



June 18, 2026

Kanglongda Vietnam Protection Technology Company Limited
Thamira Ranasinghe
Vice President - Technical and Sales
Lot Cn 05, Viglacera - Phong Dien Industrial Park
Phong Dinh Ward
Hue City, 530000
Vietnam

Re: K253824

Trade/Device Name: Powder Free Nitrile Examination Gloves Non-Sterile Black
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 19, 2026
Received: May 19, 2026

Dear Thamira Ranasinghe:

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.

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.

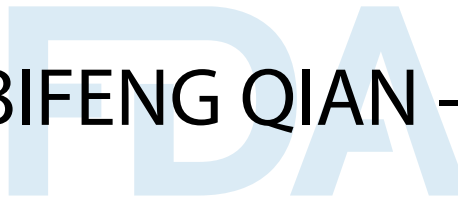
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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 Infection
Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K253824

Device Name

Powder Free Nitrile Examination Gloves Non-Sterile Black

Indications for Use (Describe)

Powder Free Nitrile Examination Gloves Non-Sterile Black is a disposable device intended for medical purposes that is worn on a examiner's hand to prevent the 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 (K253824)

0.0 Summary Preparation Date: 2026-06-18

1.0 Applicant Information

- Name: Kanglongda Vietnam Protection Technology Company Limited
- Address: Lot CN 05, Viglacera - Phong Dien Industrial Park, Phong Dinh Ward, Hue City, Vietnam
- Establishment Registration Number: 3024897455

2.0 CORRESPONDENT

- Contact Name: Thamira Ranasinghe
- Contact Title: Vice President -Technical
- Phone Number: +84788611640
- Email: thamira@kanglongda.com.cn

3.0 Name of the Device

- Proprietary/Trade name: Powder Free Nitrile Examination Gloves Non-Sterile Black
- Common Name: Nitrile Examination Gloves
- Classification Name: Non-powdered Patient Examination Glove
- Device Classification: Class I
- Regulation Number: 21 CFR 880.6250
- Product Code: LZA
- 510(K) Number: K253824

4.0 Predicate

- Device Name: Disposable Medical Examination Nitrile Gloves
- Company name: Raxwell Industries LLC
- Device Classification: Class I
- Regulation Number: 21 CFR 880.6250
- Product Code: LZA
- 510(K) Number: K232008

5.0 Device Description:

"Powder Free Nitrile Examination Gloves Non-Sterile Black" is a patient examination glove made from nitrile compound, nonsterile (as per 21 CFR 880.6250, Class I). The principal operation of this medical device is to provide single use barrier protection for the wearer and the device meets the specifications for barrier protection and physical

properties as defined in ASTM D6319-19, Standard specification for Nitrile Examination Gloves.

6.0 Device Indications for Use:

“Powder Free Nitrile Examination Gloves Non-Sterile Black” is a nonsterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

7.0 Comparison of Device Technological Characteristics:

Device Characteristic	Predicate Device	Subject Device	Comparison
Product Name	Disposable Medical Examination Nitrile Gloves	Powder Free Nitrile Examination Gloves Non-Sterile Black	similar
510(K) No.	K232008	K253824	n/a
Applicant	Raxwell Industries LLC	Kanglongda Vietnam Protection Technology Company Limited	Different
Product Code	LZA	LZA	Same
Regulation	21 CFR 880.6250	21 CFR 880.6250	Same
Class	1	1	Same

Indications for Use	The Disposable Medical Examination Nitrile Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	"Powder Free Nitrile Examination Gloves Non-Sterile Black" is a nonsterile disposable device intended for medical purpose that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powder free	Yes	Yes	Same
Material	Nitrile	Nitrile	Same
Colorant	Black	Black	Same
Size	XS/S/M/L/XL/XXL	XS/S/M/L/XL/XXL	Same
Single Use	Yes	Yes	Same
Non-Sterile	Yes	Yes	Same
Dimensions - Length	Complies with ASTM D6319-19 XS/S: ≥ 220 ; M/L/XL/XXL: ≥ 230 ;	Complies with ASTM D6319-19 XS/S: ≥ 220 ; M/L/XL/XXL: ≥ 230 ;	Same

