March 16, 2023

Ecoglove Medical Manufacturing Company Limited
% Manoj Zacharias
US Agent
Liberty Management Group Limited
75 Executive Drive Suite 114
Aurora, Illinois 60504

Re: K222813
Trade/Device Name: 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: February 13, 2023
Received: February 22, 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,

Allan Guan -S

For 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)*
K222813

Device Name

Nitrile Examination Gloves

Indications for Use *(Describe)*
Nitrile Examination Gloves 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.

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

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510(k) SUMMARY (K222813)

[AS REQUIRED BY 21CFR807.92]

I. SUBMITTER DETAILS

510(k) Owner's Name	**:**	**ECOGLOVE MEDICAL MANUFACTURING COMPANY LIMITED**
Address	:	A part of land plot No. 679, map No. 41, N4 Street, Bau Bang Hamlet, Lai Uyen Town, Bau Bang District, Binh Duong Province, Vietnam
Telephone	:	02743599000
Contact person	:	NGUYEN ANH TU
Designation	:	President
Contact Email	:	info@ecoglove.com
Correspondent Contact Details (US Agent Information)	:	Mr. Manoj Zacharias, Liberty Management Group Limited, 75 Executive Drive Suite 114, Aurora, Illinois, 60504, USA Phone: +1 (630) 270 2921 Fax: (815) 986-2632 Email: manoj@libertymanagement.us
Date of Summary Prepared	:	03-15-2023

II. DEVICE DETAILS

Device Name	**:**	**Nitrile Examination Gloves**
Device Classification Name	:	Non-powdered patient examination glove
Regulation Number	:	21 CFR 880.6250
Class	:	I
Product Code	:	LZA

III. PREDICATE DEVICE DETAILS

Predicate Device Name	:	ATM® Glove Powder free Nitrile Examination gloves
510(k) Number	:	K213016
Regulation Number	:	21 CFR 880.6250
Class	:	I
Product Code	:	LZA

IV. DEVICE DESCRIPTION

Nitrile Examination Gloves is a Class I device bearing the product code LZA (21CFR 880.6250). They meet all the current specifications listed under the ASTM Specification D6319 -19, Standard Specification for Nitrile Examination Gloves for Medical Application. They are made from acrylonitrile-butadiene copolymer dispersion. These gloves are blue in color have Finger Texture, Ambidextrous, single-use, and are powder-free. The product is non-sterile.

V. INDICATIONS FOR USE

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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K222813	K213016	-
2.	Manufacturer	ECOGLOVE Medical Manufacturing Company Limited	PHU DUC HUY Production Trading Services Corporation	-
3.	Classification	I	I	
4.	Regulation number	21 CFR 880.6250	21 CFR 880.6250	Same
5.	Product Code	LZA	LZA	Same
6.	Indication For Use	Nitrile Examination Gloves is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.	ATM® Glove Powder free Nitrile Examination gloves are intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
7.	Material	Nitrile	Nitrile	Same
8.	Color	Blue	Blue	Same
9.	Texture	Finger Texture	Finger texture	Same
10.	Ambidextrous	Yes	Yes	Same
11.	Size	S, M, L, XL	S, M, L, XL	Same
12.	OTC Use	Yes	Yes	Same
13.	Reusability	Single use	Single use	Same
14.	Sterility	Non- sterile	Non- sterile	Same
15.	Dimensions	Length Min 230 mm Width Min 95±10 mm (for medium size)	Length Min 230 mm Width Min 95±10 mm (for medium size)	Same

Sl. No	Features compared		Proposed Device	Predicate Device	Result
16.	Thickness		Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.05 mm Finger min 0.05 mm	Same
17.	Physical Properties		<u>Before Aging</u> Tensile Strength min 14 MPa Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength min 14 MPa Ultimate Elongation Min 400%	<u>Before Aging</u> Tensile Strength min 14 MPa Ultimate Elongation Min 500% <u>After Aging</u> Tensile Strength min 14 MPa Ultimate Elongation Min 400%	Same
18.	Detection of Holes		Passes AQL 2.5	Passes AQL 2.5	Same
19.	Powder Free Residue		≤2 mg/glove	≤2 mg/glove	Same
20.	Biocompatibility Study	In vitro Cytotoxicity	Under the conditions of the study, cytotoxic.	Under the conditions of the study non- cytotoxic to L-929 cells.	Different *Refer Note1*
		Skin Sensitization	Under the condition of the study not a sensitizer	Under the condition of the study not a sensitizer	Same
		Skin Irritation	Under the condition of the study not an irritant	Under the condition of the study not an irritant	Same
		Acute systemic toxicity	Under the conditions of study, the device extracts do not pose a systemic toxicity concern	Under the conditions of the study, the device extracts do not pose a systemic toxicity concern	Same

