May 26, 2022

EG Group Product and Services CO., Ltd
℅ Tim Kania
Official Correspondent
MDI Consultants Inc.
55 Northen Blvd, Suite 200
Great Neck, New York 11021

Re: K212629
Trade/Device Name: PP Care 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: April 25, 2022
Received: April 26, 2022

Dear Tim Kania:

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,

Clarence W. Murray, III, PhD
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)*

K212629

Device Name
PP CARE Nitrile Examination Gloves

Indications for Use *(Describe)*
The PP CARE Nitrile Examination Gloves is a disposable devices intended for medical purposes that are worn on the examiner's hands 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.

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510(K) SUMMARY
K212629

A. APPLICANT INFORMATION

510(K) Owner's Name	EG GROUP PRODUCT AND SERVICE CO., LTD
Address	27/58 MOO 8, Tumbon Buen, Sriracha District Sriracha, Chonburu , Thailand 20230
Phone	+6638-320-999
Fax	+6638-320-999
E-mail	ceo.info@egroup.co.th
Contact Person	Ms.Pakkaporn Phattanaliampaiboon
Title	President
Contact Number	+6638-320-999
Contact Email	ceo.info@egroup.co.th
Date 510(K) summary prepared	February 8th ,2021

B. DEVICE IDENTIFICATION

Name of the device	PP CARE Nitrile Examination Gloves
Product proprietary or trade name	PP CARE Nitrile Examination Gloves
Common or usual name	Nitrile Examination Gloves
Classification name	POLYMER PATIENT EXAMINATION GLOVE
Device Classification	Class-I
Product Code	LZA
Regulation Number	21 CFR 880.6250
Review Panel	General Hospital

C. PREDICATE DEVICE

Predicate Device	Hi-Care Thai Gloves Co., Ltd
510(k) Number	K202384
Regulatory Class	I
Product code	LZA

D. DESCRIPTION OF THE DEVICE:

PP CARE Nitrile Examination Gloves are Class I patient examination gloves bearing the product code LZA (21CFR880.6250). The gloves are made from acrylonitrile butadiene rubber. These gloves are blue in color and are powder free.

E. INTENDED USE OF THE DEVICE:

The PP CARE Nitrile Examination Gloves is a disposable devices intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.

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F. Summary of The Technological Characteristics of the device compared to the predicate Device

CHARACTERISTIC	STANDARDS	DEVICE PERFORMANCE		REMARKS
		PREDICATE	SUBJECT	
510(K) Number		**K202384**	**K212629**	
Name of Device		Blue Nitrile Examination Gloves Powder Free	PP CARE Nitrile Examination Gloves	----
Dimensions	ASTM D 6319-19	Length Min 230 mm Width Min 110+10/mm (For Large size)	Length Min 240 mm Width Min 105 mm (For Large size)	Passed
Physical Properties	ASTM D 6319-19	**Before Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 Mpa Ultimate Elongation Min 400%	**Before Aging** Tensile Strength min 17 Mpa Ultimate Elongation Min 520% **After Aging** Tensile Strength min 20 Mpa Ultimate Elongation Min 512%	Passed
Thickness	ASTM D 6319-19	Palm min 0.05 mm Finger min 0.05 mm	Palm min 0.10 mm Finger min 0.15 mm	Passed
Powder Residue	ASTM D 6319-19	_<2mg/glove	0.35 mg/glove	Passed
Biocompatibility	SKIN IRRITATION TEST OF NITRILE EXAMINATION GLOVE, NON STERILE IN NEW ZEALAND WHITE RABBITS [As per ISO 10993-10:2010(E)]	Under the condition of study not an irritant	Under the condition of study not an irritant	Same

	SKIN SENSITIZATION STUDY OF NITRILE EXAMINATION GLOVE, NON STERILE IN GUINEA PIGS BY MAXIMIZATION TEST [As per ISO 10993-10:2010(e)]	Under the condition of study not a sensitizer	Under the conditions of the study, not a sensitizer	Same
	IN VITRO CYTOTOXICITY STUDY OF NITRILE EXAMINATION GLOVE, NON STERILE BY ELUTION METHOD [As per ISO 10993-5:2009(E)]	Under the conditions of the study, non-cytotoxic	Under the conditions of the study, the sample was 100% cytotoxic	Different
	ACUTE SYSTEMIC TOXICITY STUDY OF NITRILE EXAMINATION GLOVE, NON STERILE IN SWISS ALBINO MICE [As per ISO 10993-11:2017]	Predicate device did not perform this test	Under the conditions of the study, the device was non-toxic	Different
Water Tight (2000)	The Testing of unreferenced nitrile gloves in accordance with EN 455-1:2000	Passes AQL-1.5	Passes AQL-1.5	Passed
Intended 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 PP Care Nitrile Examination Gloves is a disposable devices intended for medical purposes that are worn on the examiner's hands to prevent contamination between patient and examiner.	Same

Material	Meet the requirements of EN455-1:2000, EN455-2:2015, ISO 21171:2016, EN1186-1,2,3:2002	Nitrile (NBR)	Nitrile (NBR)	Same
Color	-	Blue	Blue	Same
Texture	-	Finger Texture	Finger Texture	Same
Size		Large	Large	Same
Single use		Single use	Single use	Same
Manufacturer(s)		Hi-Care Thai Gloves Co., Ltd. Thailand	EG Group Product and Service Co., Ltd. Thailand	

There are no significant differences between the two products and are identical in terms of intended use, materials, manufacturing methods. The subject device was cytotoxic under the conditions of the study, these conditions are not similar to the intended use conditions and as such a systemic toxicity test was performed. The systemic toxicity test demonstrates that the subject device is not toxic under the conditions of the study. Both devices meet the ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application.

G. Non-Clinical Testing Summary

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	Min 230 mm for size L	Large : 240 mm		
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	Large : 110 +/-10 mm	Large : 105 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 Finger 0.05 mm min For all sizes	**Size** Large	**Palm** 0.10 mm	**Finger** 0.15 mm
The Testing of unreferenced nitrile gloves in accordance	To determine the holes in the gloves	Number of samples tested : 200	Passed		

with EN 455-1 : 2000		Number of Leaks allowed : 7			
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the residual powder in the gloves	2 Mg/Glove Max	Size Large	Residual Powder Content 0.35 mg/glove	
ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties-Tensile strength	**Before Aging** Tensile Strength 14 MPa Minimal for Large size **After Aging** Tensile Strength 14 MPa for Large size	**Size** Large	**Before ageing** 17MPa	**After ageing** 20MPa
	To Determine the physical properties-Ultimate Elongation	**Before Aging** Ultimate Elongation 500% Min for Large size **After Aging** Ultimate Elongation 400% Min for Large size	**Size** Large	**Before ageing** 520%	**After ageing** 512%

H. Clinical Testing Summary

Not applicable- Clinical data is not needed for glove or for most devices by the 510(k) process.

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, The PP Care Nitrile Examination Gloves, are as safe, as effective, and performs as well as or better than the legally marketed predicate device, Blue Nitrile Examination Gloves Powder Free cleared under K202384.