November 22, 2021

Rubberex Alliance Sdn Bhd
% Aristotle Nafpliotis
Regulatory Affairs Consultant/Engineer
mdi Consultants, Inc.
55 Northern Blvd
Great Neck, New York 11021

Re: K210990
Trade/Device Name: Non-sterile Powder Free Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: October 18, 2021
Received: October 19, 2021

Dear Aristotle Nafpliotis:

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,

For Clarence W. Murray, III, Ph.D.
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)*
K210990

Device Name
Non-sterile Powder Free Nitrile Examination Gloves

Indications for Use *(Describe)*
A non-sterile 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.

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

K210990

1. Submitter's Identification:

RUBBEREX ALLIANCE SDN BHD
Lot 138201 Off ¾ Mile, Jalan
Bercham Kawasan Perindustrian
Bercham 31400 Ipoh, Perak,
Malaysia

Date Summary Prepared: 17 November 2021

Contact: Sabri Hamid

2. Name of the Device:

Non-sterile Powder Free Nitrile Examination
Gloves K#: K210990
Regulation Number: 880.6250
Regulation Name: Polymer Patient Examination Glove
Regulatory Class: 1
Product Code: LZA

3. Information for the 510(k) Cleared Device (Predicate Device):

Predicate device: K200326
Trade/Device Name: Powder Free Nitrile Examination Glove (Aqua Green) Device Classification Name: Patient Examination gloves (21 CFR 880.6250) Device Class: Class I
Product Code: LZA
Applicant name: Riverstone Resources SDN BHD
Lot 55, No 13 Jalan Jasmin 2 Kawasan
Perindustrian Bukit Beruntung, 48300 My

4. Device Description:

The subject device in this 510(k) Notification is Powder Free Nitrile Examination Glove. The subject device is a patient examination glove made from nitrile compound, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets the specifications in ASTM D6319-19, standard specification for Nitrile Examination Gloves.

Specifications: Dimension and Thickness of Gloves (ASTM D6319-10)

Dimension	Size XS	Size S	Size M	Size L	Size XL
Overall Length (mm)	min 220	min 220	min 230	min 230	min 230
Width (± 10mm)	70	80	95	110	120
Thickness at Palm (mm)	min 0.05	min 0.05	min 0.05	min 0.05	min 0.05
Thickness at Finger Tip (mm)	min 0.05	min 0.05	min 0.05	min 0.05	min 0.05

Specifications: Gloves Physical Properties and Holes (ASTM D6319-19)

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

5. Indications for Use:

A non-sterile 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.

6. Technological Characteristics Comparison between the predicate and subject devices:

Item description	Subject Device, Non-sterile Powder Free Nitrile Examination Glove K210990	Predicate Device, Powder Free Examination Glove (Aqua green), K200326	Similar or Different
K Number:	K210990	K200326	
Product Code	LZA	LZA	Similar

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.	Similar
Material use	Nitrile compound	Nitrile compound	Similar
Colour	Blue	Aqua Green	Different
Sterility	Non sterile	Non sterile	Similar
Single used	Single used	Single used	Similar
Dimensions	Overall Length (mm) Min 220mm Width (± 10mm) Size XS = 70mm S = 80mm Size M= 95mm Size L = 110mm Size XL = 120mm Thickness at Palm (mm) Min; 0.05 mm Thickness at Finger Tip (mm) Min 0.05 mm	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	Similar
Physical properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70 +- 2 oC for 166 +- 2 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	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	Similar

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Freedom from pinholes	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1	Similar
Residual Powder	< 2.0 mg/pc	< 2.0 mg/pc	Similar
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.	Similar
Biocompatibility 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.	Similar
Biocompatibility ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Under the conditions of this study, the test was found cytotoxic at 100% after an exposure period of 48 hours, non-cytotoxic at 10%	Predicate did not perform this test as part of this submission.	Different
Biocompatibility ISO 10993-11- Acute Systemic test	Not induce systemic toxicity	Not induce systemic toxicity	Similar

7. Summary of Non-Clinical Tests Performed

Non-sterile Powder Free Nitrile Examination Glove was tested and found in conformance with the following standards:

ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D412-16	Standards test method for Vulcanized Rubber and Thermoplastics Elastomer - Tension
ASTM D5151-19	Standard Test Method for detection of Holes in Medical Gloves

ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation on medical device Part 10: Test for irritation and Skin Irritation
ISO 10993-11	Biological evaluation on medical device Part 11: Test for acute 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.

Summary of non-clinical performance test

Test item	Test standard	Acceptance Criteria	Conclusion
Dimensions	ASTM D6319-19	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	Passed
Physical properties	ASTM D6319-19	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	Passed
Freedom from pinholes	ASTM D6319-19	AQL 2.5 Inspection Level G-1	Passed
Residual Powder	ASTM D6124-06 (Reapproved 2017)	< 2.0 mg/pc	Passed

8. Conclusions:

The Conclusion drawn from the Non-Clinical test demonstrates that the subject device, Non-sterile Powder Free Nitrile Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K200326.