile compound, Aqua Green color, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

5. Intended use of the Device

Powder Free Nitrile Examination Glove (Aqua Green) 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. It is for over-the-counter use.

6. Technological characteristics Comparison for the proposed and predicate devices

Characteristics	Acceptance Criteria	Subject device, Powder Free Examination Glove (Aqua green), K200326	Predicate device, EMG Blue Nitrile Medical Examination Glove, K141579	Remarks
Product Code	LZA.	LZA.	LZA.	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.	same
Material use	Nitrile compound	Nitrile compound	Nitrile compound	same
Colour	N/A	Aqua Green	Blue	Different
Sterility	N/A	Non sterile	Non sterile	same
Single used	Single used	Single used	Single used	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	same
Physical properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70oC for 168 hrs @ 100oC for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10	same

Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06	same
Residual Powder	< 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06	same
Biocompatibility	ISO 10993-10-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.	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.	same
	ISO 10993-11-Acute Systemic test	Not induce systemic toxicity	N/A	Same

7. Summary of non-clinical testing results

Powder Free Nitrile Examination Glove (Aqua Green) was tested and found in conformance with the following standards:

ASTM D6319-10	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D412-16	Standards test method for Vulcanized Rubber and Thermoplastics Elastomer - Tension
ASTM D5151-06	Standard Test Method for detection of Holes in Medical Gloves
ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves
16 CFR:1500.41	Method of Testing Primary Irritant Substance
ISO 10993-10	Biological evaluation on medical device Part 10: Test for irritation and Skin Irritation
ISO 10993-11	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ISO 28590:2017	Sampling Procedure for Inspection by Attributes: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes.

Dimension and Thickness of Gloves (ASTM D6319-10)

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

Gloves Physical Properties and Holes (ASTM D6319-10)

Measurement	Before Ageing	After Aging at 70^{O}C for 168 hrs @ 100^{O}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

Residual Powder (ASTM D6124-06)

Sample No.	Residual Powder (mg/glove)
1	0.49
2	0.38
3	0.43
4	0.51
5	0.22
Requirements	< 2.0

8. Conclusion

The Conclusion drawn from the Non-Clinical test demonstrates that the subject device, Powder Free Nitrile Examination Glove (Aqua Green) is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K141579.