Note1: *Additional testing was performed to determine if this was a systemic toxicity concern.*

There are no significant differences between the two products and are similar in terms of intended use, materials, design, and manufacturing methods. Both devices met the performance standards.

VII. PERFORMANCE DATA

A. Non-Clinical Data

1 Performance Tests

Nitrile Examination Gloves are subjected to the following performance tests according to the requirements of Guidance for Industry and FDA Staff - Medical Glove Guidance Manual

- Dimension.
- Physical property
- Barrier property tests
  - Detection of Holes in Medical Gloves
- Powder-Free Residue

Table 2: Performance Testing Summary

Sl No.	Tests	Proposed Device actual Data			Acceptance Criteria		
1.	**Dimension** **Length, Width and Thickness** ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	**Size**	**Length**	**Width**	**Size**	**Length**	**Width**
		S	243 mm	84.92 mm	S	220mm min	80 mm±10
		M	242.30 mm	95.30 mm	M	230mm min	95 mm ±10
		L	243.30 mm	110.53 mm	L		110 mm ±10
		XL	243.07 mm	120.62 mm	XL		120 mm ±10
		Thickness			**Thickness**		
		Size	**Palm**	**Finger**	**Size**	**Palm**	**Finger**
		S	0.086 mm	0.115 mm	S	0.05 mm min	0.05 mm min
		M	0.086 mm	0.110 mm	M		
		L	0.085 mm	0.115 mm	L		
		XL	0.085 mm	0.115 mm	XL		
2.	**Physical property** **Tensile strength and Ultimate Elongation** ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	**Tensile strength**			**Tensile strength**		
		Size	**Before aging**	**After aging**	**Size**	**Before aging**	**After aging**
		S	17.44 MPa	16.52 MPa	S	14 MPa Min for all sizes	14 MPa Min for all sizes
		M	17.60 MPa	16.79 MPa	M		
		L	16.75 MPa	15.48 MPa	L		
		XL	16.03 MPa	15.07 MPa	XL		
		Ultimate elongation			**Ultimate elongation**		
		Size	**Before aging**	**After aging**	**Size**	**Before aging**	**After aging**
		S	519%	511%	S	500% Min for all sizes	400%Min for all sizes
		M	521%	511%	M		
		L	565%	510%	L		
		XL	550%	514%	XL		
3.	**Detection of Holes in Medical Gloves** ASTM D6319-19 /ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	**Size**	AQL 2.5		**Size**	AQL 2.5	
		S			S		
		M			M		
		L			L		
		XL			XL		
4.	**Powder-Free Residue** ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	**Size**	**Residual powder content**		**Size**	**Residual powder content**	
		S	0.02 Mg/glove		S	≤ 2 mg/Glove Max	
		M	0.01 Mg/glove		M		
		L	0.01 Mg/glove		L		
		XL	0.01 Mg/glove		XL		

2 Biocompatibility Tests

The Biocompatibility Tests performed are:

- In vitro Cytotoxicity
- Skin Sensitization
- Skin Irritation
- Acute Systemic Toxicity

Table 3: Biocompatibility Test Summary

SL no	Title of Test	Purpose of Test	Reference Source	Acceptance Criteria	Result
1	In Vitro Cytotoxicity	To ensure the device is biocompatible	ISO 10993-5:2009	Non-cytotoxic	Fail
2	Skin Sensitization		ISO 10993-10:2021	Non-sensitizer	Pass
3	Skin Irritation		ISO 10993-23:2021	Non-irritant	Pass
4	Acute Systemic Toxicity		ISO 10993-11:2017	Nontoxic	Pass

3 Sterilization

A sterilization study was not conducted as Nitrile Examination Gloves is provided non-sterile.

C Clinical Test Data

The clinical study was not conducted as clinical data is not needed for Nitrile Examination Gloves.

VII. CONCLUSION

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device in K213016.