May 30, 2023

First Glove Sdn. Bhd.
℅ Manoj Zacharias
Consultant
Liberty Management Group Ltd.
75 Executive Dr. Ste 114
Aurora, Illinois 60504

Re: K230958
Trade/Device Name: First Glove Blue Nitrile Examination Gloves Powder Free
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 13, 2023
Received: April 4, 2023

Dear Manoj Zacharias:

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 -S

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)*
K230958

Device Name
First Glove Blue Nitrile Examination Gloves Powder Free

Indications for Use *(Describe)*

First Glove Blue Nitrile Examination Gloves Powder Free is a disposable device intended for medical purpose 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.

510(K) SUMMARY
K230958
AS REQUIRED BY: 21CFR§807.92

A. APPLICANT INFORMATION

510(K) Owner's Name	FIRST GLOVE SDN. BHD.
Address	Unit 23-2, Level 23, Binjai 8, No. 2, Lorong Binjai, Kuala Lumpur, Wilayah Persekutuan, Malaysia 50450.
Phone	+60 12-389 1644, +603 2181 8201
Fax	+603 2181 7201
E-mail	dean@firstglove.com,
Contact Person	Mr. Dean Segal
Designation	President
Contact Number	+60 12-389 1644
Contact Email	dean@firstglove.com
Date Submitted	13 March 2023

B. DEVICE IDENTIFICATION

Name of the device	First Glove Blue Nitrile Examination Gloves Powder Free
Product proprietary or trade name	First Glove
Common or usual name	Blue Nitrile Examination Gloves Powder Free
Classification name	Non-powdered patient examination glove
Device Classification	Class-1
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Palm Care Blue Nitrile Examination Gloves Powder free
510(k) Number	K202384
Regulatory Class	Class 1
Product code	LZA

Reference Device	Nitrile Patient Examination Gloves
510(k) Number	K211351
Regulatory Class	Class 1
Product code	LZA

D. DESCRIPTION OF THE DEVICE:

First Glove Blue Nitrile Examination Gloves Powder Free are equivalent to Class I patient examination gloves bearing the product code LZA (21CFR880.6250). They meet all the current specifications listed under the ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from Nitrile (NBR)100%. These gloves are blue in color and are powder free. The product is non-sterile, finger textured, ambidextrous with beaded cuff and single use only.

First Glove Blue Nitrile Examination Gloves Powder Free with sizes Extra Small, Small, Medium, Large, Extra Large and Extra Extra Large are included in the submission.

E. INDICATIONS FOR USE OF THE DEVICE:

First Glove Blue Nitrile Examination Gloves Powder Free is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

F. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON
		PREDICATE	REFERENCE	SUBJECT	
510(k) Number	---	**K202384**	**K211351**	**K230958**	---
Name of device	---	Palm Care Blue Nitrile Examination Gloves Powder free	Nitrile Patient Examination Gloves	First Glove Blue Nitrile Examination Gloves Powder Free	---
Product Code	---	LZA	LZA	LZA	Same
Indications for Use	---	Blue Nitrile Examination Gloves Powder Free is disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.	The Nitrile Patient Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands or finger to prevent contamination between patient and examiner.	First Glove Blue Nitrile Examination Gloves Powder Free is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Regulation Number	---	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Material	ASTM D6319-19	Nitrile (NBR)	Nitrile	Nitrile (NBR)	Same
Color	---	Blue	Blue	Blue	Same
Texture	---	Finger Texture	---	Finger Texture	Same as predicate device

