April 22, 2024

UG Global Resources Sdn. Bhd.
Lee Mei Ling
General Manager, QA
Lot 62 & 63, Lorong Senawang 3/2,
Kawasan Perindustrian Senawang,
Seremban, Negeri Sembilan 70450
Malaysia

Re: K232319
Trade/Device Name: Black Pearl Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 12, 2024
Received: March 12, 2024

Dear Lee Mei Ling:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232319

Device Name
Black Pearl Nitrile Examination Glove

Indications for Use *(Describe)*
Black Pearl Nitrile Examination Glove is a disposable device, intended for medical purposes that is worn on the examiner's hand to prevent contamination between 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

K232319

1.0 Submitter:

Name	: UG Global Resources Sdn Bhd
Address	: Lot 62 & 63 Lorong Senawang 3/2, Kawasan Perindustrian Senawang, 70450 Seremban, Negeri Sembilan, Malaysia.
Phone No.	: 606-676 0450
Fax No.	: 606-679 5694
Contact Person	: Ms. Lee Mei Ling
Email	: meiling.lee@unigloves.com.my
Date of Preparation	: 19th April 2024

2.0 Name of the Device

Trade Name	: Black Pearl Nitrile Examination Glove
Common Name	: Non-Sterile, Powder Free, Nitrile Examination Gloves, Black
Classification Name	: Non-Powdered Patient Examination Glove (21 CFR 880.6250)
Class	: Class I
Product Code	: LZA

3.0 Identification of the Predicate Devices that equivalency is claimed:

Primary Predicate	: K112012, Non-Sterile, Powder-Free, Nitrile Examination Gloves Blue
Company	: UG Healthcare (USA) Inc.
510(k)	: K112012
Classification Name	: Non-Powdered Patient Examination Glove (21 CFR 880.6250)
Class	: Class I
Product Code	: LZA

4.0 Description of the Device:

Black Pearl Nitrile Examination Glove is a single use examination glove, intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. The nitrile glove is an ambidextrous, beaded cuff and black in colour. It meets the performance requirements in accordance with ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

5.0 Intended Use of the Device

Black Pearl Nitrile Examination Glove is a disposable device, intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

6.0 Comparison of Technological Characteristics Between the Subject Device and Predicate Device:

The Black Pearl Nitrile Examination Glove and predicate device are summarized with the following technological characteristics. Both gloves are made with nitrile and meets ASTM D6319-19 - Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

The device has similar technological characteristics with the predicate device in terms of product code, intended use, indications for use, device material, additive, direction for use, construction, sterility, acceptance criteria, physical properties, biocompatibility test, residual powder test and freedom from holes. The technological characteristics differences between both devices are colour and dimensions. However, both colour pigment are with same intended use (colourant for nitrile products) and both dimensions are within ASTM D6319-19 standard. The comparison analysis is presented in the table below:

Characteristic and parameters	**Non-Sterile, Powder Free, Nitrile Examination Gloves Blue UG Healthcare (USA) Inc. K112012 (Predicate)**	**Black Pearl Nitrile Examination Glove (K232319)**	**Comparison Analysis**
Product Code	LZA	LZA	Same
Intended use	A 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 the patient and the examiner.	Black Pearl Nitrile is a disposable device, intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Indications for Use	Non-Sterile, Powder Free, Nitrile Examination Gloves Blue is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Black Pearl Nitrile is a disposable device, intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Device Material	Nitrile	Nitrile	Same
Colour	Blue	Black	Different

<table>
<tr><td></td><td>(Colourant for nitrile products)</td><td>(Colourant for nitrile products)</td><td></td></tr>
<tr><td>Additives</td><td>No flavour additive</td><td>No flavour additive</td><td>Same</td></tr>
<tr><td>Direction for Use</td><td>Single Use Only</td><td>Single Use Only</td><td>Same</td></tr>
<tr><td>Construction</td><td>Ambidextrous</td><td>Ambidextrous</td><td>Same</td></tr>
<tr><td>Sterility</td><td>Non-sterile</td><td>Non-sterile</td><td>Same</td></tr>
<tr><td>Acceptance Criteria</td><td>ASTM D6319-10</td><td>ASTM D6319-19</td><td>Same</td></tr>
<tr><td colspan="4">Device Tolerance & Specifications:</td></tr>
<tr><td>Dimensions</td><td>Meets ASTM D6319-10
Thickness at Finger – min. 0.05mm
Thickness at Palm – min. 0.05mm

