June 4, 2021

Huayuan Medical Technology(Shangqiu) Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K211028
Trade/Device Name: Nitrile Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: April 2, 2021
Received: April 6, 2021

Dear Boyle Wang:

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 Ryan Ortega
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)*
K211028

Device Name
Nitrile Patient Examination Gloves

Indications for Use *(Describe)*
The Nitrile Patient Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands 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.

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# 510(k) Summary

# （K211028）

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

## 1.0 Submitter's Information

Name: Huayuan Medical Technology (Shangqiu) Co., Ltd.
Address: In The North Yard of West 1000m Road at The Intersection of Zhuangzhou Avenue and Pingyuan Road, Liangyuan District, Shangqiu City, Henan Province,China.
Phone Number: +86-13705111918
Contact: Huamei Wang
Date of Preparation: Jun.03,2021

## Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong,Shanghai 200120 ,China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

## 2.0 Device Information

Trade name: Nitrile Patient Examination Gloves
Common name: Patient Examination Gloves
Classification name: Non-powdered patient examination glove
Model(s): XS、S、M、L、XL、XXL

## 3.0 Classification

Production code: LZA
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

## 4.0 Predicate Device Information

Manufacturer: Ever Global (Vietnam) Enterprise Corp
Device: Disposable Powder Free Nitrile Examination Glove, White/ Blue/ Black/ Pink Color

510(k) number: K171422

## 5.0 Indication for Use

The Nitrile Patient Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands or finger to prevent contamination between patient and examiner.

## 6.0 Device Description

The subject device is powder free nitrile examination gloves. The subject device is blue. The subject device is non-sterile.

## 7.0 Technological Characteristic Comparison Table

**Table1-General Comparison**

| Item | Subject Device （K211028） | Predicated Device (K171422) | Remark |
|---|---|---|---|
| Product Code | LZA | LZA | Same |
| Regulation No. | 21CFR880.6250 | 21CFR880.6250 | Same |
| Class | I | I | Same |
| Intended Use | The Nitrile Patient Examination Gloves are non-sterile disposable devices intended for medical purposes that are worn on the examiner's hands or finger to prevent contamination between patient and examiner. | The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. | Same |
| Powdered or Powered free | Powdered free | Powdered free | Same |
| Design Feature | Ambidextrous | Ambidextrous | Same |
| Labeling Information | Single-use indication, powder free, device color, device name, glove size and quantity, Nitrile Glove Powder Free, Blue, | Single-use indication, powder free, device color, device name, glove size and quantity, Disposable Powder Free Nitrile | Same |

| | | | |
|---|---|---|---|
| | Non-Sterile | Examination Glove, Non-Sterile | |

**Table2 Device Dimensions Comparison**

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Predicate Device(K171422) | Designation | Size | | | | | | Tolerance |
| | | XS | S | M | L | XL | | |
| | Length, mm | 230 | 230 | 230 | 230 | 230 | | min |
| | Width, mm | 75 | 85 | 95 | 105 | 115 | | ±5 |
| | Thickness, mm: | | | | | | | |
| | Finger | 0.05 | | | | | | min |
| | Palm | 0.05 | | | | | | min |
| Subject Device (K211028) | Designation | Size | | | | | | Tolerance |
| | | XS | S | M | L | XL | XXL | |
| | Length, mm | 220 | 230 | 230 | 230 | 230 | 230 | min |
| | Width, mm | 70 | 80 | 95 | 110 | 120 | 130 | ±10 |
| | Thickness, mm: | | | | | | | |
| | Finger | 0.05 | | | | | | min |
| | Palm | 0.05 | | | | | | min |
| Remark | Similar | | | | | | | |

Analysis: The physical dimensions are different with that of the predicate, but they all meet the requirements of ASTM D6319-19,so the differences do not raise any new safety or performance questions.

**Table3 Performance Comparison**

| Item | | | Subject device (K211028) | Predicated device (K171422) | Remark |
|---|---|---|---|---|---|
| Colorant | | | Blue | White/ Blue/ Black/ Pink | Same |
| Physical Properties | Before Aging | Tensile Strength | 14MPa, min | 14MPa, min | Same |
| | | Ultimate Elongation | 500% min | 500% min | Same |
| | After Aging | Tensile Strength | 14MPa, min | 14MPa, min | Same |
| | | Ultimate Elongation | 400%min | 400%min | Same |
| | Comply with ASTM D6319 | | | Comply with ASTM D6319 | Same |
| Freedom from Holes | | | Be free from holes when tested in | Be free from holes when tested in | Same |

| | | | |
|---|---|---|---|
| | accordance with ASTMD5151 AQL=2.5 | accordance with ASTMD5151 AQL=2.5 | |
| Powder Content | 0.07 mg per glove. Meet the requirements of ASTM D6124 | Meet the requirements of ASTM D6124 | Same |

**Table4 Safety Comparison**

| Item | | Subject device (K211028) | Predicated device (K171422) | Remark |
|---|---|---|---|---|
| Material | | Nitrile | Nitrile | Same |
| Biocompatibility | Irritation (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization) | Under the conditions of the study, not an irritant | Comply with ISO10993-10 | Same |
| | Sensitization (ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization) | Under conditions of the study, not a sensitizer. | | |
| | Cytotoxicity (ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity) | Under conditions of the study, device extract is not cytotoxic | / | Similar |

## 8.0 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 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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

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 D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

## 9.0 Discussion of Clinical and Performance Testing

Clinical testing is not needed for this device.

## 10.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Nitrile Patient Examination Gloves ,are as safe, as effective, and perform as well as or better than the legally marketed predicated device in K171422.