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92

<table>
<tr><th rowspan="2">CHARACTERISTICS</th><th rowspan="2">STANDARDS</th><th colspan="3">DEVICE PERFORMANCE</th><th rowspan="2">COMPARISON</th></tr>
<tr><th>PREDICATE</th><th>REFERENCE</th><th>SUBJECT</th></tr>
<tr><td>510(k) Number</td><td>---</td><td>K202384</td><td>K211351</td><td>K230958</td><td>---</td></tr>
<tr><td>Size</td><td>ASTM D6319-19</td><td>Extra Small, Small, Medium, Large, Extra Large</td><td>XS, S, M, L, XL, XXL</td><td>XS, S, M, L, XL, XXL</td><td>Same as reference device</td></tr>
<tr><td>Design Feature</td><td>---</td><td>Ambidextrous</td><td>Ambidextrous</td><td>Ambidextrous</td><td>Same</td></tr>
<tr><td>Single Use</td><td>Medical Glove Guidance Manual-Labeling</td><td>Single Use</td><td>Single Use</td><td>Single Use</td><td>Same</td></tr>
<tr><td>Sterile/non sterile</td><td>---</td><td>Nonsterile</td><td>Non-Sterile</td><td>Nonsterile</td><td>Same</td></tr>
<tr><td>Powder/Powder free</td><td>---</td><td>Powder free</td><td>Powder free</td><td>Powder free</td><td>Same</td></tr>
<tr><td>Dimensions- Length</td><td>ASTM D6319-19</td><td>Length Min 230 mm
(for medium size)</td><td>Length (mm):
XS/S:≥220；
M/L/XL/XXL:
≥230</td><td>Length (mm):
XS/S:≥220；
M/L/XL/XXL:
≥230
Size | Average
XS | 247.00
S | 247.23
M | 252.54
L | 250.92
XL | 245.54
XXL | 251.00</td><td>Same as reference device</td></tr>
<tr><td>Dimensions- Width</td><td>ASTM D6319-19</td><td>Width Min 95+/-10mm
(for medium size)</td><td>Width (mm):
XS:70±10;
S:80±10;
M:95±10；
L:110±10；
XL:120±10;
XXL:130±10</td><td>Width (mm):
XS:70±10;
S:80±10;
M:95±10；
L:110±10；
XL:120±10;
XXL:130±10
Size | Average
XS | 74.31
S | 85.08
M | 94.85
L | 105.38
XL | 110.77
XXL | 121.31</td><td>Same as reference device</td></tr>
<tr><td>Physical Properties-Tensile Strength</td><td>ASTM D6319-19</td><td><u>Before Ageing</u>
Tensile Strength Min 14 MPa</td><td><u>Before Ageing</u>
Tensile Strength 14MPa, min</td><td><u>Before Ageing</u>
Tensile Strength Min 14 MPa
Size | Average
XS | 35.25
S | 29.47
M | 27.72
L | 30.12
XL | 36.26
XXL | 33.60</td><td>Same</td></tr>
</table>

