September 2, 2021

Great Eco Glove Sdn. Bhd.
Soh Li
QA/QC Manager
Lot 1675, Jalan Makmur, Batu 28, Ijok
Bestari Jaya, Selangor 45600
Malaysia

Re: K210868
Trade/Device Name: Nitrile Examination Gloves Powder Free (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: August 6, 2021
Received: August 6, 2021

Dear Soh Li:

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,

Liqun Zhao -S

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)*
K210868

Device Name
Nitrile Examination Gloves Powder Free (Blue)

Indications for Use *(Describe)*
Disposable device intended for medical purpose that is worn on the examiner's hand or finger 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1.0 510(k) Summary – K210868

1.1 Submitter:

Name: Great Eco Glove Sdn. Bhd.
Address: Lot 1675, Jalan Makmur, Batu 28, Ijok,
45600, Bestari Jaya, Selangor, Malaysia.
Contact: +603-3279 2199 / +603-3279 3633

1.2 Contact Person:

Name: Dr. Neoh Vee Heng (Executive Chairman)
Email: drneoh.geg@gmail.com

Name: Mr. Ian Neoh Puay Guan (Assistant General Manager)
Email: iannpg.geg@gmail.com

Name: Ms. Shahnaz Sakinah Binti Shaiful Bahri (QA/QC Executive)
Email: qaqc.geg@gmail.com

Date of summary prepared: 23rd December 2020

1.3 Name of Device:

Trade Name: Nitrile Examination Gloves Powder Free (Blue)
Common Name: Patient Examination Glove
Classification Name: Patient Examination Glove
Classification Regulation: 21 CFR 880.6250
Device Class: I
Product Code: LZA
Classification Panel: General Hospital

1.4 Legally Marketed Predicate Device:

	Predicate Device
Manufacturer	Central Medicare Sdn. Bhd.
Trade Name	Orange Non Sterile Powder Free Nitrile Examination Gloves
510 (k) Number	K172642
Product Code	LZA
Classification Regulation	21 CFR 880.6250
Device Class	I

1.5 Device Description:

Nitrile Examination Gloves Powder Free (Blue) are available in blue color. The proposed device is single use, non-sterile, ambidextrous and meets all the requirements of ASTM Specification D6319-10 (2015) – Standard Specification for Nitrile Examination Gloves for Medical Application.

1.6 Intended Use:

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

1.7 Technological Characteristics:

Nitrile Examination Gloves Powder Free (Blue) have either similar or the same technological characteristics as compared to the legally marketed predicated device, K172642, Orange Non Sterile Powder Free Nitrile Examination Gloves:

Characteristics	Standards	Proposed Device: K210868	Predicate Device: K172642	Comparison
General				
Manufacturer	N/A	Great Eco Glove Sdn. Bhd.	Central Medicare Sdn. Bhd.	N/A
Trade Name		Nitrile Examination Gloves Powder Free (Blue)	Orange Non Sterile Powder Free Nitrile Examination Gloves	Different
Product Code	N/A	LZA	LZA	Same
Classification Regulation	N/A	21 CFR 880.6250	21 CFR 880.6250	Same
Device Class	N/A	I	I	Same
Indication for use	N/A	Nitrile Examination Gloves Powder Free (Blue) is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient.	Orange Non Sterile Powder Free Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Material Composition	ASTM D6319-10 (2015)	Synthetic nitrile rubber	Synthetic nitrile rubber	Similar
Color	N/A	Blue	Orange	Different
Design	N/A	Non-sterile	Non-sterile	Same
		Single use	Single use	
		Powder free	Powder free	

