November 10, 2021

Shandong Shangwei Medical Products Co.,Ltd
℅ Chu Xiaoan
Official Correspondent
Beijing Easy-Link Company
Rm. F302 Bldg., 41, Jing Cheng Ya Ju,
Courtyard 6 of Southern Dou Ge Zhuang, Chaoyung District
Beijing, 100121
China

Re: K210779
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 17, 2021
Received: October 19, 2021

Dear Chu Xiaoan:

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,

Clarence W. Murray, III, PhD
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K210779

Device Name

Powder Free Nitrile Patient Examination Gloves, Blue Color

Indications for Use *(Describe)*

Powder Free Nitrile Patient Examination Gloves, Blue Color is a 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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**

**K210779**

This summary of 510(k) is being submitted in accordance with 21 CFR 807.

Premarket Notification [510(k)] Summary

**1.0 Submitter:**

Submitter's name: Shandong Shangwei Medical Products Co.,Ltd
Submitter's address: North Road, Fumin Avenue,Qinghe Street, Caoxian County, Heze City, Shandong Province, 274400,P.R. China
Name of contact person: Ms. Li Hua
Phone number: 0086-530-2069711
Date of preparation: 2021-11-08

**2.0 Name of the Device**

Proprietary/Trade name: Powder Free Nitrile Patient Examination Gloves, Blue Color
Common Name: Patient Examination gloves
Classification Name: Non-powdered Patient examination glove
Device Classification: I
Regulation: 21 CFR 880.6250
Panel: General Hospital
Product Code: LZA

**3.0 Predicate device**

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Color
Company name: Tangshan Zhonghong Pulin Plastic Co., Ltd.
510(K) Number: K120970

**4.0 Device Description:**

The proposed device is Powder Free Nitrile Examination Gloves. The proposed device is blue. The proposed device is non-sterile.

**5.0 Indications for Use Statement:**

Powder Free Nitrile Patient Examination Gloves, Blue Color is a 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.

**6.0 Technological Characteristic Comparison:**

| Features & Description | Predicate Device (K120970) | Subject Device (K210779) | Result of Comparison |
|---|---|---|---|
| Product name | Powder Free Nitrile Patient Examination Glove, Blue Color | Powder Free Nitrile Patient Examination Gloves, Blue Color | Same |
| Regulation Number | 21CFR880.6250 | 21CFR880.6250 | Same |
| Product Code | LZA | LZA | Same |
| Color | Blue | Blue | Same |
| Size | Small/ Medium/ Large/X large | Small/ Medium/ Large/X large | Same |
| Indications for Use | Powder Free Nitrile Patient Examination Glove, Blue Color is a 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 Nitrile Patient Examination Gloves, Blue Color is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. | Same |

