April 27, 2023

Guangdong Kingfa Sci. & Tech. Co., LTD.
Xiaoge Yu
Manager
No.28, Delong Ave., Shijiao Town, Qingcheng District
Qingyuan, Guangdong 511545
China

Re: K221983
Trade/Device Name: Biodegradable Powder Free Nitrile Examination Glove, Blue Color,
Biodegradable Powder Free Nitrile Examination Glove, Blue Violet Color,
Biodegradable Powder Free Nitrile Examination Glove, Green Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: November 8, 2022
Received: April 24, 2023

Dear Xiaoge Yu:

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 -S

Bifeng Qian., M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221983

Device Name
Biodegradable Powder Free Nitrile Examination Glove, Blue Color
Biodegradable Powder Free Nitrile Examination Glove, Blue Violet Color
Biodegradable Powder Free Nitrile Examination Glove, Green Color

Indications for Use *(Describe)*
The biodegradable nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

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.**

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**K221983-510(k) Summary**

## I. Submitter

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Revision date: September 7, 2022

## II. Proposed Device

| | |
|---|---|
| Device Trade Name | Biodegradable Powder Free Nitrile Examination Glove, Blue Color<br>Biodegradable Powder Free Nitrile Examination Glove, Blue Violet Color<br>Biodegradable Powder Free Nitrile Examination Glove, Green Color |
| Common name: | Polymer Patient Examination Glove |
| Regulation Number: | 21 CFR 880.6250 |
| Regulatory Class: | Class I |
| Product code: | LZA |
| Review Panel | General Hospital |

## III. Predicate Device

| | |
|---|---|
| 510(k) Number: | K162312 |
| Trade name: | Biodegradable Powder Free Nitrile Exam Gloves With Aloe Vera, Green Color |
| Common name: | Patient Examination Gloves |
| Classification: | Class I |
| Product Code: | LZA |
| Manufacturer | Shen Wei USA Inc. |

## IV. Device description

The propose devices is powder free nitrile patient examination gloves, provided as

non-sterile and disposable device. The gloves are offered in six sizes, extra-small (6.5"), small (7"), medium (8"), large (8.5"), extra-large (9"), extra extra-large (9.5”). Three colors are available for all size, includes blue, blue violet and green.

## V. Indication for use

The biodegradable nitrile examination glove is intended to be worn on the hands of examiner’s to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

## VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Nitrile Examination Gloves

| Item | Proposed device (K221983) | Predicate device (K162312) | Discussion |
|---|---|---|---|
| Product name | Biodegradable Powder Free Nitrile Examination Glove, Blue Color<br>Biodegradable Powder Free Nitrile Examination Glove, Blue Violet Color<br>Biodegradable Powder Free Nitrile Examination Glove, Green Color | Biodegradable Powder Free Nitrile Exam Gloves With Aloe Vera, Green Color | - |
| Product Code | LZA | LZA | Same |
| Regulation No. | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| Classification | Class I | Class I | Same |
| Powder free | Yes | Yes | Same |
| Indication for use | The biodegradable nitrile examination glove is intended to be worn on the hands of examiner’s to prevent contamination between patient and examiner. This is a single-use, | The biodegradable powder free nitrile exam gloves with aloe vera, green color is a disposable device intended for medical | Same |

| | | | |
|---|---|---|---|
| | powder-free, non-sterile device. | purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only. | |
| Main Material | Nitrile rubber | Nitrile rubber | Same |
| Color | Blue\Blue violet\Green | Green | Similar |
| Size | X-Small (6.5), Small(7), Medium (8), Large(8.5),X-large(9), XX-large(9.5), | Ambidextrous in different sizes per ASTM D6319-10 Dimensions requirement | Similar Only the different standard version. This requirement given in the standard is the same. |
| Palm width | X- Small(70±10mm)<br>Small (80±10mm)<br>Medium(95±10mm)<br>Large(110±10mm)<br>X-large(120±10mm)<br>XX-large(≧120mm) | Ambidextrous in different sizes per ASTM D6319-10 dimensions requirement | Similar Only the different standard version. This requirement given in the standard is the same. |
| Length | XS(220mm min)<br>S (220mm min)<br>M (230mm min)<br>L (230mm min)<br>XL (230mm min)<br>XXL (230mm min) | Ambidextrous in different sizes per ASTM D6319-10 Dimensions requirement | Similar Only the different standard version. This requirement given in the standard is the same. |
| | Palm: 0.05mm min | Ambidextrous in | Similar |

| | | | |
|---|---|---|---|
| Thickness | Finger: 0.08mm min | different sizes per ASTM D6319-10 dimensions requirement | Only the different standard version. This requirement given in the standard is the same. |
| Freedom from holes | Meets requirements of the ASTM D6319-19 | Meets requirements of the ASTM D6319-10 | Similar<br>Only the different standard version. This requirement given in the standard is the same. |
| Physical Properties (before aging) | Meets requirements of the ASTM D6319-19 | Meets requirements of the ASTM D6319-10 | Similar<br>Only the different standard version. The requirements of physical properties given in the standard are the same. |
| Physical Properties (after aging) | Meets requirements of the ASTM D6319-19 | Meets requirements of the ASTM D6319-10 | Similar<br>Only the different standard version. The requirements of physical properties given in the standard are the same. |
| Powder residual | ≤2.0 mg/gloves | ≤2.0 mg/gloves | Same |
| Sterility | Non-sterile | Non-sterile | Same |
| Biodegradation Properties | Biodegradable | Biodegradable | Same |
| For single use | Yes | Yes | Same |
| Type of use | Over the counter use | Over the counter use | Same |
| Biocompatibility | Skin Sensitization-ISO 10993-10<br>Irritation-ISO 10993-10 | Skin Sensitization-ISO10993-10<br>Irritation-ISO 10993-10 | Similar |

| | | | |
|---|---|---|---|
| | Acute Systemic Toxicity-ISO 10993-11 | | |

As above comparison, the difference in the reference standard version of the subject and predicate device does not raise additional questions for safety and effectiveness of the device. The biocompatibility test and performance test of the subject devices have been performed on the final finished device. The test results shows the predicate device meet the specifications of ASTM D 6319. So we consider this as the proposed device is similar to the predicate device.

## VII. Non-Clinical Testing

Non clinical tests were conducted in accordance with following standards to verify that the proposed device met all design specifications.

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- 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 - Part11:Tests for Systemic Toxicity

Table 2 Summary of Non-Clinical Performance Testing

| Test Method | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| 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<br>Extra- Extra- Large: | Pass |

| | | | | | |
|---|---|---|---|---|---|
| | | Length：≥ 230mm Width: ≥120mm | | | |
| | | Thickness (mm):<br>Finger:≥0.05<br>Palm: ≥0.08 | | | Pass |
| | Physical properties | Before Aging | Tensile Strength | ≥14MPa | Pass |
| | | | Ultimate Elongation | ≥500% | |
| | | After Aging | Tensile Strength | ≥14MPa | Pass |
| | | | Ultimate Elongation | ≥500% | |
| ASTM D5151 | Freedom from pinholes | Meet the requirements of ASTM D5151Test for AQL 2.5 | | | Pass |
| ASTM D6124 | Powder Residue | Meet the requirements of ASTM D6124< 2.0mg | | | 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 |
| 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 |

## VIII. Clinical Testing

No clinical study is included in this submission.

## IX. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K221983, Biodegradable Powder Free Nitrile Examination Gloves, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Shen Wei Biodegradable Powder Free Nitrile Examination Gloves, cleared under 510(k) K162312.