August 5, 2022

Rubberex Alliance Products Sdn Bhd
% Kewin Tham
Official Correspondent
Mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K221350
Trade/Device Name: Non-Sterile Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, OPJ
Dated: May 9, 2022
Received: May 10, 2022

Dear Kewin Tham:

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.
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)*
K221350

Device Name
Non-Sterile Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

Indications for Use *(Describe)*
Non-sterile Powder Free Nitrile Examination Gloves (tested for use with Chemotherapy Drugs) is a non-sterile, single-use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves have been

tested for use with chemotherapy drugs per ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

List of Drugs tested concentration and breakthrough detection time in minutes. The maximum testing time is 240 minutes.

Drug Tested	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/mL (3300 ppm)	14.6
Cisplatin	1.0 mg/mL (1000 ppm)	> 240
Cyclophosphamide (Cytoxan®)	20 mg/mL (20000 ppm)	> 240
Dacarbazine (DTCI)	10 mg/mL (10000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/mL (2000 ppm)	> 240
Etoposide (Toposar®)	20 mg/mL (20000 ppm)	> 240
Fluorouracil	50 mg/mL (50000 ppm)	> 240
Paclitaxel (Taxol®)	6.0 mg/mL (6000 ppm)	> 240
Thiotepa	10 mg/mL (10000 ppm)	15.0

Warning: Do not use with Carmustine and Thiotepa.

Please note that the following drugs have low permeation times:

Camustine (BCNU)	3.3 mg/mL (3300 ppm)	14.6 minutes
Thiotepa	10.0 mg/mL (10000 ppm)	15.0 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K221350
Date Summary Prepared: 29 July 2022

1. Submitter's Identification:

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

b. Applicant Contact Person:
Sabri Bin Abdul Hamid
Lot 138201 Off ¾ Mile, Jalan Bercham
Kawasan Perindustrian Bercham
31400 Ipoh, Perak, Malaysia

c. Official 510k Correspondent:
Ms. Kewin Tham
Official Contact for RUBBEREX ALLIANCE SDN BHD

d. Official 510k Correspondent Firm
Mdi Consultants, Inc
55 Northern Blvd. Suite 200
Great Neck, New York 11021
(516) 482-9001
Fax: (516) 482-0186
Email: kewin@mdiconsultants.com

2. Name of the Device:

Non-Sterile Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)

Regulation Number:	21 CFR 880.6250
Regulation Name:	Non-Powdered Patient Examination Glove
Regulatory Class:	Class I, reserved
Product Code:	LZA, LZC, OPJ

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

Predicate device:	K213227
Trade/Device Name:	Uweport Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs
Device Classification Name:	Non-Powdered Patient Examination gloves
Regulation Number:	21 CFR 880.6250
Device Class:	Class I
Product Code:	LZA, LZC, OPJ
Applicant name:	Uweport LLC.

4. Device Description:

The subject device, Non-sterile Powder Free Nitrile Examination Gloves (tested for use with Chemotherapy Drugs), is a single use, disposable device intended for medical purposes that is worn

on the examiner's hand to prevent contamination between patient and examiner. These gloves have been tested for use with chemotherapy drugs per ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs. These gloves are made of synthetic copolymer of acrylonitrile and butadiene with a blue color additive. The gloves are provided in sizes XS, S. M, L and XL.

5. Indications for Use:

Non-sterile Powder Free Nitrile Examination Gloves (tested for use with Chemotherapy Drugs) is a non-sterile, single-use, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves have been tested for use with chemotherapy drugs per ASTM D6978-05 (2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

List of Drugs tested concentration and breakthrough detection time in minutes. The maximum testing time is 240 minutes.

Drug Tested	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/mL (3300 ppm)	14.6
Cisplatin	1.0 mg/mL (1000 ppm)	> 240
Cyclophosphamide (Cytoxan®)	20 mg/mL (20000 ppm)	> 240
Dacarbazine (DTCI)	10 mg/mL (10000 ppm)	> 240
Doxorubicin Hydrochloride	2.0 mg/mL (2000 ppm)	> 240
Etoposide (Toposar®)	20 mg/mL (20000 ppm)	> 240
Fluorouracil	50 mg/mL (50000 ppm)	> 240
Paclitaxel (Taxol®)	6.0 mg/mL (6000 ppm)	> 240
Thiotepa	10 mg/mL (10000 ppm)	15.0

Warning: Do not use with Carmustine and Thiotepa.

