August 6, 2022

Medical Glove Co., Ltd
Teoh Choh Shee
Managing Director
288, Moo 7, Tambon
Lam Thap, Krabi 81190
Thailand

Re: K213934
Trade/Device Name: Pro Guard 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: June 17, 2022
Received: June 30, 2022

Dear Teoh Choh Shee:

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, 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)*
K213934

Device Name
Pro Guard® Nitrile Powder Free Examination Glove

Indications for Use *(Describe)*
Pro Guard ® Nitrile Powder free Examination Glove is a disposable device intended for medical purposes 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.

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."

MEDICAL GLOVE CO., LTD
288 Moo 7 T. Lam Thap, A. Lam Thap, Krabi 81190 Thailand.
Cell Phone: +66 98016 6138 . Email :inquiry@medicalglove.net

510(k) SUMMARY
(K213934)
Nitrile Powder Free Examination Gloves

1.0 Submitter:

Applicant:	Medical Glove Co., Ltd. 288, Moo 7, Tambon Lam Thap, Amphur Lam Thap, Krabi 81190, Thailand
Phone Number:	+66 98 0166138
Fax Number:	+66 75 626500
Name of Contact Person:	Teoh Choh Shee (Mr.)
Preparation date:	July 19, 2022

2.0 Identification of the subjected device:

Trade/Proprietary Name(s):	Pro Guard® Nitrile Powder Free Examination Glove.
Common Name:	Nitrile Powder Free Examination Gloves
Classification Name:	Patient Examination Gloves
Device Classification:	I
Product code	LZA
Regulation Number:	21 CFR 880.6250

3.0 Predicate Device:

Device Name:	Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile.
510(k):	K143131
Common Name:	Patient Examination Gloves
Classification Name:	Patient Examination Gloves
Device Classification:	I
Product Code:	LZA
Regulation Number:	21 CFR 880.6250

4.0 Description of the Device:

Black Nitrile Examination Gloves Powder Free are Class I patient examination gloves bearing the product code Nitrile - LZA (21 CFR 880.6250). The gloves are made from acrylonitrile-butadiene copolymer dispersion. These gloves are black in color and are powder free.

5.0 Indication for Use:

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

6.0 Summary of Technological Characteristics of the Device Compared to the Predicate Device:

Characteristics	Standards	Device performance		Comparison
		Predicate	Current (K213934)	
510(k) Number	-	K143131	New 510(k) submission	Not Available
Manufacturer(s)	-	Kossan International Sdn. Bhd	Medical Glove Co., Ltd	----
Indication for Use	Medical Gloves Guidance Manual - Issued on January 22, 2008	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Pro Guard® Nitrile Powder free Examination Glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Similar
Design Material	ASTM D6319-19	Nitrile	Nitrile	Same
Color	-	Black	Black	Same
Design	-	Ambidextrous, in different sizes per ASTM D6319 dimension requirement	Ambidextrous, in different sizes per ASTM D6319 dimension requirement	Same
Device Classification	-	Class I	Class I	Same
Shelf life		No data is available	3 years	Different
Size	ASTM D6319-19	Extra Small Small Medium Large Extra Large XX-Large	Extra Small Small Medium Large Extra Large	Different
Single Use	Medical Gloves Guidance Manual - Issued on January 22, 2008	Single use	Single use	Same
Sterility	-	Non-sterile	Non-sterile	Same

Characteristics	Standards	Device performance		Comparison
		Predicate	Current (K213934)	
Dimension	ASTM D6319-19	**Length** ≥230 mm minimum **Width** X-Small 70-80 mm Small 80-90 mm Medium 90-100 mm Large 101-111 mm X-Large 111-121 mm XX-Large 121-131 mm	**Length** 230 mm min **Width** Extra Small: 70 ± 10 mm Small: 80 ± 10 mm Medium: 95 ± 10 mm Large: 110± 10 mm Extra Large: 120 ± 10 mm	Similar
Thickness	ASTM D6319-19	Finger: 0.05 mm min Palm: 0.05 mm min	Finger: 0.05 mm min Palm: 0.05 mm min	Same
Physical Properties	ASTM D6319-19	**Before aging** Tensile Strength: 14 MPa min Ultimate Elongation: 500% min **After aging** Tensile Strength 14 MPa min Ultimate Elongation: 400% min	**Before aging** Tensile Strength: 14 MPa min Ultimate Elongation: 500% min **After aging** Tensile Strength 14 MPa min Ultimate Elongation: 400% min	Same
Watertight test (1000 ml)	ASTM D5151-19	Pass AQL 1.5	Pass AQL 1.5	Same
Powder Residue	ASTM D6124-06 (Reapproved 2017)	≤ 2.0 mg/glove	≤ 2.0 mg/glove	Similar

