April 3, 2022

Protect Gloves Co., Ltd.
% Paweena U-Thainual
CEO
MDR Solutions Co., Ltd.
1435 Kanchanapisek Rd., Bang Khae Nuea
Bangkok, Bang Khae 10160
Thailand

Re: K213604
Trade/Device Name: ELAZ Nitrile Powder Free 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 21, 2022
Received: March 24, 2022

Dear Paweena U-Thainual:

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)*
K213604

Device Name
ELAZ Nitrile Powder Free Examination Glove

Indications for Use *(Describe)*
ELAZ Nitrile Powder Free Examination Glove is 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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"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."

K213604

510(k) Summary

1. General Information

Applicant/Submitter:	Protect Gloves Company Limited
Address:	60/138 Moo 3 Mabyangporn Pluakdang Rayong, 21140 THAILAND Tel: +66-2-384-3049 Email: nathaphon@me.com
Contact Person:	Paweena U-Thainual, PhD
Address:	MDR Solutions, Co., Ltd. 1435 Kanchanapisek Rd., Bang Khae Nuea Bang Khae, Bangkok 10160 THAILAND Email: paweena@mdrsolutions.co.th
Preparation Date:	November 8, 2021

2. Device Name and Code

Device Trade Name:	ELAZ Nitrile Powder Free Examination Glove
Common Name:	Nitrile Patient Examination Glove
Classification Name:	Non-Powdered Patient Examination Glove
Product Code:	LZA
Regulation Number:	21 CFR 882.6250
Classification:	I
Review Panel:	General Hospital

3. Predicate Device

Provided below is the legally marketed predicate device.

Table 1 Primary Predicate device

Applicant	Device Name	510(k) Number
Tangshan Lanhai Medical Supplies Co., Ltd.	Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue)	K210898

4. Device Description

ELAZ Nitrile Powder Free Examination Glove is non-sterile, single use only, disposable, powder free examination glove. The glove is made of Acrylonitrile-butadiene rubber. The glove is designed to meets the specification of ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

5. Indications / Intended Use

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

6. Technological Characteristics Comparison:

ELAZ Nitrile Powder Free Examination Glove is compared to the legally marketed predicate device.

	Proposed Subject Device	**Predicate Device**	**Comparison**
Manufacturer	Protect Gloves Co., Ltd.	Tangshan Lanhai Medical Supplies Co., Ltd.	N/A
Trade Name	ELAZ Nitrile Powder Free Examination Glove	Disposable Nitrile Examination Gloves (Powder free, Purple-Blue, Blue)	N/A
510(k) Number	K213604	K210898	N/A
Classification	Class I	Class I	YES
Product Code	LZA	LZA	YES
Regulation Number	880.6250	880.6250	YES
Intended Use/ Indications For use	ELAZ Nitrile Powder Free Examination Glove is disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	The DISPOSABLE NITRILE EXAMINATION GLOVES (Powder free, Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	YES
Powdered Free	Yes	Yes	YES

