K131832

JAN - 7 2014



# 510 (K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification:**

Shandong Binxiang Medical Products Co., Ltd.
No.11, Longshan Road, Wolong Industry Park
Linqu, Shandong, China

**Contact Person:**
Jeffrey Wang
Product Manager

Date summary prepared: Dec 05, 2013

2. **Name of the Device:**

Shandong Binxiang Medical Products Co., Ltd.
Powder-Free Vinyl Patient Examination Gloves, Non-Sterile

3. **Common Name**

Powder-Free Vinyl Patient Examination Gloves, Non-Sterile

4. **Trade Name**

Shandong Binxiang Medical Products Co., Ltd.
Powder-Free Vinyl Patient Examination Gloves, Non-Sterile

5. **Predicate Device Informaton:**

Shijiazhuang Star Plastic Co., Ltd.
Powder Free Vinyl Examination Gloves – (K100699)

Tangshan Zhonghong Pulin Food Products Co., Ltd.
Powder Free Vinyl Examination Gloves – (K022091)

6. **Device Description:**

A Powder-Free Vinyl Patient Examination Gloves is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250). Our Powder-Free Vinyl Patient Examination Gloves do not contain any UPS powder according to the results of testing conducted on the gloves. The residual powder testing is conducted per standards of ASTM D-6124-06, which demonstrates that the powder free glove is less than 2mg/pc. Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Glove, 80LYZ, and meets all requirement of ASTM Standard D5250-06.

7. **Indication for Use:**

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250).

8. **Comparison to Predicate Devices:**

Shandong Binxiang Medical Products Co., Ltd. Powder-Free Vinyl Patient Examination Gloves are substantially equivalent in safety and effectiveness to Tangshan Zhonghong Pulin Food Products Co., Ltd. (K022091) and Shijiazhuang Star Plastic., Co., Ltd. (K100699) Powder-Free Vinyl Patient Examination Gloves. Please find table 7-2 below for comparison details.

9. **Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:**

The standards used for Shandong Binxiang Medical Products Co., Ltd. glove production are based on ASTM-D-5250-06. All testing meets requirements for Physical and Dimensions Testing conducted on gloves, Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AOL 2.5, Inspection Level I, meeting these requirements. Primary Skin irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted with results showing no primary skin irritant or sensitization reactions.

There are no special labeling claims and we do not claim our gloves as hypoallergenic is conducted to insure that our gloves meet our "powder-free" claims (contain no more than 2 mg powder per glove).

10. **Sterilization**

There is no specific device for non-sterile examination gloves. Hand hygiene by rubbing with an alcohol-based hand rub or by washing with soup and water should be performed when appropriate.

11. **Conclusions:**

Shandong Binxiang Medical Products Co., Ltd. Powder-Free Vinyl Patient Examination Gloves conforms fully to ASTM-D-5250-06 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims as shown by data in Section 7. There are no safety/efficacy issues or new claims from the "substantial equivalence" products cited.

**Table 7-2: Side-by-Side Comparison of Intended Use, Design, Material, Physical, Biocompatibility, and Performance Testing**

| | Proposed Device | Predicate Device (K022091) | Predicate Device (K100699) |
|---|---|---|---|
| Description | Shandong Binxiang Medical Products Co., Ltd Powder Free Vinyl Patient Examination Gloves, Clear | Tangshan Zhonghong Pulin Food Products Co., Lid Class I vinyl patient examination gloves, powder-free | Shijiazhuang Star Plastic Co., Ltd Powder Free Vinyl Patient Examination Gloves, Clear |
| Indication for Use | Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner | Substantially equivalent | Substantially equivalent |
| Basic Design | A garment covering the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb. | Substantially equivalent | Substantially equivalent |
| Materials Used | Poly Vinyl Chloride | Same | Same |
| Single Use | Yes | Yes | Yes |
| Size | S,M,L,XL | S,M,L,XL | Information Unavailable |
| Sterile | Not sterile | Not sterile | Not sterile |
| Dimension | Meets ASTM D5150-06 | Meets ASTM D5150-06 | Meets ASTM D5150-06 |
| Physical Property | Meets ASTM D5150-06 | Meets ASTM D5150-06 | Meets ASTM D5150-06 |
| Free of Pinhole | Meets ASTM D5151-99 | Meets ASTM D5151-99 | Meets 21 CFR 800.20 |
| Residue Powder | Meets ASTM D6124-06 | Meets ASTM D6124-06 | Meets ASTM D6124-06 |
| Primary Skin Irritation | ISO 10993-10 passes. The test material was not irritating to the skin of the rabbits | ISO 10993-10 passes | ISO 10993-10 passes |
| Dermal Sensitization | ISO 10993-10 passes. An extract of this test material did not to produce any skin irritation on the pigs | ISO 10993-10 passes | ISO 10993-10 passes |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 7, 2014

Shandong Binxiang Medical Products Company, Limited
Mr. Ray Zhou
Official Correspondent
12390 East End Ave
Chino, CA 91710

Re: K131832
Trade/Device Name: Shandong Binxiang Medical Products Company, Limited
Powder-Free Vinyl Patient Examination Gloves, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Examination Gloves
Regulatory Class: I
Product Code: LYZ
Dated: November 25, 2013
Received: December 2, 2013

Dear Mr. Zhou:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*
K131832

Device Name
Shandong Binxiang Medical Products Co., Ltd. Powder-Free Vinyl Patient Examination Gloves, Non-Sterile

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner (21CFR 880.6250)

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2013.12.31 13:29:35 -05'00'