| | | | | | |
|---|---|---|---|---|---|
| Device Description and Specifications | Meets ASTM D6319-10 | | Meets ASTM D6319-10 (Reapproved 2015) | | Same |
| Dimensions --Length ILS-2 AQL4.0 (ASTMD 6319-10) | ≥230mm min | | 232 mm min for all sizes | | Similar |
| Dimensions -- Width IL S-2 AQL4.0 (ASTM D6319-10) | Small | 70-90 mm | Small | 76-90 mm | Similar |
| | Medium | 85-105mm | Medium | 87-102 mm | |
| | Large | 100-120mm | Large | 108-119mm | |
| | X large | 110-130 mm | X large | 115-128 mm | |
| Dimensions --Thickness IL S-2 AQL4.0 (ASTM D6319-10) | Finger 0.05mm min.<br>Palm 0.05mm min. | | Thickness (mm) min.<br>Finger 0.08<br>Palm 0.08 | | Similar |
| Physical Properties IL S-2 AQL4.0 (ASTM D D6319-10) | Before aging/after aging Tensile Strength≥ 14MPa<br><br>Before aging Elongation ≥500%<br>After aging Elongation ≥400% | | Before Aging Elongation (%): 550-610<br>After Aging Elongation (%): 450-570<br><br>Before Aging Tensile Strength (MPa): 18-25<br>After Aging Tensile Strength (MPa): 17-22 | | Similar |
| Freedom from Pinholes<br><br>Inspection Level I AQL2.5 | Meets<br>• 21 CFR 800.20<br>• ASTM D6319-10 | | 1) Inspection Level I AQL2.5, and Accept/Reject criteria of 10/11<br>2) Water leakage test: 5 noncompliance is allowed. | | Similar |
| Residual Powder (ASTM D 6124-06(Reaffirmation 2011)) | below 2mg of residual powder | | 1) Checked on 5pcs sub-samples (N=5).<br>2) Result as following:<br>Mean: 0.1mg/pcs | | Similar |
| Materials used to fabricate the devices | Nitrile | | Nitrile | | Same |
| Single Patient Use | Single Patient Use | | Single Patient Use | | Same |
| Biocompatibility | Under the conditions of this study, the test article was a non- irritant or non- sensitizer (ISO 10993-10:2002/Amd.1: 2006) | | Under the conditions of this study, the test article was a non- irritant or non- sensitizer (ISO 10993-10: Third Edition 2010-08-01) | | Similar |
| | N/A | | Cytotoxicity study meets ISO 10993-5 Third edition 2009-06-01 | | Different |
| | N/A | | Under the conditions of study, the device extracts do not pose a systemic toxicity concern (ISO 10993-11:2017) | | Different |
| Labeling | -Powder Free<br>-Patient Examination Glove<br>-Single Use Only<br>- Manufactured For:<br>- Lot<br>-Blue color<br>- Non sterile | | -Powder Free<br>-Patient Examination Glove<br>-Single Use Only<br>- Manufactured For:<br>- Lot<br>-Blue color<br>- Non sterile | | Same |

## 7.0 Discussion of Non-clinical and Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

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

ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D6319-10(Reapproved 2015), Standard Specification for Nitrile Examination Gloves for Medical Application.

| Test Methodology | Purpose | Acceptance Criteria | | Results |
|---|---|---|---|---|
| ASTM D 6319-06(Reapproved 2015). | Dimension | Length | ≥230mm | |
| | | Width | Small | 76-90 mm |
| | | | Medium | 87-102 mm |
| | | | Large | 108-119mm |
| | | | X large | 115-128 mm |
| | | Thickness | Fingertip | ≥0.08mm |
| | | | Palm | ≥0.08mm |
| ASTM D 6319-06(Reapproved 2015). | Physical Properties | Tensile strength (Before & After aging) | ≥14MPa | 17-25 |
| | | Before aging Elongation | ≥500% | 550-610 |
| | | After aging Elongation | ≥400% | 450-570 |
| • 21 CFR 800.20<br>• ASTM D 6319-06(Reapproved 2015).<br>• ASTM D5151-19 | Freedom from pinholes | Water leakage test: Inspection Level I, AQL2.5, and Accept/Reject criteria of 10/11. | | 5 noncompliance is allowed.<br><br>Pass |
| • ASTM D6319-10(Reapproved 2015)<br>• ASTM D6124-06 (Reapproved 2017), | Powder Residual | Meets <2mg/glove | | Mean: 0.1mg/pcs<br><br>Pass |
| Primary Skin Irritation in rabbits ISO 10993-10: 2010-08-01 | Biocompatibility | Under the conditions of the study, the subject device is not a primary skin irritant. | | Passes |
| Dermal sensitization in the guinea pig ISO 10993-10: 2010-08-01 | | Under the conditions of the study, the subject device is not a skin sensitizer. | | Passes |

| | | | |
|---|---|---|---|
| The test article was added to L929 cells measured by MTT assay ISO 10993-5: 2009 | | Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells. | Under the conditions of the study, cytotoxic. Additional testing was performed to determine if this was a systemic toxicity concern. |
| Acute Systemic Toxicity Systemic injection in mice ISO 10993-11:2017 | | Under the conditions of study the device extracts do not pose a systemic toxicity concern | Pass |

**8.0 Discussion of Clinical and Performance Testing**

Clinical testing is not needed for this device.

**9.0 Conclusion**

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.