Device Dimensions Comparison										
Size	S, M, L, XL				XS, S, M, L, XL					YES*
Color	Blue				Purple-Blue, Blue					YES
Sterility	Non-Sterile				Non-Sterile					YES
Length (mm)	**S**	**M**	**L**	**XL**	**XS**	**S**	**M**	**L**	**XL**	YES
	≥ 220	≥ 230	≥ 230	≥ 230	≥ 220	≥ 220	≥ 230	≥ 230	≥ 230	
Width (mm)	**S**	**M**	**L**	**XL**	**XS**	**S**	**M**	**L**	**XL**	YES
	80±10	95±10	110±10	120±10	70±10	80±10	95±10	110±10	120±10	
Finger Thickness (mm)	≥ 0.05				≥ 0.05					YES
Palm Thickness (mm)	≥ 0.05				≥ 0.05					YES
Performance and Physical Comparison										
Tensile Strength (MPa)	**Before Aging**		**After Aging**		**Before Aging**		**After Aging**			YES
	≥ 14		≥ 14		≥ 14		≥ 14			
Ultimate Elongation (%)	**Before Aging**		**After Aging**		**Before Aging**		**After Aging**			YES
	≥ 500		≥ 400		≥ 500		≥ 400			
Single Use	Yes				Yes					YES
Freedom from hole	Be free from holes when tested in accordance with ASTM D5151 AQL 2.5				Be free from holes when tested in accordance with ASTM D5151 AQL 2.5					YES
Powder Content	Powder residue ≤ 2.0 mg				Powder residue ≤ 2.0 mg					YES
Comply with ASTM D6319	Yes				Yes					YES
Material Used	Nitrile				Nitrile					YES
Shelf life	3 years				N/A					N/A
Safety Comparison – Biocompatibility Test										
Irritation	Under the conditions of the study, not an irritant				Under the conditions of the study, not an irritant					YES
Sensitization	Under conditions of the study, not a sensitizer				Under conditions of the study, not a sensitizer					YES
Cytotoxicity	Under conditions of the study, it was considered as "non-cytotoxic" at 25%, 12.5%, and 6.25% and demonstrate cytotoxicity at the 50% and 100% of the test item extract.				N/A					N/A
Acute Systemic Toxicity	Under the conditions of the study, there was no evidence of systemic toxicity from the extract				Under the conditions of the study, there was no evidence of systemic toxicity from the extract					YES

*When compared to the same size, the dimensions, and physical design are identical.

7. Performance Data

Non-clinical tests:

Bench tests were conducted according to the FDA-recognized consensus standard, to verify that the proposed device met all design specifications. The proposed device complies with 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 D6124-17, Standard Test Method for Residual Powder on Medical Gloves.

Biocompatibility tests were conducted according to the FDA-recognized consensus standard, to verify the safety of the device.

- ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for In vitro cytotoxicity.
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM D6319-19	Physical Dimensions Test (mm)	Length (mm) S ≥ 220 M ≥ 230 L ≥ 230 XL ≥ 230	Length (mm) S ≥ 220 M ≥ 230 L ≥ 230 XL ≥ 230
		Width (mm) S: 80±10 M: 95±10 L: 110±10 XL: 120±10	Width (mm) S: 87-89 M: 99-101 L: 110-113 XL: 112-115
		Finger Thickness (mm) ≥0.05	Finger Thickness (mm) S ≥ 0.16 M ≥ 0.15 L ≥ 0.15 XL ≥ 0.13
		Palm Thickness (mm) ≥0.05	Palm Thickness (mm) S ≥ 0.11

			M ≥ 0.11 L ≥ 0.11 XL ≥ 0.10
ASTM D5151-19	Testing for Freedom from holes	AQL 2.5	Gloves pass AQL 2.5
ASTM D6124-17	Determine the powder residue for powder free gloves	< 2 mg/glove	Average 0.43 mg/glove
ASTM D412 ASTM D573	Testing for Physical property characteristics	Before Aging Tensile strength ≥14 MPa Ultimate Elongation ≥500% After Aging Tensile strength ≥14 MPa Ultimate Elongation ≥400%	Before Aging Tensile strength ≥21 MPa Ultimate Elongation ≥502% After Aging Tensile strength ≥18 MPa Ultimate Elongation ≥465%
ISO 10993-5	Tests for In vitro cytotoxicity	Under the conditions of the study non-cytotoxic.	Under conditions of the study, it was considered "non-cytotoxic" at 25%, 12.5%, and 6.25% and demonstrate cytotoxicity at the 50% and 100% of the test item extract.
ISO 10993-10	Evaluate the endpoint of irritant for biocompatibility	Under the conditions of the study, not an irritant.	Under the conditions of the study, not an irritant.
	Evaluate the endpoint of sensitization for biocompatibility	Under the conditions of the study, not a sensitizer.	Under the conditions of the study, not a sensitizer.
ISO 10993-11	Tests for systemic toxicity	Under the conditions of the 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.

8. Conclusions

The conclusions drawn from the non-clinical tests demonstrate that the subject device, ELAZ Nitrile Powder Free Examination Glove, is as safe, as effective, and performs as well as or better than the legally marketed device.