Overall Length – 240mm minimum

Width –
Size M – 95mm</td><td>Meets ASTM D6319-19
Thickness at Finger – min. 0.05mm
Thickness at Palm – min. 0.05mm

Length –
Size XS – min. 220mm
Size S – min. 220mm
Size M – min. 230mm
Size L – min. 230mm
Size XL – min. 230mm

Width -
Size XS – 70±10mm
Size S – 80±10mm
Size M – 95±10mm
Size L – 110±10mm
Size XL - 120±10mm</td><td>Different</td></tr>
<tr><td>Physical Properties</td><td>Meets ASTM D6319-10:
Tensile Strength:
<table><tr><td>Before Aging</td><td>After Aging</td></tr><tr><td>Min. 14 MPa</td><td>Min. 14 MPa</td></tr></table>
Ultimate Elongation:
<table><tr><td>Before Aging</td><td>After Aging</td></tr><tr><td>min. 500%</td><td>min. 400%</td></tr></table></td><td>Meets ASTM D6319-19:
Tensile Strength:
<table><tr><td>Before Aging</td><td>After Aging</td></tr><tr><td>Min. 14 MPa</td><td>Min. 14 MPa</td></tr></table>
Ultimate Elongation:
<table><tr><td>Before Aging</td><td>After Aging</td></tr><tr><td>min. 500%</td><td>min. 400%</td></tr></table></td><td>Same</td></tr>
<tr><td>Biocompatibility Test</td><td></td><td></td><td></td></tr>
<tr><td>a. Skin Sensitization Tests</td><td>Non-sensitizer under the conditions of the study.</td><td>Non-sensitizer under the conditions of the study.</td><td>Same</td></tr>
</table>

b. Irritation Tests	Non-irritant under the conditions of the study.	Non-irritant under the conditions of the study.	Same
c. Cytotoxicity Test	Nil	Cytotoxic in undiluted (100%), 1:2 (50%), 1:4 (25%) and 1:8 dilution (12.5%). Non-cytotoxic to L-929 cells in 1:16 (6.25%) and 1:32 dilution (3.125%)	No test reports were submitted for predicate device
d. Acute Systemic Toxicity	Nil	Did not induce any acute systemic toxicity in swiss albino mice under the conditions of the study.	No test reports were submitted for predicate device
Residual Powder Test	Meets ASTM D6124-06: ≤ 2 mg/ glove	Meets ASTM D6124-06: ≤ 2 mg/ glove	Same
Freedom from Holes	Meets ASTM D6319-10 Standard requirements	Meets ASTM D6319-19 Standard requirements	Same

7.0 Summary of Non-Clinical Testing

The performance test data of non-clinical tests meets ASTM D6319-19 and ASTM D6124 -06 (Reapproved 2017) standards requirements.