Dimensions - Palm Width	Complies with ASTM D6319-19 XS: 70 ± 10 mm; S: 80 ± 10 mm; M: 95 ± 10 mm; L: 110 ± 10 mm; XL: 120 ± 10 mm; XXL: 130 ± 10 mm;	Complies with ASTM D6319-19 XS: 70 ± 10 mm; S: 80 ± 10 mm; M: 95 ± 10 mm; L: 110 ± 10 mm; XL: 120 ± 10 mm; XXL: 130 ± 10 mm;	Same
Dimensions - Thickness	Complies with ASTM D6319-19 Palm ≥ 0.05 mm; Finger ≥ 0.05 mm	Complies with ASTM D6319-19 Palm ≥ 0.05 mm; Finger ≥ 0.05 mm	Same
Physical Properties - Tensile Strength	Complies with ASTM D6319-19 Before aging ≥ 14MPa After aging ≥ 14MPa	Complies with ASTM D6319-19 Before aging ≥ 14MPa After aging ≥ 14MPa	Same
Physical Properties - Elongation	Complies with ASTM D6319-19 Elongation: Before Aging: ≥ 500% After Aging: ≥ 400%	Complies with ASTM D6319-19 Elongation: Before Aging: ≥ 500% After Aging: ≥ 400%	Same
Residual powder	Complies with ASTM D6319-19 < 2.0mg per glove	Complies with ASTM D6319-19 < 2.0mg per glove	Same
Freedom from Holes	In accordance with ASTM D6319-19 (G-1 with AQL 2.5)	In accordance with ASTM D6319-19 (G-1 with AQL 2.5)	Same

Biocompatibility	ISO 10993-10, under the conditions of the study, the device is not a sensitizer	ISO 10993-10, under the conditions of the study, the device is not a sensitizer	Same
	ISO 10993-10, under the conditions of the study, the device is not an irritant	ISO 10993-23, under the conditions of the study, the device is not an irritant	Similar*
	ISO 10993-5, under conditions of the study, device extract is cytotoxic	Not test, addressed by alternative testing	Different – Evaluation results demonstrate conformity with the requirements for acute systemic toxicity.
	ISO 10993-11, under the conditions of the study, the device showed no evidence of acute systemic toxicity	ISO 10993-11, under the conditions of the study, the device showed no evidence of acute systemic toxicity	Same

*Note 1: The skin irritation test was conducted in accordance with the latest applicable standard, ISO 10993-23, which supersedes and refines the methodology previously found in ISO 10993-10. The test is equivalent in its objective and acceptance criteria, and the passing result confirms the device meets the required safety profile for skin irritation.

8.0 Assessment of Non-Clinical Performance Data:

Non-clinical testing was performed to verify that the subject devices meet the acceptance criteria of the performance test and all design specifications. The test results demonstrated that the subject device complies with the following standards as shown

Test	Purpose	Criteria	Result
Standard Test Method for Detection of Holes in Medical Gloves ASTM D5151-19 (2023)	To demonstrate glove integrity.	Freedom from holes. AQL 2.5.	Pass
Standard Test Method for Residual Powder on Medical Gloves ASTM D6124-06 (2022)	To demonstrate the gloves are 'powder free'.	Average less than 2 mg per glove.	Pass
Dimensional Conformance ASTM D6319-19(2023)	To demonstrate appropriate dimensions for labeled sizes.	Conforms to ASTM D6319 width, thickness, and length requirements for sizes XS, S, M, L, XL and XXL AQL 4	Pass
Tensile Performance ASTM D6319-19(2023)	To demonstrate adequate tensile and elongation properties.	Conforms to ASTM D6319 requirements: - Tensile Strength (Before & After Aging): ≥ 14 MPa - Ultimate Elongation (Before Aging): $\geq 500\%$ - Ultimate Elongation (After Aging): $\geq 400\%$ AQL 4	Pass

Biocompatibility: Skin Irritation ISO 10993-23	To demonstrate low potential for skin irritation.	Under the conditions of the study, the device is not an irritant.	Pass
Biocompatibility: Skin Sensitization ISO 10993-10	To demonstrate low potential for skin sensitization.	Under the conditions of the study, the device is not a sensitizer.	Pass
Biocompatibility: Acute Systemic Toxicity ISO 10993-11	To demonstrate low acute systemic toxicity.	Under conditions of the study, the device showed no evidence of acute systemic toxicity	Pass

9.0 Assessment of Clinical Performance Data:

Clinical data is not needed for this type of device.

10.0 Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device “Powder Free Nitrile Examination Gloves Non-Sterile Black” is as safe, as effective, and performs as well as or better than the legally marketed device, K232008.