November 5, 2019

Anhui Powerguard Technology Co.,Ltd
% Chu Xiaoan
Official Correspondent
Beijing Easylink CO., LTD
Rm. F302 Bldg., 41, Jing Cheng Ya Ju
Courtyard 6 of Southern Dou Ge Zhuang
Beijing, 100021 Cn

Re: K191292
Trade/Device Name: Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: September 27, 2019
Received: October 7, 2019

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*

K191292

Device Name
Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)

Indications for Use *(Describe)*
Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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.

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

# K191292

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

**1.0 Submitter:**

| | |
|---|---|
| Submitter's name: | Anhui Powerguard Technology Co.,Ltd |
| Submitter's address: | North Development Zone, Lingbi County, Suzhou City, Anhui Province,234200, China |
| Name of contact person: | Mr. Nike Dai |
| Date of preparation: | 2019-11-05 |

**Designated Submission Correspondent**

| | |
|---|---|
| *Company's name* | Beijing Easy-Link Company |
| Company's address | Rm. F302 Bldg., 41, Jing Cheng Ya Ju, Courtyard 6 of Southern Dou Ge Zhuang, Chaoyang District, Beijing 100121, P.R. China |
| Contact person | Chu Xiaoan |

**2.0 Name of the Device**

| | |
|---|---|
| Device Name: | Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) |
| Proprietary/Trade name: | Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) |
| Common Name: | Exam gloves |
| Classification Name: | Patient examination glove |
| Device | I |
| Regulation Number: | 21 CFR 880.6250 |
| Panel: | General Hospital |
| Product Code: | LYZ |

| **3.0 Predicate device** | |
|---|---|
| Device Name: | Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) |
| Company name: | Zhang Jia Gang Fengyuan Plastic Product Co. Ltd. |
| 510(K) Number: | K091663 |

**4.0 Device Description:**

The proposed device is Powder Free Examination Gloves. The proposed device is Clear (non-colored). The proposed device is non-sterile.

**5.0 Indications for Use Statement:**

Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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 Table:**

<table>
<tr><th>Features & Description</th><th colspan="2">Predicate Device (K091663)</th><th colspan="2">Subject Device (K191292)</th><th>Comparison</th></tr>
<tr><td>Product name</td><td colspan="2">Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)</td><td colspan="2">Powder Free Vinyl Patient Examination Gloves, Clear (non-colored)</td><td>Same</td></tr>
<tr><td>Regulation Number</td><td colspan="2">21CFR880.6250</td><td colspan="2">21CFR880.6250</td><td>same</td></tr>
<tr><td>Product Code</td><td colspan="2">LYZ</td><td colspan="2">LYZ</td><td>same</td></tr>
<tr><td>Color</td><td colspan="2">Clear(non-colored)</td><td colspan="2">Clear(non-colored)</td><td>same</td></tr>
<tr><td>Size</td><td colspan="2">Small/ Medium/ Large/X large</td><td colspan="2">Small/ Medium/ Large/X large</td><td>same</td></tr>
<tr><td>Indications for Use</td><td colspan="2">Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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.</td><td colspan="2">Powder Free Vinyl Patient Examination Gloves, Clear (non-colored) 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.</td><td>same</td></tr>
<tr><td>Device Description and Specifications</td><td colspan="2">Meets ASTM D5250-06</td><td colspan="2">Meets ASTM D5250-06(Reapproved 2011)</td><td>Same</td></tr>
<tr><td>Dimensions -- Length<br>ILS-2<br>AQL4.0</td><td colspan="2">Meets ASTM D5250-06<br>≥230mm min</td><td colspan="2">233 mm min for all sizes</td><td>Similar</td></tr>
<tr><td rowspan="5">Dimensions -- Width<br>IL S-2<br>AQL4.0<br>(mm)</td><td colspan="2">Meets ASTM D5250-06</td><td colspan="2"></td><td rowspan="5">Similar</td></tr>
<tr><td>Small</td><td>80-90</td><td>Small</td><td>84-88</td></tr>
<tr><td>Medium</td><td>90-100</td><td>Medium</td><td>94-98</td></tr>
<tr><td>Large</td><td>100-110</td><td>Large</td><td>103-109</td></tr>
<tr><td>X large</td><td>110-120</td><td>X large</td><td>114-117</td></tr>
</table>

| | | | |
|---|---|---|---|
| Dimensions<br>--Thickness<br>IL S-2<br>AQL4.0 | Meets ASTM D5250-06<br><br>Finger 0.05mm min.<br>Palm 0.05mm min. | <br>Thickness (mm) min.<br>Finger 0.08<br>Palm 0.10 | Similar |
| Physical Properties<br>IL S-2<br>AQL4.0 | Meets ASTM D5250-06<br>Before aging/after aging | | Similar |
| | Tensile Strength≥ 11MPa | 15-17 MPa | |
| | Elongation ≥300% | 350-390% | |
| 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: 3 noncompliance is allowed. | similar |
| Residual Powder | Meets ASTM D 6124-06 (Reaffirmation 2011)<br><br>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 | PVC | PVC | 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 | Under the conditions of this study, the test article was a non-irritant or non-sensitizer | similar |
| | | Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells. | |
| Labeling for the legally marketed device to which substantial equivalence is claimed. | -Powder Free<br>-Patient Examination Glove<br>-Single Use Only<br>- Manufactured For:<br>- Lot<br>- Clear(non-colored)<br>- Non sterile | -Powder Free<br>-Patient Examination Glove<br>-Single Use Only<br>- Manufactured For:<br>- Lot<br>- Clear(non-colored)<br>- Non sterile | same |

## 7.0 Discussion of Non-clinical Testing

Non-clinical tests were conducted to verify that the proposed device will meet acceptance crtiteria for each test. The test results demonstrated that the proposed device met the acceptance criteria found in the following standards below:

| Name of Test | Purpose | Acceptance Criteria | | | Result |
|---|---|---|---|---|---|
| Dimension | Meet ASTM D 5250-06(Reapproved 2011). | Length | ≥230mm | | 233-241mm |
| | | Width | Small | 80-90 mm | 84-88 mm |
| | | | Medium | 90-100mm | 94-98 mm |
| | | | Large | 100-110mm | 103-109 mm |
| | | | X large | 110-120 mm | 114-117 mm |
| | | Thickness | Fingertip | ≥0.05mm | 0.08-0.11mm |
| | | | Palm | ≥0.08mm | 0.10-0.11mm |
| Physical Properties | Meet ASTM D 5250-06(Reapproved 2011). | (Before & After aging) | | | |
| | | Tensile strength | | ≥11MPa | 15-17 MPa |
| | | Elongated rate | | ≥300% | 350-390% |
| Freedom from pinholes | Meet ASTM D5151-06 (Reapproved 2011) | Holes at Inspection Level I AQL2.5 Act/Re:10/11 | | | 3 non-compliance |
| Powder Residual | Meet ASTM D6124-06 (Reaffirmation 2011) | <2mg/glove | | | 0.1mg/pcs |
| Biocompatibility | Meet ISO 10993-10: 2010-08-01 | Primary Skin Irritation in rabbits | | | Passes Under the conditions of the study, the subject device is not a primary skin irritant. |
| | Meet ISO 10993-10: 2010-08-01 | Dermal sensitization in the guinea pigs | | | Passes Under the conditions of the study, the subject device is not a skin sensitizer. |
| | Meet ISO 10993-5: 2009 | The test article was added to L929 cells measured by MTT assay | | | Pass Under the conditions of this study, the test article was non-cytotoxicity to L-929 cells. |

## 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.