June 3, 2026

Vista Industries,, LLC
℅ Andrew Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai, Shanghai 200122
China

Re: K260806
Trade/Device Name: Nitrile Disposable Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: March 12, 2026
Received: March 12, 2026

Dear Andrew Wang:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K260806

Device Name
Nitrile Disposable Examination Gloves

Indications for Use *(Describe)*
Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger 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

# K260806

*Document Prepared Date: 2026-05-18*

## 1. Applicant Information

Vista Industries, LLC.
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Contact: James Yu
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14th Floor, Dongfang Building, 1500# Central Ave., Shanghai 200122, China
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## 2. Subject Device

Device Name: Nitrile Disposable Examination Gloves
Models: D2000, D3000, D6600, D9000
Sizes: S, M, L, XL
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination
Glove Regulatory Class: Class I
Product Code: LZA

## 3. Predicate Device

510(k) Number: K240361
Product Name: Powder Free Green Nitrile Examination Gloves (XS/S/M/L/XL); Powder Free Pink Nitrile Examination Gloves (XS/S/M/L/XL); Powder Free Purple Nitrile Examination Gloves (XS/S/M/L/XL)
Applicant/Sponsor: Hebei Titans Hongsen Medical Technology Co., Ltd.

## 4. Device Description

Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The gloves are pink, yellow, grey or green color, powder free, nitrile ambidextrous gloves. The gloves are offered in S, M, L or XL size, packed in a paper box.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard.

## 5. Indication for Use

Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

## 6. Substantial Equivalent (SE) Comparison

| Device | | Proposed Device | Predicate Device | Result |
|---|---|---|---|---|
| **510K #** | | K260803 | K240361 | |
| **Product Name** | | Nitrile Disposable Examination Gloves | Powder Free Green/Pink/Purple Nitrile Examination Gloves | |
| **Product Code** | | LZA | LZA | Same |
| **Regulation Number** | | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| **Indications for use** | | Nitrile disposable examination gloves are non-sterile disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Powder Free Green Nitrile Examination Gloves, Powder Free Pink Nitrile Examination Gloves and Powder Free Purple Nitrile Examination Gloves is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. | Same |
| **Powder free** | | Yes | Yes | Same |
| **Design feature** | | Ambidextrous | Ambidextrous | Same |
| **Material** | | Nitrile | Nitrile | Same |
| **Color** | | Pink, Yellow, Grey, Green | Green, Pink, Purple | Different 1 |
| **OTC use** | | Yes | Yes | Same |
| **Sterility** | | Non-sterile | Non-sterile | Same |
| **Use** | | Single use | Single use | Same |
| **Label** | | Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile. | Single-use indication, powder free, device color, device name, glove size and quantity, non-sterile. | Same |
| **Size and Dimensions (mm)** | | Length(mm):<br>S/M/L/XL: 240±10mm<br>Width(mm):<br>S: 85±10mm; M: 96±10mm; L: 107±10mm; XL: 118±10mm | Length(mm):<br>XS/S/M/L/XL: ≥230<br>Width(mm):<br>XS: 70±10mm; S: 85±10mm; M: 95±10mm; L: 110±10mm; XL: 120±10mm | Different 2 |
| **Thickness (mm)** | | Middle finger: 0.11±0.02mm;<br>Palm: 0.06±0.02mm | Finger: ≥0.05; Palm: ≥0.05 | Different 3 |
| **Physical Properties** | **Before Aging** | Tensile≥14MPa | Tensile Strength: 14MPa, min | Same |
| | | Elongation≥500% | Ultimate Elongation: 500% min | Same |
| | **After Aging** | Tensile≥14MPa | Tensile Strength: 14MPa, min | Same |
| | | Elongation≥400% | Ultimate Elongation: 400% min | Same |
| **Freedom from Holes** | | Be free from holes when tested in Accordance with ASTM D5151 | Be free from holes when tested in Accordance with ASTM D5151 | Same |

| Device | | Proposed Device | Predicate Device | Result |
|---|---|---|---|---|
| **Powder Content** | | Meet the requirements of ASTM D6124<br>Less than 2mg per glove | Meet the requirements of ASTM D6124<br>Less than 2mg per glove | Same |
| **Biocompatibility** | **Irritation ISO 10993-23** | Under the conditions of the study, not an irritant. Comply with ISO 10993-23. | Under the conditions of the study, not an irritant. Comply with ISO 10993-23. | Same |
| | **Sensitization ISO 10993-10** | Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10. | Under the conditions of the study, not a sensitizer. Comply with ISO 10993-10. | Same |
| | **Cytotoxicity ISO 10993-11** | Under the conditions of the study, the device did not show acute systemic toxicity in vivo. Comply with ISO 10993-11. | Under the conditions of the study, the device did not show acute systemic toxicity in vivo. Comply with ISO 10993-11. | Same |

**Different 1-Color**

The color of the proposed device is different from the predicate device. However, the biocompatibility and specification performance tests have been performed on each of the proposed devices and the test results show no significant concerns. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

**Different 2-Size and dimensions**

The size and dimensions of the proposed device is not exactly same as the predicate device. However, the size and dimension of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user's hand. In addition, its dimension has been tested and met the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

**Different 3-Thickness**

The thickness of the proposed device is not exactly same as the predicate device. However, the thickness of the proposed device has been tested and met the requirement of ASTM D6319-19. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

## 7. Non Clinical Test

7.1 Product Material Safety

The following tests for the subject device were conducted to evaluated the biocompatibility of Nitrile Disposable Examination Gloves:

- ISO 10993-11: 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

7.2 Performance of the products

The testing was done according to the following standards:

- ASTM D6319-19:2023, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06:2022, Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19:2023, Standard Test Method for Detection of Holes in Medical Gloves.

| Test Method | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| ASTM D6319-19 | Physical Dimensions Length | Min 220mm for size XS, S Min 230mm for size M-XXL Thickness (mm): Finger: ≥0.05; Palm: ≥0.05 | Pass |
| ASTM D6319-19 | Physical Dimensions Palm Width | XS: 70±10mm, S: 80±10mm, M: 95±10mm, L: 110±10mm, XL:120±10mm, XXL:130±10mm | Pass |
| ASTM D6319-19 | Physical Dimensions Thickness | Finger: 0.05mm (min) Palm: 0.05mm (min) | Pass |
| ASTM D6319-19 | Physical Properties | Tensile Strength (Min 14MPa) and Elongation (Before Aging 500% and after aging 400%) Min | Pass |
| ASTM D6319- 19 ASTM D5151-19 | Water leak test | AQL 2.5 (ISO 2859-1) | Pass |
| ASTM D6319- 19 ASTM D6124-06 | Powder Residue | Max 2mg/glove | Pass |
| ISO 10993-11 | Acute systemic toxicity study | Under the conditions of the study, the device extract does not induce acute systemic toxicity response. | Pass |
| ISO 10993-10 | Skin sensitization | Under the condition of the study, the device is not a sensitizer | Pass |
| ISO 10993-23 | Irritation | Under the condition of the study, the device is not an irritant | Pass |

## 8. Summary of Clinical Testing

Not Applicable

## 9. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Medical Examination Nitrile Gloves, cleared under K240361.