June 22, 2022

Hangzhou Runheng Medical Co., Ltd.
Yaya Lu
QC Manager
Room 201, Shunfeng Building, NO.109 Hongxing Road,
Qiaonan Block
Hangzhou, Zhejiang 311215
China

Re: K213739
Trade/Device Name: Nitrile Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 10, 2022
Received: May 25, 2022

Dear Yaya Lu:

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.
Acting 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)*
K213739

Device Name
Nitrile Examination Gloves

Indications for Use *(Describe)*
Nitrile Examination Gloves are disposable devices intended for medical purpose that are 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.***

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# K213739-510(k) summary

## I Submitter

Device submitter: Hangzhou Runheng Medical Co., Ltd.
Room 201, Shunfeng Building, NO.109 Hongxing Road, Qiaonan Block, Xiaoshan Economic and Technological Development Zone, Hangzhou, Zhejiang Province, P.R.China.

Contact person: Yaya Lu
QC Manager
Phone: +86 18285158974
E-mail: 1264726347@qq.com

Date of Preparation: May 16th, 2022

## II Proposed Device

| | |
|---|---|
| 510(k) Number: | K213739 |
| Trade/Device Name: | Nitrile Examination Gloves |
| Regulation Number: | 21 CFR 880.6250 |
| Regulation Name: | Non-powdered patient examination glove |
| Regulatory Class: | Class I |
| Product code: | LZA |
| Review Panel: | General Hospital |

## III Predicate Devices

| | |
|---|---|
| 510(k) Number: | K211515 |
| Trade/Device Name: | Nitrile Examination Gloves |
| Regulation Number: | 21 CFR 880.6250 |
| Regulation Name: | Non-powdered patient examination glove |
| Classification: | Class I |
| Product Code: | LZA |
| Manufacturer | Beijing Reagent Latex Products Co., Ltd. |

## IV Device description

Nitrile Examination Gloves are made of Nitrile rubber and are blue in color. The device is powder free nitrile examination gloves. It can be available in five specifications: XS, S, M, L and XL.

The subject device is non-sterile.

**V Indication for use**

Nitrile Examination Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner.

**VI Non-Clinical Test Conclusion**

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

- ASTM D5151 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6319 Standard Specification for Nitrile Examination Gloves for Medical Application
- 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

Table 1 Summary of Non-Clinical Performance Testing

| Test Method | Purpose | Acceptance Criteria | | | Result |
|---|---|---|---|---|---|
| ASTM D6319 | Physical Dimensions Test | Extra-Small:<br>Length：≥ 220mm; Width: 70±10 mm<br>Small:<br>Length：≥ 220mm; Width: 80±10mm<br>Medium:<br>Length：≥ 230mm; Width: 95±10mm<br>Large:<br>Length：≥ 230mm; Width: 110±10mm<br>Extra- Large:<br>Length：≥ 230mm; Width: 120±10mm | | | Pass |
| | | Thickness (mm):<br>Finger:≥0.05<br>Palm: ≥0.05 | | | Pass |
| | Physical properties | Before Aging | Tensile Strength | ≥14MPa | Pass |
| | | | Ultimate Elongation | ≥500% | |
| | | After Aging | Tensile Strength | ≥14MPa | Pass |
| | | | Ultimate Elongation | ≥500% | |
| ASTM D5151 | Watertightness Test for Detection of Holes | Meet the requirements of ASTM D5151Test for AQL 2.5 | | | Pass |

| | | | |
|---|---|---|---|
| ASTM D6124 | Powder Content | Meet the requirements of ASTM D6124< 2.0mg | Pass |
| ISO 10993-11 | To determine if the finished device material extracts pose a systemic toxicity concern. | Non- acute systemic toxicity | Under conditions of the study, did not show acute systemic toxicity in vivo / Pass |
| ISO 10993-10 | To determine if the finished device material is an irritant. | Non-irritating | Under the conditions of the study not an irritant/ Pass |
| ISO 10993-10 | To determine if the finished device material is a sensitizer. | Non-sensitizing | Under conditions of the study, not a sensitizer. / Pass |

**VII Clinical Test Conclusion**

No clinical study is included in this submission.

