August 24, 2021

Beijing Reagent Latex Products Co., Ltd.
℅ Stephen Beier
Head of Regulatory Affairs and Quality Systems
Bayside Life Science Consultants, LLC
252 Nassau Street, Floor 2
Princeton, New Jersey 08542

Re: K211515
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: July 21, 2021
Received: August 5, 2021

Dear Stephen Beier:

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,

For Clarence W. Murray III, 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)*
K211515

Device Name
Beijing Reagent Latex Products Co., Ltd. Nitrile Examination Gloves

Indications for Use *(Describe)*
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.

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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*"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."*

# 510(k) Summary

# (K211515)

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

## 1.0 Submitter's Information

Name: Beijing Reagent Latex Products Co., Ltd.
Address: No. 6 Xingguang 5th Street Opto-Mechatronics Industrial Park Beishenshu Village Est, Taihu Town Tongzhou District, Beijing, China 101111
Phone Number: +86-10-81502524
Contact: HaiTao Liu, Export Manager
Date of Preparation: July.30,2021

## Designated Submission Correspondent

Stephen Beier, Head of Regulatory Affairs & Quality Systems
Bayside Life Science Consultants, LLC 252 Nassau Street, Floor 2 Princeton, NJ 08542
Tel: +1-800-881-2063
Email: stephen@baysideops.com

## 2.0 Device Information

Trade name: Snow Lotus Nitrile Examination Gloves
Common name: Nitrile Examination Gloves
Classification name: Non-powdered patient examination gloves
Model(s): S, M, L, XL

## 3.0 Classification

Production code: LZA,
Regulation number: 21 CFR 880.6250
Classification: Class I
Panel: General Hospital

## 4.0 Predicate Device Information

Manufacturer: Beijing Reagent Latex Products Co., Ltd.
Device: Beijing Reagent Latex Products Co., Ltd. Nitrile Examination Gloves
510(k) number: K211515

## 5.0 Device Description

The Beijing Reagent Latex Products Co., Ltd. Nitrile Examination Gloves are powder-free Class I patient examination gloves. The gloves are manufactured from nitrile and are blue in

color. The examination gloves are intended for medical purpose, will be worn on the examiner's hand, and will be available in four sizes (Small, Medium, Large, and Extra-Large).

## 6.0 Indication for Use

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.

## 7.0 Technological Characteristic Comparison Table

| Item | Predicate Device (K192333) | Subject Device (K211515) | Remark |
|---|---|---|---|
| Product Code | LZA | LZA | Same |
| Regulation No. | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| Class | I | I | Same |
| Intended Use | Blue Nitrile Examination Gloves Powder Free is disposable device intended for medical purpose that are won 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. | Same |
| Dimensions (Length and Width) per ASTM D6319 | Length: Minimum 230 mm<br>Width: Minimum 95+/-10mm (for medium sized glove) | Length: Minimum 230 mm<br>Width: Minimum 95+/-10mm (for medium sized glove) | Same |
| Thickness per ASTM D6319 | Palm thickness: Minimum 0.05 mm | Palm thickness: Minimum 0.05 mm | Same |
| | Finger thickness: Minimum 0.05 mm | Finger thickness: Minimum 0.05 mm | |
| Physical Properties Before Aging per ASTM D6319 | Tensile Strength: Minimum 14 MPa<br>Ultimate Elongation: Minimum 500% | Tensile Strength: Minimum 14 MPa<br>Ultimate Elongation: Minimum 500% | Same |
| Physical Properties After Aging per ASTM D6319 | Tensile Strength: Minimum 14 MPa<br>Ultimate Elongation: Minimum 400% | Tensile Strength: Minimum 14 MPa<br>Ultimate Elongation: Minimum 400% | Same |
| Water tight (hole detection) per ASTM D5151 | Passes at AQL of 2.5 | Passes at AQL of 2.5 | Same |

| | | | |
|---|---|---|---|
| Powder Residue per ASTM D6319 | ≤ 2 mg/glove | ≤ 2 mg/glove | Same |
| 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. | Same |
| 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. | Same |
| Biocompatibility: In Vitro Cytotoxicity per ISO 10993-5 | Under the conditions of the study, cytotoxic. Additional testing performed to determine if this was a systemic toxicity concern. | Under the conditions of the study, cytotoxic at elevated test article extracts. Additional analysis was performed to determine if this was a systemic toxicity concern. Non-cytotoxic at 25% test article extract. | Similar |
| 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. | Same |
| Device Material | Nitrile | Nitrile | Same |
| Color | Blue | Blue | Same |
| Size Offering | Extra-Small, Small, Medium, Large, Extra-Large | Small, Medium, Large, Extra- Large | Different (no Extra Small size offered) |
| Number of Uses | Single Use | Single Use | Same |

Analysis: There are no significant differences between the subject device and its predicate device, and the two are identical in terms of intended use, materials, design, and performance specifications. Both the predicate device under K192333 as well as the subject device are compliant with ASTM D6319.

## 8.0 Summary of Non-Clinical Testing

| Test Method | Purpose | Acceptance Criteria | Result |
|---|---|---|---|
| ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | Small: Min 220 mm<br>Medium: Min 230 mm<br>Large: Min 230 mm<br>Extra-Large: Min 230 mm | Pass |
| ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the width of the gloves. | Small: 80 ± 10 mm<br>Medium: 95 ± 10 mm<br>Large: 110 ± 10 mm<br>Extra-Large: 120 ± 10 mm | Pass |

| | | | |
|---|---|---|---|
| ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the Thickness of the gloves. | Min palm thickness: 0.05 mm<br>Min finger thickness: 0.05 mm<br>(for all sizes) | Pass |
| ASTM D 5151 Standard Test Method for Detection of Holes in Medical Gloves | To determine the presence of holes in the gloves. | AQL = 2.5 | Glove inspection passes at an AQL of 2.5 |
| ASTM D 6124 Standard Test Method for Residual Powder on Medical Gloves | To determine the residual powder content on the gloves. | ≤ 2 mg/glove | Pass |
| ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the tensile strength of the gloves. | *Before Aging*<br>Minimum of 14 MPa for all Sizes<br>*After Aging*<br>Minimum of 14 Mpa for all sizes | Pass |
| ASTM D 6319 Standard Specification for Nitrile Examination Gloves for Medical Application | To determine the ultimate elongation of the gloves. | *Before Aging*<br>Minimum of 500% for all sizes<br>*After Aging*<br>Minimum of 400% for all sizes | Pass |
| Biocompatibility: Primary Skin Irritation per ISO 10993-10 | To determine if the finished device material is an irritant. | Not an irritant under the conditions of the study. | Pass |
| Biocompatibility: Dermal Sensitization per ISO 10993-10 | To determine if the finished device material is a sensitizer. | Not a sensitizer under the conditions of the study. | Pass |
| Biocompatibility: In Vitro Cytotoxicity per ISO 10993-5 | To determine if the finished device material is cytotoxic. | Non-cytotoxic under the conditions of the study. | noncytotoxic at 25% test article extract. |
| Biocompatibility: Acute Systemic Toxicity Test per ISO 10993-11 | To determine if the finished device material extracts pose a systemic toxicity concern. | Device extracts do not pose a systemic toxicity concern under the conditions of the study. | Pass |

## 9.0 Summary of Clinical Testing

This section is not applicable to this Premarket Notification 510(k); there was no clinical testing conducted on this product.

## 10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K211515, Beijing Reagent Latex Products Co., Ltd. Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under 510(k) K192333.