Test Performed	Device Description/ Sample Size	Test Method/Applicable Standard	Purpose of Testing	Gloves Size	Acceptance Criteria		Results	Status
Test Title: Dimensions	Gloves sampled from the finished product and identified as Non-Sterile, Powder Free, Nitrile Examination Gloves, Black. The inspection level is S-2 and the acceptable quality level (AQL) is 4.0. The lot size for this sampling is 35,001 to 150,000. Therefore, 13 pieces of gloves from each size were used for the testing.	ASTM D6319-19	To measure the length, width, and thickness of gloves	XS	Length	Min. 220mm	Min. 242mm	Pass
					Width	70mm ±10mm	77mm to 80mm	Pass
					Thickness	Palm - Min. 0.05mm Finger - Min. 0.05mm	Palm – Min. 0.06mm Finger – Min. 0.08mm	Pass
				S	Length	Min. 220mm	Min. 244mm	Pass
					Width	80mm ±10mm	83mm to 86mm	Pass
					Thickness	Palm - Min. 0.05mm Finger - Min. 0.05mm	Palm – Min. 0.06mm Finger – Min. 0.08mm	Pass
				M	Length	Min. 230mm	Min. 241mm	Pass
					Width	95mm ±10mm	96mm to 98mm	Pass
					Thickness	Palm - Min. 0.05mm Finger - Min. 0.05mm	Palm – Min. 0.06mm Finger – Min. 0.08mm	Pass
				L	Length	Min. 230mm	Min. 240mm	Pass
					Width	110mm ±10mm	107mm to 110mm	Pass
					Thickness	Palm - Min. 0.05mm Finger - Min. 0.05mm	Palm – Min. 0.06mm Finger – Min. 0.09mm	Pass
				XL	Length	Min. 230mm	Min. 241mm	Pass
					Width	120mm ±10mm	119mm to 124mm	Pass
					Thickness	Palm - Min. 0.05mm Finger - Min. 0.05mm	Palm – Min. 0.06mm Finger – Min. 0.09mm	Pass

Test Performed	Device Description/ Sample Size	Test Method/Applicable Standard	Purpose of Testing	Acceptance Criteria		Results		Status
Test Title: Freedom From Holes	Gloves sampled from the finished product and identified as Non-Sterile, Powder Free, Nitrile Examination Gloves, Black. The inspection level is G-1 and the acceptable quality level (AQL) is 2.5. The lot size for this sampling is 35,001 to 150,000. Therefore, 200 pieces of M-size gloves were used for the testing.	ASTM D6319-19	To detect holes that leak water and thereby compromise the usefulness of the gloves.	Sample size: 200 pcs Inspection level: G-I AQL: 2.5 Accept: 10 pieces Reject: 11 pieces		During the test, 2 pieces were found with holes.		Pass
Test Title: Physical Properties	Gloves sampled from the finished product and identified as Non-Sterile, Powder Free, Nitrile Examination Gloves, Black. The inspection level is S-2 and the acceptable quality level (AQL) is 4.0. The lot size for this sampling is 35,001 to 150,000. Therefore, 13 pieces of M-size gloves were used for the testing.	ASTM D6319-19	To evaluate the physical property characteristics of gloves.	Before Aging Tensile Strength: Min. 14 MPa Ultimate Elongation: Min. 500%	After Accelerated Aging Tensile Strength: Min. 14 MPa Ultimate Elongation: Min. 400%	Before Aging Tensile Strength: Min. 18.2 MPa Ultimate Elongation: Min. 500%	After Accelerated Aging Tensile Strength: Min. 17.4 MPa Ultimate Elongation: Min. 400%	Pass

Test Performed	Device Description/ Sample Size	Test Method/Applicable Standard	Purpose of Testing	Acceptance Criteria	Results	Status
Test Title: Powder-free Residue	5 pieces of gloves were sampled from the finished product and identified as Non-Sterile, Powder Free, Nitrile Examination Gloves, Black.	ASTM D6124-06 (Reapproved 2017)	To determine the amount of residual powder and non-powder solids found on gloves.	≤ 2.0mg/ glove	0.70mg/ glove	Pass