**VIII Summary of Technological characteristics**

Table 2 Technological Characteristics Comparison Table

| Item | Subject device | Predicate device | Discussion |
|---|---|---|---|
| Product name | Nitrile Examination Gloves | Snow Lotus Nitrile Examination Gloves | NA |
| 510(k) Number | K213739 | K211515 | NA |
| Product Code | LZA | LZA | Identical |
| Intended use | Nitrile Examination Gloves are disposable devices intended for medical purpose that are worn on the examiner's hand to prevent contamination between patient and examiner. | Beijing Reagent Latex Products Co., Ltd Nitrile Examination Gloves are disposable devices intended for medical purpose that are worn on the examiner’s hand to prevent contamination between patient and examiner. | Identical |
| Dimensions | Extra-Small:<br>Length：Minimum 220mm<br>Width: 70±10 mm | Extra-Small:<br>None | Different 1 |
| | Small:<br>Length：Minimum 220mm | Small:<br>Length：Minimum 220mm | |

| | | | |
|---|---|---|---|
| | Width: 80±10mm | Width: 80±10mm | |
| | Medium:<br>Length：Minimum 230mm<br>Width: 95±10mm | Medium:<br>Length：Minimum 230mm<br>Width: 95±10mm | |
| | Large:<br>Length：Minimum 230mm<br>Width: 110±10mm | Large:<br>Length：Minimum 230mm<br>Width: 110±10mm | |
| | Extra- Large:<br>Length：Minimum 230mm<br>Width: 120±10mm | Extra- Large:<br>Length：Minimum 230mm<br>Width: 120±10mm | |
| Thickness per ASTM D6319 (for all sizes) | Palm thickness:<br>Minimum 0.05 mm | Palm thickness:<br>Minimum 0.05 mm | Identical |
| | Finger thickness: Minimum 0.05 mm | Finger thickness: Minimum 0.05 mm | |
| Physical Properties Before Aging per ASTM D6319 | Tensile Strength:<br>Minimum 14 MPa<br>Ultimate Elongation:<br>Minimum 500% | Tensile Strength:<br>Minimum 14 MPa<br>Ultimate Elongation:<br>Minimum 500% | Identical |
| Physical Properties After Aging per ASTM D6319 | Tensile Strength:<br>Minimum 14 MPa<br>Ultimate Elongation:<br>Minimum 400% | Tensile Strength:<br>Minimum 14 MPa<br>Ultimate Elongation:<br>Minimum 400% | Identical |
| Water tight (hole detection) per ASTM D5151 | Passes at AQL of 2.5 | Passes at AQL of 2.5 | Identical |
| Powder Residue per ASTM D6319 | ≤2 mg/glove | ≤2 mg/glove | Identical |
| Biocompatibility: Primary Skin Irritation per ISO 10993-10 | Not an irritant under the conditions of the study. | Not an irritant under the conditions of the study. | Identical |
| Biocompatibility: Dermal Sensitization per ISO 10993-10 | Not a sensitizer under the conditions of the study. | Not a sensitizer under the conditions of the study. | Identical |
| Biocompatibility: Acute Systemic Toxicity Test per ISO 10993-11 | Device extracts do not pose a systemic toxicity concern under the conditions of the study. | Device extracts do not pose a systemic toxicity concern under the conditions of the study. | Identical |

| | | | |
|---|---|---|---|
| Device Material | Nitrile | Nitrile | Identical |
| Color | Blue | Blue | Identical |
| Size Offering | Extra-Small, Small, Medium, Large, Extra-Large | Small, Medium, Large, Extra-Large | Different 1 |
| Number of Uses | Single Use | Single Use | Identical |

Different 1:
The models of proposed device are different with predicate device, but all proposed devices are meet the specifications of ASTM D 6319. So we consider this as the proposed device is similar to the predicate device.

**IX Conclusion**

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K213739, Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Snow Lotus Nitrile Examination Gloves, cleared under 510(k) K211515.