Characteristics	Standards	Device performance		Comparison
		Predicate	Current (K213934)	
Biocompatibility	Primary Skin Irritation – ISO 10993-10 Third Edition 2010-08-01	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Dermal Sensitization – ISO 10993-10 Third Edition 2010-08-01	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
	In vitro cytotoxicity ISO10993-5 :2009(E)	No data is available	Under the conditions of the study, cytotoxic for undiluted, 1:2, 1:4 and 1:8 dilutions, but non-cytotoxic for 1:16 and 1:32 dilutions. Moreover, under the conditions of the study, non acute systemic toxic.	Different
	Acute Systemic Toxicity ISO10993-11:2017(E)	No data is available	Under the conditions of the study, did not induce any systemic toxicity.	Different

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

7.0 Non-clinical testing summary

Performance Data

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Dimension	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the length of the gloves	Min 230 mm for all sizes	Extra Small: min 240 mm Small: min 243 mm Medium: min 241 mm Large: min 240 mm Extra Large: min 240 mm	Pass
	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To determine the width of the gloves	*Extra Small: 70 ± 10 mm* *Small: 80 ± 10 mm* Medium: 95 ± 10 mm Large: 110± 10 mm Extra Large: 120 ± 10 mm	Extra Small: 75 mm Small: 85 mm Medium: 95 mm Large: 105 mm Extra Large: 115 mm	Pass
	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	Extra Small: Palm 0.09 mm, Finger: 0.12 mm Small: Palm 0.09 mm, Finger: 0.13 mm Medium: Palm: 0.09 mm, Finger: 0.12 mm Large: Palm 0.09 mm, Finger: 0.12 mm Extra Large: Palm 0.09 mm, Finger: 0.12 mm	Pass
Watertight test	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves	To determine the holes in the gloves	Sample size: 200 pcs Inspection level : GI AQL 1.5 Acceptance Number 7 Rejection Number 8	The batch size for this sampling is 35,001-150,000. Hence, according to the single sampling plan GI, the sample to be drawn is under code L equivalent to 200 pcs with accept 7 and reject 8 to be accept under AQL 1.5. Extra Small: 0 (Zero) Small: 0 (Zero) Medium: 0 (Zero) Large:0 (Zero) Extra Large:0 (Zero)..	Pass

MEDICAL GLOVE CO., LTD
288 Moo 7 T. Lam Thap, A. Lam Thap, Krabi 81190 Thailand.
Cell Phone: +66 98016 6138 . Email :inquiry@medicalglove.net

Test Method	Standard	Purpose of testing	Acceptance Criteria	Result	Status
Residual powder	ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves	To determine the residual powder in the gloves	2 mg per glove or less	Sample size : 5 pcs Requirement: 2 mg per glove or less Result : Extra Small: 1.35 mg/glove Small:1.42 mg/glove Medium: 1.24 mg/glove Large: 1.34 mg/glove Extra Large:1.36 mg/glove	Pass
Physical Properties	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application	To Determine the physical properties- Tensile strength	**Before Ageing** Tensile Strength 14Mpa Minimal for all sizes **After Ageing** Tensile Strength 14Mpa Minimal for all sizes	**Before Ageing** Extra Small: 18.08 MPa Small: 18.37 MPa Medium: 24.56 MPa Large: 18.30 MPa Extra Large: 18.20 MPa **After ageing**: Extra Small: 14.01 MPa Small: 14.08 MPa Medium: 20.41 MPa Large: 14.00 MPa Extra Large: 14.00 MPa	Pass
		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	**Before Ageing** Extra Small: 611 % Small: 612% Medium: 645 % Large:620% Extra Large:587% **After ageing**: Extra Small: 412 % Small:408% Medium: 584% Large:403% Extra Large:416%	Pass

8.0 Clinical Testing Summary

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

9.0 Conclusion:

The conclusions drawn from the non-clinical test demonstrate that the subject device Nitrile Powder Free Examination Glove is as safe, as effective, and performs as well as or better than the legally marketed predicate device K143131

---END---