		Ambidextrous Beaded cuff	Ambidextrous Beaded cuff	
Labeling	N/A	Meet FDA's recommendations	Meet FDA's recommendations	Similar
Performance				
Dimension	ASTM D6319-10 (2015)	Length ≥ 230 mm	Length ≥ 230 mm	Similar
		Palm Width: Size S – 85 ± 5 mm Size M – 95 ± 5 mm Size L – 105 ± 5 mm Size XL – 115 ± 5 mm	Palm Width: Size S – 80 ± 10 mm Size M – 95 ± 10 mm Size L – 110 ± 10 mm Size XL – 120 ± 10 mm	Similar
		Thickness: Finger ≥ 0.05 mm Palm ≥ 0.05 mm	Thickness: Finger ≥ 0.05 mm Palm ≥ 0.05 mm	Similar
Physical Properties	ASTM D6319-10 (2015)	Tensile Strength: Before aging ≥ 15 MPa After aging ≥ 14 MPa	Tensile Strength: Before aging ≥ 15 MPa After aging ≥ 14 MPa	Similar
		Ultimate Elongation: Before aging ≥ 500 % After aging ≥ 400 %	Ultimate Elongation: Before aging ≥ 500 % After aging ≥ 400 %	Similar
Freedom of Holes	ASTM D6319-10 (2015) ASTM D5151-19	Passes or exceeds ASTM D6319-10 (2015) and ASTM D5151-19 requirements of AQL 2.5 / Inspection level G1	Passes or exceeds ASTM D6319-10 (2015) and ASTM D5151-19 requirements of AQL 2.5 / Inspection level G1	Similar
Powder Content	ASTM D6319-10 (2015) ASTM D6124-06 (2011)	≤ 2 mg/glove	≤ 2 mg/glove	Similar
Biocompatibility	ISO 10993-10:2010	Primary Skin Irritation: Under conditions of the study not an irritant Dermal Sensitization: Under conditions of the study not a sensitizer	Primary Skin Irritation: Under conditions of the study not an irritant Dermal Sensitization: Under conditions of the study not a sensitizer	Similar

1.8 Summary of Non-Clinical Performance Data:

Test results below demonstrated that the proposed device complies with the following specification and guidance:

- ASTM D6319-10, Standard Specification for Nitrile Examination Gloves for Medical Application.
- Guidance for Industry and FDA Staff Medical Glove Guidance Manual (Document issued on January 22, 2008)

The following standards were followed to carry out the testing:

- 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.
- ISO 2859-1:1999, "Sampling Procedures for Inspection by Attributes – Part I: Sampling Plans Indexed by Acceptable Quality Level (AQL) for Lot-by-Lot Inspection.
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ASTM D412-16 Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers -Tension
- ASTM D7160-16 Standard Practice for Determination of Expiration Dating for Medical Gloves
- ASTM D573 - 04 Standard Test Method for Rubber—Deterioration in an Air Oven

Non-clinical Testing Summary

Test Method	Purpose	Acceptance Criteria	Result
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Length ≥ 230 mm for all sizes	Pass
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Size S – 85 ± 5 mm Size M – 95 ± 5 mm Size L – 105 ± 5 mm Size XL – 115 ± 5 mm	Pass
ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the thickness of the gloves	Finger ≥ 0.05 mm Palm ≥ 0.05 mm for all sizes	Pass
ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.	To determine the holes in the gloves	Accept: 5 out of 125 pieces sample size	Pass
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	Pass (0.70 mg/glove)

ASTM D6319-10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the physical properties – Tensile strength	Tensile Strength: Before aging ≥ 14 MPa After aging ≥ 14 MPa	Before aging, Average: 24.83 MPa Median: 24.90 MPa After aging, Average: 26.23 MPa Median: 25.95 MPa
	To determine the physical properties – Ultimate Elongation	Ultimate Elongation: Before aging ≥ 500 % After aging ≥ 400 %	Before aging, Average: 509.23 % Median: 500 % After aging, Average: 436.92 % Median: 440 %

1.9 Summary of Clinical Performance Data:

Clinical data is not necessary for Class I Patient Examination Glove 510(k) Submissions.

1.10 Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicated device, K172642, Orange Non Sterile Powder Free Nitrile Examination Gloves.