510(K) SUMMARY

AS REQUIRED BY: 21CFR§807.92

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<tr><th>CHARACTERISTICS</th><th>STANDARDS</th><th colspan="3">DEVICE PERFORMANCE</th><th>COMPARISON</th></tr>
<tr><th></th><th></th><th>PREDICATE</th><th>REFERENCE</th><th colspan="2">SUBJECT</th><th></th></tr>
<tr><td>510(k) Number</td><td>---</td><td>K202384</td><td>K211351</td><td colspan="2">K230958</td><td>---</td></tr>
<tr><td>Physical Properties-Tensile Strength</td><td>ASTM D6319-19</td><td><u>After Ageing</u>
Tensile Strength Min14 MPa</td><td><u>After Ageing</u>
Tensile Strength 14MPa, min</td><td colspan="2"><u>After Ageing</u>
Tensile Strength Min 14 MPa
Size | Average
XS | 35.75
S | 30.02
M | 28.75
L | 29.55
XL | 31.20
XXL | 35.66</td><td>Same</td></tr>
<tr><td>Physical Properties-Ultimate Elongation</td><td>ASTM D6319-19</td><td><u>Before Ageing</u>
Ultimate Elongation Min 500%</td><td><u>Before Ageing</u>
Ultimate Elongation 500% min</td><td colspan="2"><u>Before Ageing</u>
Ultimate Elongation Min 500%
Size | Average
XS | 537
S | 525
M | 525
L | 523
XL | 528
XXL | 533</td><td>Same</td></tr>
<tr><td>Physical Properties-Ultimate Elongation</td><td>ASTM D6319-19</td><td><u>After Ageing</u>
Ultimate Elongation Min 400%</td><td><u>After Ageing</u>
Ultimate Elongation 400% min</td><td colspan="2"><u>After Ageing</u>
Ultimate Elongation Min 400%
Size | Average
XS | 493
S | 478
M | 516
L | 495
XL | 485
XXL | 502</td><td>Same</td></tr>
<tr><td>Thickness</td><td>ASTM D6319-19</td><td>Palm Min 0.05mm
Finger Min 0.05mm</td><td>Thickness (mm):
Palm: ≥0.05
Finger: ≥0.05</td><td colspan="2">Palm Min 0.05 mm
Finger Min 0.05mm
Size | Palm (Avg) mm | Finger (Avg) mm
XS | 0.07 | 0.10
S | 0.06 | 0.10
M | 0.07 | 0.10
L | 0.06 | 0.10
XL | 0.07 | 0.11
XXL | 0.07 | 0.10</td><td>Same</td></tr>
<tr><td>Powder Free Residue</td><td>ASTM D6319-19</td><td>≤2 mg/glove</td><td>Meet the requirements of ASTM D6124 ＜2.0mg</td><td colspan="2">≤2 mg/glove
Size | Average
XS | 0.04 mg/glove
S | 0.28 mg/glove
M | 0.04 mg/glove
L | 0.04 mg/glove
XL | 0.26 mg/glove
XXL | 0.48 mg/glove</td><td>Same</td></tr>
</table>

510(K) SUMMARY
AS REQUIRED BY: 21CFR§807.92

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE			COMPARISON
		PREDICATE	REFERENCE	SUBJECT	
510(k) Number	---	**K202384**	**K211351**	**K23958**	---
Freedom from Holes	ASTM D5151-19	Passes AQL - 1.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Passes AQL - 2.5	Similar to reference device
Biocompatibility	Primary Skin Irritation- ANSI AAMI ISO 10993-10:2010/(R)2014	Under the condition of study, not an irritant	Under the conditions of the study, not an irritant or a sensitizer.	Under the condition of the study, the test article is considered a non-irritant.	Same
	Dermal Sensitization- ANSI AAMI ISO 10993-10:2010/(R)2014	Under the conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer.	Under the conditions of the study, the test article is not considered to be a contact sensitizer.	Same
	In vitro cytotoxicity- ANSI AAMI ISO 10993-5:2009/(R)2014	Under the conditions of the study, non-cytotoxic	Under conditions of the study, did not show potential toxicity to L-929 cells.	Under the conditions of the study, the test article is considered cytotoxic at extract concentrations of 100%, 66.7%, 44.4%, 29.6% and 19.8% and did not produce a cytotoxic effect at 13.2%. Moreover, under the conditions of the study, non acute systemic toxic.	Similar
	Acute Systemic Toxicity-ANSI AAMI ISO 10993-11:2017	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	---	Under the condition of study, the test article did not induce any systemic toxicity.	Same as predicate device

There are no significant differences between the products and are identical in terms of intended use materials, design and manufacturing methods. Devices meet the ASTM standard D6319-19.

G. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

BENCH TEST DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the length of the gloves	X-Small : 220 mm min Small : 220 mm min Medium : 230 mm min Large : 230 mm min X-Large : 230 mm min XX-Large : 230 mm min	XS: - 247.00 mm S: - 247.23 mm M: - 252.54 mm L: - 250.92 mm XL: - 245.54 mm XXL: - 251.00 mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the width of the gloves	XS: 70+/-10 mm S: 80+/-10 mm M: 95+/-10 mm L: 110+/-10 mm XL: 120+/-10 mm XXL: 130+/-10 mm	XS: - 74.31 mm S: - 85.08 mm M: - 94.85 mm L: - 105.38 mm XL: - 110.77 mm XXL: - 121.31 mm
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the thickness of the gloves	**Palm** 0.05 mm min (for all sizes) **Finger** 0.05 mm min (for all sizes)	**Size** / **Palm(mm)** / **Finger(mm)** XS / 0.07 / 0.10 S / 0.06 / 0.10 M / 0.07 / 0.10 L / 0.06 / 0.10 XL / 0.07 / 0.11 XXL / 0.07 / 0.10
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.	To determine the physical properties- Tensile strength	**Before Ageing** Tensile Strength 14MPa Min for all sizes **After Ageing** Tensile Strength 14MPa Min for all sizes	**Size** / **Before Ageing** / **After ageing** XS / 35.25 MPa / 35.75 MPa S / 29.47 MPa / 30.02 MPa M / 27.72 MPa / 28.75 MPa L / 30.12 MPa / 29.55 MPa XL / 36.26 MPa / 31.20 MPa XXL / 33.60 MPa / 35.66 MPa
	To determine the physical properties- Ultimate Elongation	**Before Ageing** Ultimate Elongation 500% Min for all sizes **After Ageing** Ultimate Elongation 400% Min for all sizes	**Size** / **Before Ageing** / **After Ageing** XS / 537 % / 493 % S / 525 % / 478 % M / 525 % / 516 % L / 523 % / 495 % XL / 528 % / 485 % XXL / 533 % / 502 %
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	AQL 2.5	Gloves Passes AQL 2.5
ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	≤ 2 mg/glove	XS: - 0.04 mg/glove S: - 0.28 mg/glove M: - 0.04 mg/glove L: - 0.04 mg/glove XL: - 0.26 mg/glove XXL: - 0.48 mg/glove

BIOCOMPATIBILITY DATA

TEST METHOD	PURPOSE	ACCEPTANCE CRITERIA	RESULT
ANSI AAMI ISO 10993-10:2010/(R)2014 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization Test done for irritation	To evaluate the test item, for skin irritation test in New Zealand Albino Rabbits.	Under the condition of study not an irritant	Under the condition of the study, the test article is considered a non-irritant.
ANSI AAMI ISO 10993-10:2010/(R)2014 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization Test done for skin sensitization	To evaluate the test item, for the skin sensitization in Guinea pigs by maximization test.	Under the conditions of the study, not a sensitizer	Under the conditions of the study, the test article is not considered to be a contact sensitizer.
ANSI AAMI ISO 10993-5:2009/(R)2014 - Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	To evaluate the test item, for its ability to induce cytotoxicity using mouse cell line L929 by XTT Dye Method.	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, the test article is considered cytotoxic at extract concentrations of 100%, 66.7%, 44.4%, 29.6% and 19.8% and did not produce a cytotoxic effect at 13.2%. Moreover, under the conditions of the study, non acute systemic toxic.
ANSI AAMI ISO 10993-11:2017 - Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	To evaluate the test item, for acute systemic toxicity in Albino CD-1 Mouse.	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the condition of study, the test article did not induce any systemic toxicity.

The performance test data of the non-clinical tests meet the following standards:

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves

ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves

ANSI AAMI ISO 10993-10:2010/(R)2014 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

ANSI AAMI ISO 10993-5:2009/(R)2014 Biological Evaluation of Medical Devices - Part 5, Tests for In Vitro Cytotoxicity.

ANSI AAMI ISO 10993-11:2017 Biological Evaluation of Medical Devices - Part 11, Tests for Systemic Toxicity.

H. SUMMARY OF CLINICAL PERFORMANCE TESTING

Not applicable - Clinical data is not needed for gloves.

I. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission, First Glove Blue Nitrile Examination Gloves Powder free is as safe, as effective, and performs as well as or better than the legally marketed predicate device **K202384**.