Please note that the following drugs have low permeation times:

Camustine (BCNU)	3.3 mg/mL (3300 ppm)	14.6 minutes
Thiotepa	10.0 mg/mL (10000 ppm)	15.0 minutes

6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

Table 1: Comparison to Predicate Device

Characteristic	Predicate Device	Subject Device	Comparison Analysis
Manufacturer	Uweport LLC	Rubberex Alliance Sdn Bhd	N/A
Device Name	Nitrile Exam Glove (tested for use with Chemotherapy Drugs)	Non-sterile Powder Free Nitrile Examination Gloves (tested for use with Chemotherapy Drugs)	Similar
510(k) Reference	K213227	K221350	N/A
Product Code	LZA, LZC, OPJ	LZA, LZC, OPJ	Same

Characteristic	Predicate Device	Subject Device	Comparison Analysis
Indication for Use	Uweport Powder-Free Nitrile Exam Gloves Tested for Use with Chemotherapy Drugs is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination. The Gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Non-sterile Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) is a non-sterile, disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination. The gloves have been tested for use with chemotherapy drugs per ASTM D6978-05(2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.	Similar
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Material	Nitrile	Nitrile	Same
Color	Blue	Blue	Same
Design Features	Ambidextrous Textured fingertips Beaded cuff Straight fingers	Ambidextrous Textured fingertips Beaded cuff Straight fingers	Same
Sizes	Small, Medium, Large, Extra Large	Extra Small, Small, Medium, Large, Extra Large	Different (1) See Below
Dimension-Thickness	Complies with ASTM D6319-19 Palm: 0.07S; 0.08M; 0.08L; 0.08XL all ± 0.03mm Finger: 0.09 ± 0.03mm	Complies with ASTM D6319-19 Palm: min 0.05mm Finger: min 0.05mm	Different (2) See Below
Dimension-Width	Complies with ASTM D6319-19 Small: 85 ± 5mm Medium: 96 ± 5mm Large: 108 ± 5mm Extra Large: 115 ± 5mm	Complies with ASTM D6319-19 Extra Small: 70 ± 10mm Small: 80 ± 10mm Medium: 95 ± 10mm Large: 110 ± 10mm Extra Large: 120 ± 10mm	Different (3) See Below
Dimension-Length	Complies with ASTM D6319-19 Small: ≥ 220mm Medium/Large/Extra Large: ≥ 240mm	Complies with ASTM D6319-19 Extra Small/Small: ≥ 220mm Medium/Large/Extra Large: ≥ 230mm	Different (4) See Below
Rx vs OTC	OTC	OTC	Same
Sterile vs Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs Non-Disposable	Disposable	Disposable	Same
Biocompatibility **Cytotoxicity** ISO 10993-5	At 100% extraction the cell viability was 17.1%.	Exhibited "Severe" reactivity at 100% concentration and no	Different (5) See Below

