



September 10, 2020

Best Care Trading Co., LTD
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 608, No. 738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K202008

Trade/Device Name: Disposable Vinyl Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: June 15, 2020
Received: July 21, 2020

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 Elizabeth Claverie, M.S.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K202008

Device Name
Disposable Vinyl Glove

Indications for Use (Describe)

The Disposable Vinyl Glove is intended for medical purposes that is worn on the examiner's hands 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.

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510(k) Summary

K202008

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

1.0 Submitter's Information

Name: Best Care Trading Co.,Ltd.
Address: Yuying Village, Fangzhen, Zhangdian District, 255000 Zibo, Shandong,China.
Phone Number: +86-13508943885
Contact: Mr. Chongfeng Zhao
Date of Preparation: 9/4/2020

Designated Submission Correspondent

Mr. Boyle Wang
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Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Disposable Vinyl Gloves
Common name: Vinyl Patient Examination Glove
Classification name: Non-powdered Patient Examination Glove
Model(s): XS, S, M, L, XL

3.0 Classification

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

4.0 Predicate device information

Manufacturer: Hebei Hongtai Plastic Products Company Limited

Device: Vinyl Patient Examination Gloves (White, Blue, Yellow)
 510(k) number: K163168

5.0 Indication for Use

The Disposable Vinyl Glove is intended for medical purposes that is worn on the examiners hands to prevent contamination between patient and examiner.

6.0 Device description

The subject device is powder free vinyl patient examination gloves. The subject device is clear, non-colored. The design of subject device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250. The subject device is non-sterile.

7.0 Summary comparing technological characteristics with predicate device

Table1-General Comparison

| Item | Subject device | Predicated device | Comparison |
|--------------------------|---|---|------------|
| 510(k) number | K202008 | K163168 | / |
| Product Code | LYZ | LYZ | Same |
| Regulation No. | 21CFR880.6250 | 21CFR880.6250 | Same |
| Class | I | I | Same |
| Intended Use | The Disposable Vinyl Glove is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. | The Vinyl Examination Glove (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands 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, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile | Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile | Similar |

Table2 Device Dimensions Comparison

| | | | | | | | |
|---------------------------|----------------|------|-----|-----|-----|-----|-----------|
| Predicate Device(K163168) | Designation | Size | | | | | Tolerance |
| | | XS | S | M | L | XL | |
| | Length, mm | 230 | 230 | 235 | 245 | 245 | min |
| | Width, mm | 80 | 85 | 95 | 105 | 115 | ±5 |
| | Thickness, mm: | | | | | | |
| | Finger | 0.05 | | | | | min |
| | Palm | 0.08 | | | | | min |
| Subject Device | Designation | Size | | | | | Tolerance |
| | | XS | S | M | XS | S | |
| | Length, mm | 240 | 240 | 240 | 240 | 240 | min |
| | Width, mm | 80 | 85 | 95 | 105 | 115 | ±5 |
| | Thickness, mm: | | | | | | |
| | Finger | 0.05 | | | | | min |
| | Palm | 0.08 | | | | | min |
| Remark | SAME | | | | | | |

Table3 Performance Comparison

| Item | | | Subject device | Predicated device | Comparison |
|---------------------|------------------------|---------------------|---------------------|--|--|
| Colorant | | | Clear, Non-Colored | White, Blue, Yellow | Analysis1 |
| Physical Properties | Before Aging | Tensile Strength | 14MPa, min | 15MPa, min | Analysis2 |
| | | Ultimate Elongation | 500%min | 380%min | Analysis2 |
| | After Aging | Tensile Strength | 14MPa, min | 15MPa, min | Analysis2 |
| | | Ultimate Elongation | 400%min | 380%min | Analysis2 |
| | Comply with ASTM D5250 | | | Comply with ASTM D5250 | SAME |
| | Freedom from Holes | | | Be free from holes when tested in accordance with ASTM D5151 AQL=2.5 | Be free from holes when tested in accordance with ASTM D5151 AQL=2.5 |
| Powder Content | | | < 0.08 mg per glove | Meet the requirements of ASTM D6124 | SIMILAR |

Analysis1: The subject device (colorless) has different color to the predicate device (White, Blue, Yellow), but all proposed devices are conducted the biocompatibility test, the test results shown that the color difference do not affect the safety of proposed device.

Analysis2: The tensile strength and ultimate elongation are different with that of the predicate, but they all meet the requirements of ASTM D5250, so the differences do not raise any new safety or performance questions.

Table4 Safety Comparison

| Item | | Subject device | Predicated device | Comparison |
|--------------------|---------------|--|-------------------------|------------|
| Material | | Vinyl | Vinyl | SAME |
| Biocompatibility | Irritation | Under the conditions of the study, not an irritant | Comply with ISO10993-10 | SAME |
| | Sensitization | Under conditions of the study, not a sensitizer. | | |
| | Cytotoxicity | Under conditions of the study, did not show potential toxicity to L-929 cells. | / | SIMILAR |
| Label and Labeling | | Meet FDA's Requirement | Meet FDA's Requirement | SAME |

8.0 Non-Clinical Test Conclusion

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

ASTMD5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D5250-19, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

9.0 Clinical Test Conclusion

Clinical testing is not needed for this device.

10.0 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.