October 29, 2026

Vietglove Corporation
Harry Vuong
Vice Director of Sales
Land Lot # 3, Map No 37, Cau Sat Hamlet, Ben Cat Ward
Ho Chi Minh, 75950
Vietnam

Re: K253508
Trade/Device Name: Powder Free Nitrite Examination Glove, Cobalt Blue, Violet Blue, and White, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 30, 2025
Received: November 3, 2025

Dear Harry Vuong:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253508

Please provide the device trade name(s).

POWDER FREE NITRILE EXAMINATION GLOVE, COBALT BLUE, VIOLET BLUE, AND WHITE, NON-STERILE

Please provide your Indications for Use below.

A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand or fingers to prevent contamination between patient and examiner.

Please select the types of uses.	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510 (K) SUMMARY (K253508)
(As required by 21 CFR 807.92)

1.0 Submitter **Viet Glove Corporation**

Land Lot No. 03, Map No. 37, Cau Sat Hamlet, Ben Cat Ward Ho Chi Minh, VN 75950
Tel/Fax +84-274 3535 677
Name of Contact Person: Harry Vuong
Email Address: Harryvuong@vietglove.vn
Date of Summary Prepared: October 28, 2026

2.0 Name of Device:

510(k) number	: K253508
Trade Name:	: Powder Free Nitrile Examination Glove, Cobalt Blue, Violet Blue, and White, Non-Sterile
Common Name	: Powder Free Nitrile Examination Glove
Classification Name:	: Non-powdered Patient Examination Glove
Device Classification:	: Class 1
Regulation Number:	: 21 CFR 880.6250
Product Code:	: LZA

3.0 Identification of The Legally Marketed Device

Predicate Device Name:
Powder Free Nitrile Patient Examination Glove, Blue colored, and White (non-Colored), Non-sterile
Predicate 510(K) Number: K123469
Manufacturer's Name: Wear Safe (Malaysia) Sdn Bhd

4.0 Description of the Subject Device

Powder Free Nitrile Examination Glove, Cobalt Blue, Violet Blue and White, Non-Sterile, meets all of requirements of ASTM D6319-19.

5.0 Intended Use/Indication for Use

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of Non-Clinical Testing

Powder Free Nitrile Examination Glove, Cobalt Blue, Violet Blue, and White, Non-Sterile, have the following technological characteristics (as compared to ASTM or equivalent standards) as shown in Table below. The performance test data from non-clinical test met the specifications from ASTM testing methodology.

Characteristic	**Standards Requirements**	**Results Summary (K253508)**			**Conclusions**
		Cobalt Blue	Violet Blue	White	
Dimensions	ASTM D6319-19	Length ≥ 230mm Palm Thickness ≥ 0.05mm Finger Thickness ≥ 0.05mm Width : Small : 80-90mm Medium : 90-100mm Large : 101-111mm X-Large : 111-121mm			Meets Standard Requirements
Physical Properties	ASTM D6319-19		Before Aging	After Aging	Meets Standard Requirements
		Tensile Strength	≥ 14 MPA	≥ 14 MPA	
		Elongation	≥ 500%	≥ 400%	
Freedom from pinholes	ASTM D6319-19	Pass quality level at G1 AQL 2.5			Meets Standard Requirements
Powder Free Residue	ASTM D6319-19	Result generated values ≤ 2 mg of residual powder per glove.			Meets Standard Requirements
Primary Skin Irritation	ISO 10993-23	Under the conditions of the study, the device is not an irritant			Not a primary Irritant
Skin Sensitization	ISO 10993-10	Under the conditions of the study, the device is not a sensitizer			Not a sensitizer
Cytotoxicity test/ Acute Systemic Toxicity Test	Cytotoxicity: ISO 10993-5 Acute systemic toxicity: ISO 10993-11	Under the conditions of the study, device failed cytotoxicity test. Acute systemic toxicity was conducted on the device. The device does not induce acute systemic toxicity.			Does not induce acute systemic toxicity

8.0 Comparison of Technological Characteristics with the predicate device.

Characteristics Parameters	Subject Device			Predicate Device		Characteristic Comments
	Powder Free Nitrile Examination Glove, Cobalt Blue, Violet Blue and White, Non-Sterile (New K253508)			**Powder Free Nitrile Patient Examination Glove, Blue colored, and White (non-Colored), Non-sterile. (K123469)**		
Color	Cobalt Blue	Violet Blue	White	Blue	White	Different
Manufacturer	Viet Glove Corporation			Wear Safe (Malaysia) Sdn Bhd		Different
Product Code	LZA			LZA		Same
Indication for Use/ Intended Use	*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*			*A patient examination glove is a disposable device intended for medical purposes that is worn on the hand or finger to prevent contamination between patient and examiner.*		Same
Classification	Class 1			Class 1		Same
(Raw Rubber Material	Nitrile (Acrylonitrile-butadiene)			Nitrile (Acrylonitrile-butadiene)		Same
Design	1. Ambidextrous 2. Finger Textured 3. Powder Free 4. Single Use			1. Ambidextrous 2. Finger Textured 3. Powder Free 4. Single Use		Similar
Sterility	Non-Sterile			Non-Sterile		Same
Length	Meet ASTM D6319-19 Minimum 230mm			Meet ASTM D6319-10 Minimum 230mm		Same
Dimension	Meets ASTM D6319-19 S : 80 +/- 10mm M : 95 +/- 10 mm L : 110 +/- 10 mm XL : 120 +/- 10mm			Meets ASTM D6319-10 S : 80 +/- 10mm M : 95 +/- 10 mm L : 110 +/- 10 mm XL : 120 +/- 10mm		Same
Thickness	Meets ASTM D6319-19 Palm Thickness: min 0.05 mm Finger Thickness: min 0.05 mm			Meets ASTM D6319-10 Palm Thickness: min 0.05 mm Finger Thickness: min 0.05 mm		Same
Freedom of pinholes	Meets ASTM D5151 and ASTM D6319 AQL 2.5			Meets ASTM D5151 and ASTM D6319		Same
Physical Properties	Meets ASTM D6319-19 Tensile Strength Before Aging ≥ 14 MPa Tensile Strength After Aging ≥ 14 MPa Elongation Before Aging ≥ 500% Elongation After Aging ≥ 400%			Meets ASTM D6319-10 Tensile Strength Before Aging ≥ 14 MPa Tensile Strength After Aging ≥ 14 MPa Elongation Before Aging ≥ 500% Elongation After Aging ≥ 400%		Same

Powder Residue	Meet ASTM D6319-19 & ASTM D6124-06 Residual Powder ≤ 2 mg per glove	Meet ASTM D6319-10 & ASTM D6124-06 Residual Powder ≤ 2 mg per glove	Same
Primary Skin Irritation	As per ISO 10993-23 : Under the conditions of the study, the device is not an irritant.	As per ISO 10993-10 : Under the conditions of the study, the device is not an irritant.	Same
Skin Sensitization	As per ISO 10993-10 : Under the conditions of the study, the device is not a sensitizer.	As per ISO 10993-10 : Under the conditions of the study, the device is not a sensitizer.	Same
Acute Systemic Toxicity	As per ISO 10993-11 : Under the conditions of the study, the device does not induce systemic toxicity	Not Applicable	Different

9.0 Clinical Testing

Not Applicable under this application

10.0 Conclusion

The conclusions drawn from the non-clinical testing demonstrated that the subject devices, Powder Free Nitrile Examination Glove, Cobalt Blue, Violet Blue and White, Non-sterile are as safe, as effective, and perform as well as or better than the legally marketed predicate device, K123469.