Test Performed	Purpose of Testing	Device Description	Test Method	Results	Conclusion
Test title: Skin Irritation Test in New Zealand White Rabbits	To determine the skin irritation potential of the Non-Sterile, Powder Free, Nitrile Examination Gloves, Black in New Zealand White rabbits.	Non-Sterile, Powder Free, Nitrile Examination Gloves, Black is a non-sterile glove, intended for medical purpose that is worn on the examiners hand to prevent contamination between patient and examiner. It is a surface device which comes in contact with skin. The duration of contact is less than or equal to 24 hours.	The test item that was cut and used for extraction was extracted using physiological saline (polar solvent) and cottonseed oil (non-polar solvent) at 37 ± 1 °C for 72 h and 20 min under sterile conditions. Solvent controls were also subjected to the similar extraction conditions. The test item extracts (0.5 mL) was loaded on the absorbent gauze and placed topically on the fur clipped area of six rabbits (3 animals each for polar and non-polar extracts). The patches were loosely held in contact with the skin by semi-occlusive dressing with means of non-irritant adhesive tape for 24 h. The test sites were marked with non-irritant permanent ink. Animals were observed for three consecutive days for morbidity, mortality, skin reactions and abnormal clinical signs and symptoms following the patch removal. The skin reactions were visually scored according to ISO 10993-23:2021(E) at 24, 48 and 72 h.	No mortality or morbidity was observed in the experimental animals. A gradual increase in body weight was observed in all the animals at the end of the experiment. No signs of clinical toxicity or overt toxicity was observed in any of the animals. Hence, gross pathology and histopathology was not performed. No local skin irritation was observed at the test site in any of the animals and the primary irritation index obtained was '0'.	Based upon the results obtained in this study and in line with ISO 10993-23:2021(E), the given test item, Non-Sterile, Powder Free, Nitrile Examination Gloves, Black, is considered as non-irritant under the conditions of the present study.

Test Performed	Purpose of Testing	Device Description	Test Method	Results	Conclusion
Test title: Skin Sensitization Test in Guinea Pigs	To determine the skin sensitization potential of the Non-Sterile, Powder Free, Nitrile Examination Gloves, Black using guinea pig maximization test (GPMT).	Non-Sterile, Powder Free, Nitrile Examination Gloves, Black is a non-sterile glove, intended for medical purpose that is worn on the examiners hand to prevent contamination between patient and examiner. It is a surface device which comes in contact with skin. The duration of contact is less than or equal to 24 hours.	The test item that was cut and used for extraction was extracted in physiological saline (polar solvent) and cottonseed oil (non-polar solvent) at 37 ± 1 °C for 72 ± 2 h (Intradermal induction - 72 h and 10 min, Topical induction - 72 h and 05 min, Challenge phase - 72 h and 10 min) under sterile conditions. Solvent controls were subjected to similar extraction conditions. Animals were divided into four groups; G1 - five guinea pigs for polar solvent control, G2 - ten guinea pigs for polar test item extract, G3 - five guinea pigs for non-polar solvent control and G4 - ten guinea pigs for non-polar test item extract. The fur over the treatment sites was clipped and shaved on the day of treatment, prior to dosing on all the animals. Induction of sensitization was a two-stage procedure with intradermal injections on day 0 (with Freund's complete adjuvant (FCA), solvent controls and extracts), followed by a topical patch exposure on day 7 for 48 h. On day 21, challenge patches were applied for 24 h. Skin reaction grading was performed using Magnusson and Kligman scale at 24h and 48 h, after removing the challenge patches according to ISO 10993-10:2010(E).	No mortality or morbidity were observed in any of the animals used in this study. A gradual increase in body weight was observed in all the animals at the end of the experiment. No skin sensitization reactions were observed in both control and test sites of all the animals. Therefore, no gross and histopathological examination were conducted.	Based upon the results obtained in this study and in line with ISO 10993-10:2010(E), the given test item, Non-Sterile, Powder Free, Nitrile Examination Gloves, Black, is considered as non-sensitizer to Guinea Pigs under the conditions of the present study.