Characteristic	Predicate Device	Subject Device	Comparison Analysis
		cytotoxic effect at 10% concentration.	
Biocompatibility **Sensitization** ISO 10993-10	The test article passed both extracts with a 0 score.	The test article passed both extracts with a 0 score.	Same
Biocompatibility **Irritation** ISO 10993-10	The test article from both extracts was categorized as negligible under the test conditions.	The test article from both extracts was categorized as negligible under the test conditions.	Same
Biocompatibility **Acute Systemic Toxicity** ISO 10993-11:2017	Under the conditions of the study the test article extract met the requirements of the study; Body weight data and animal appearance was normal throughout the study.	Under the conditions of the study the test article extract met the requirements of the study; Body weight data and animal appearance was normal throughout the study.	Same
Single Use	Yes	Yes	Same
Physical Properties – Tensile Strength	Complies with ASTM D6319-19 at nominal conditions ≥ 14MPa	Complies with ASTM D6319-19 at nominal conditions ≥ 14MPa	Same
Physical Properties – Elongation	Complies with ASTM D6319-19 at nominal conditions; ≥ 500%	Complies with ASTM D6319-19 Before aging: min 500% After aging: min 400%	Different (6) See Below
Freedom from Holes	Complies with ASTM D5151-19; AQL = 2.5, 125 samples from batch of 35000, inspection level 1, criterion ≤ 7 Zero nonconforming	Complies with ASTM D5151-19; AQL = 2.5, Inspection level G-1	Similar
Residual Powder	ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves; residual powder 0.15; 0.18 and 0.19 mg/ glove	Complies with ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves; residual powder ≤ 2.0 mg/ glove	Similar
Chemotherapy Permeation ASTM D6978-05(2019) Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Carmustine (BCNU) 3.3 mg/mL (3300 ppm): 22.6 minutes	Carmustine (BCNU) 3.3 mg/mL (3300 ppm): 14.6 minutes	Similar
	Cisplatin 1.0 mg/mL (1000 ppm): > 240 minutes	Cisplatin 1.0 mg/mL (1000 ppm): > 240 minutes	Same
	Cyclophosphamide (Cytoxan®) 20 mg/mL (20000 ppm): > 240 minutes	Cyclophosphamide (Cytoxan®) 20 mg/mL (20000 ppm): > 240 minutes	Same
	Dacarbazine (DTIC) 10 mg/mL (10000 ppm): > 240 minutes	Dacarbazine (DTIC) 10 mg/mL (10000 ppm): > 240 minutes	Same
	Doxurubicin Hydrochloride 2.0 mg/mL (2000 ppm): > 240 minutes	Doxurubicin Hydrochloride 2.0 mg/mL (2000 ppm): > 240 minutes	Same

Characteristic	Predicate Device	Subject Device	Comparison Analysis
	Etoposide (Toposar®) 20 mg/mL (20000 ppm): > 240 minutes	Etoposide (Toposar®) 20 mg/mL (20000 ppm): > 240 minutes	Same
	Fluorouracil 50 mg/mL (50000 ppm): > 240 minutes	Fluorouracil 50 mg/mL (50000 ppm): > 240 minutes	Same
	Paclitaxel (Taxol®) 6.0 mg/mL (6000 ppm): > 240 minutes	Paclitaxel (Taxol®) 6.0 mg/mL (6000 ppm): > 240 minutes	Same
	Thiotepa 10 mg/mL (10000 ppm): 46.8 minutes	Thiotepa 10 mg/mL (10000 ppm): 15.0 minutes	Similar

1. **Sizes**
   The subject device sizes ranges from Extra Small, Small, Medium, Large, Extra Large, whereas the predicate device size ranges from Small, Medium, Large, Extra Large. This does not introduce any new risk to the device.

2. **Dimension-Thickness**
   The subject device dimension thickness Palm: measures at a min of 0.05mm and Finger: measures at a min of 0.05mm, whereas the predicate device Palm: measures at 0.07 Small; 0.08 Medium; 0.08 Large; 0.08 Extra Large all ± 0.03m and Finger measures at: 0.09 ± 0.03mm. These differences do not affect the performance nor introduce any new risk to the device.

3. **Dimension-Width**
   The subject device which complies with ASTM D6319-19 measures for:
   Extra Small: 70 ± 10mm
   Small: 80 ± 10mm
   Medium: 95 ± 10mm
   Large: 110 ± 10mm
   Extra Large: 120 ± 10mm
   Whereas, the predicate device which complies with ASTM D6319-19 measures for:
   Small: 85 ± 5mm
   Medium: 96 ± 5mm
   Large: 108 ± 5mm
   Extra Large: 115 ± 5mm
   These differences do not affect the device's performance or safety and effectiveness.