Test Performed	Purpose of Testing	Device Description	Test Method	Results	Conclusion
Test title: Test for in vitro Cytotoxicity	To evaluate the in vitro cytotoxic potential of the test item in L-929 mouse fibroblasts cells using elution method	Non-Sterile, Powder Free, Nitrile Examination Gloves, Black is a non-sterile glove, intended for medical purpose that is worn on the examiners hand to prevent contamination between patient and examiner. According to ISO 10993-1:2018, this is classified as a surface device contacting skin, for ≤ 24 hours (limited exposure)	The test item (both inner and outer surfaces) was cut and extracted at a ratio of 6 cm2 per mL in extraction medium at 37 ± 1 ºC for 24 ± 2 h. Test item was extracted in 12 mL of extraction medium at 37 ± 1 ºC for 24 h and 15 minutes under aseptic condition. Negative control (both sides) was extracted in 7 mL of extraction medium at 37 ± 1 ºC for 24 h and 15 minutes. Positive control (both sides) was extracted in 7 mL of extraction medium at 37 ± 1 ºC for 24 h and 15 minutes. Vehicle control (MEM 05) was also subjected to the same extraction condition. Exponentially growing L-929 mouse fibroblasts cells were seeded in 96-well plate at 1 x 10^4 cells per well. After 24 h, 1x MEM supplemented with 10% heat inactivated foetal bovine serum and 1% penicillin/streptomycin solution (complete growth medium) was removed and replaced with a series of six different dilution of the test item extract ((Undiluted (100%), 1:2 dilution (50%), 1:4 dilution (25%), 1:8 dilution (12.5%), 1:16 dilution (6.25%) and 1:32 dilution (3.125%)), medium blank, vehicle, positive and negative control extract. The cell cultures were then incubated at 37 ± 1°C for 24 h with 5% CO2. After incubation, the cells were subjected to qualitative measurements viz., cytotoxicity was graded based on the morphology of the cells.	The cultures treated with the test item extract at undiluted (neat extract) (100%), 1:2 dilution (50%), 1:4 dilution (25%), 1:8 dilution (12.5%) showed complete destruction of the cell layers (grade 4). However, at dilutions 1:16 dilution (6.25%) and 1:32 dilution (3.125%) did not show any cytotoxic response (grade 0).	Based upon the results obtained in this study and in line with ISO 10993-5:2009, it is concluded that the given test item, Non-Sterile, Powder Free, Nitrile Examination Gloves, Black is considered as cytotoxic in undiluted (neat extract) (100%), 1:2 dilution (50%), 1:4 dilution (25%) and 1:8 dilution (12.5%). Non-cytotoxic to L-929 cells in 1:16 dilution (6.25%) and 1:32 dilution (3.125%).

Test Performed	Purpose of Testing	Device Description	Test Method	Results	Conclusion
Test title: Acute Systemic Toxicity Test in Swiss Albino Mice	To determine the acute systemic toxicity potential of the test item in Swiss albino mice.	Non-Sterile, Powder Free, Nitrile Examination Gloves, Black is a non-sterile glove, intended for medical purpose that is worn on the examiners hand to prevent contamination between patient and examiner. According to ISO 10993-1:2018(E), this is a surface device which comes in contact with skin for ≤ 24 hours (limited exposure).	The test item that was cut and used for extraction was extracted at a ratio of 6 cm2/mL of polar solvent (physiological saline) as well as non-polar solvent (cottonseed oil) at 37 ± 1 °C for 72 h and 10 minutes. Solvent controls were also subjected to the same temperature and time conditions. Four groups of mice, each comprising of five males were used for this study. Two groups (G1 and G2) were treated intravenously with polar solvent control and polar extract, respectively at a dose volume of 50 mL/kg body weight in two divided doses at an interval of 1 h and 35 minutes within a 24 h period. Another two groups (G3 and G4) were treated intraperitoneally with non-polar solvent control and non-polar extract respectively at a dose volume of 50 mL/kg body weight in a single dose. The animals were observed for three consecutive days for morbidity, mortality, body weight and for any abnormal clinical signs and symptoms following the test item extracts administration.	No mortality or morbidity was observed in test item extracts administered animals. A gradual increase in body weight was observed in all the animals at the end of experiment. No signs of clinical toxicity or overt toxicity was observed in any of the animals; hence, gross pathology and histopathology was not performed.	Based upon the results obtained and in line with ISO 10993-11:2017(E), it is concluded that the given test item, Non-Sterile, Powder Free, Nitrile Examination Gloves, Black did not induce any systemic toxicity in swiss albino mice under the conditions of the present study.

8.0 Clinical Testing Summary

Not applicable - Clinical data is not needed for gloves.

9.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.