4. **Dimension-Length**
   The subject device which complies with ASTM D6319-19 measures for:
   Extra Small/Small: ≥ 220mm
   Medium/Large/Extra Large: ≥ 230mm
   Whereas, the predicate which complies with ASTM D6319-19 measures for:
   Small: ≥ 220mm
   Medium/Large/Extra Large: ≥ 240mm

These dimensional differences does not introduce any new risk to the device. Nor does it affect the device's safety and effectiveness.

5. **Biocompatibility- Cytotoxicity ISO 10993-5**
The subject device exhibited "severe" reactivity at 100% concentration and no cytotoxic effect at 10% concentration. Whereas, for the predicate device, at 100% extraction the cell viability was 17.1%.. To demonstrate the safety of the materials the sponsor elected to perform a systemic toxicity study in which the device was found to be non-toxic.

6. **Physical Properties – Elongation**
The subject device which complies with ASTM D6319-19 was found to be
Before aging: min 500%
After aging: min 400%
Whereas, the predicate device which complies with ASTM D6319-19 at nominal conditions was ≥ 500%
These differences do not affect the device's performance or safety and effectiveness.

7. Summary of Non-Clinical Tests Performed

Non-sterile Powder Free Nitrile Examination Gloves (tested for use with Chemotherapy Drugs) was tested and found in conformance with the following standards.

Table 2: Summary Non-Clinical Tests

Standard	Testing	Requirements	Results
ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application	Product dimension pass (between the tolerance gaps) **Width:** 70 mm (±10mm) - XS 80 mm (±10mm) - S 95 mm (±10mm) - M 110 mm (±10mm) - L 120 mm (±10mm) - XL **Overall Length:** 220 mm (Minimum) – S and XS 230 mm (Minimum) – M, L and XL **Thickness:** (for all sizes) *Finger* –0.05 mm (Minimum) *Palm* –0.05mm (Minimum)	Pass
ASTM D412-16	Standards test method for Vulcanized Rubber and Thermoplastics Elastomer - Tension	Physical properties: Before Aging: Tensile strength: min 14MPa Elongation: min 500% After Aging: Tensile strength: min 14MPa	Pass

Standard	Testing	Requirements	Results
		Elongation: min 400%	
ASTM D5151-19	Standard Test Method for detection of Holes in Medical Gloves	Pass Inspection Level G1, AQL 2.5	Pass
ASTM D6124-06	Standard Test Method for Residual Powder on Medical Gloves	Residual powder meets specification <2.0mg/glove	Pass
ASTM D6978-05	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	An assessment is made based on the permeation (breakthrough) of nine chemotherapy drugs through the glove material over a certain period of time	See Table 1 above
ISO 10993-5	Biological Evaluation on Medical Devices- Part 5: Test for In Vitro Cytotoxicity	Pass in vitro cytotoxicity	Exhibited "Severe" reactivity at 100% concentration and no cytotoxic effect at 10% concentration.
ISO 10993-10	Biological evaluation on medical device Part 10: Test for Irritation and Skin Sensitization	No irritating and sensitizing	Under the condition of study not an irritant or a sensitizer.
ISO 10993-11	Biological Evaluation of Medical Devices – Part 11: Test for Systemic Toxicity	No systemic toxic	Under the condition of the test, not a systemic toxicity.

The following National and International Standards were utilized for testing the subject device:

ASTM D6319-19	Standard Specification for Nitrile Examination Gloves for Medical Application
ASTM D412-16	Standard Test Methods for Volcanized Rubber and Thermoplastic Elastomers - 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
ASTM D6978-05	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
ISO 10993-5	Biological Evaluation on Medical Devices- Part 5: Test for In Vitro Cytotoxicity
ISO 10993-10	Biological Evaluation on Medical Devices- Part 10: Test for Irritation and Skin Sensitization
ISO 10993-11	Biological Evaluation of Medical Devices – Part 11:Test for Systemic Toxicity

8. Summary of Clinical Testing:

Clinical Testing is not required for the subject gloves.

9. Conclusions:

The conclusion drawn from the non-clinical tests demonstrates that the subject device, Non-sterile Powder Free Nitrile Examination Glove (tested for use with Chemotherapy Drugs) is as safe, as effective, and performs as well as or better than the legally marketed Predicate device cleared under K213227.