DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 19, 2016

Zibo Hongchin Plastic and Rubber Co., Ltd
% Ms. Sophie Hao
Official Correspondent
Basic Medical Industries, Inc.
805 Barrington Ave
Ontario, CA 91764

Re: K161390
Trade/Device Name: Vinyl Exam Gloves, Powder Free, Clear
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: November 2, 2016
Received: November 10, 2016

Dear Ms. Hao:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, PhD
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161390

Device Name
Vinyl Exam Gloves, Powder Free, Clear

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 fingers 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)

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)*

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.

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510 (K) SUMMARY

1. **Submitter's Identification:**

Zibo Hongchin Plastic and Rubber Co.,Ltd
No 17 Yingxiong Rd, Zhangdian District, Zibo
Shandong, 255400 China

Date summary prepared: December 8, 2016

2. **Name of the Device:**
Zibo Hongchin Plastic and Rubber Co.,Ltd
Vinyl Exam Gloves, Powder Free, Clear

3. **Common name/classification name of the Device:**
Patient Examination Gloves
Device Class: Class I
Regulation number: 21 CFR 880.6250
Product code: LYZ

4. **Contact Person:**
James Ren, Product Manager
Phone: # 86-1378989666
Zibo Hongchin Plastic and Rubber Co.,Ltd
No 17 Yingxiong Rd, Zhangdian District, Zibo
Shandong, 255400
China

5. **Predicate Device Information:**
Device name: Vinyl Examination Gloves Powder-Free
510(K) #: K022091
Manufacturer name: Tangshan Zhonghong Pulin Food Products Co., Ltd

6. **Device Description:**
Subject device: Vinyl Exam Gloves, Powder Free, Clear
Device Class: Class I
Regulation number: 21 CFR 880.6250
Product code: LYZ
Length: 230 mm min
Width: 94 mm min
Palm Thickness: 0.09 mm min
Fingertip Thickness: 0.085 mm min

Tensile Strength (Mpa)
Before aging 16.96Mpa average
After aging 14.92Mpa average

Ultimate Elongations
Before aging 519% average
After aging 480% average

Device functions: As a barrier, the subject device prevents contamination between patient and examiner

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 fingers to prevent contamination between patient and examiner

8. **Comparison to Predicate Devices:**
Zibo Hongchin Plastic and Rubber Co., Ltd Vinyl Exam Gloves, Powder Free, Clear are substantially equivalent in safety and effectiveness to the Zhonghong Pulin Food Products Co., Ltd Vinyl Examination Gloves, Powder-Free. (K022091)

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

	Proposed Device	Predicate Device (K022091)	COMMENTS
The device	Zibo Hongchin Plastic and Rubber Co.,Ltd Vinyl Exam Gloves, Powder Free, Clear	Vinyl Examination Gloves, Powder-Free Tangshan Zhonghong Pulin Food Products Co., Ltd	
Regulation #	21 CFR 880.6250	21 CFR 880.6250	Similar
Device Class	Class I	Class I	Similar
Product Code:	LYZ	LYZ	Similar
Indications for Use	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner	A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner	Similar
Basic Design	Cover the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Cover the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Similar

Device Materials	Poly Vinyl Chloride	Poly Vinyl Chloride	Similar
Residual Powder	<2 mg per glove and meet the requirement of ASTM D6124-06.	< 2 mg per glove	Similar
Length on Medium Size	230 mm min	230 mm min	Similar
Width of Palm on Medium Size	94 mm min	94 mm min	Similar
Palm Thickness	0.09 mm min	0.09 mm min	Similar
Fingertip Thickness	0.085 mm min	0.085 mm min	Similar
Tensile Strength(Mpa) and Ultimate Elongations Before Aging:	16.96 average (Tensile strength) 519% average (elongated rate) Meet requirement under ASTM D5250-06	16.96 average (Tensile strength) 519% average (elongated rate) Meet requirement under ASTM D5250-06	Similar
Tensile Strength(Mpa) and Ultimate Elongations After Aging:	14.92 average (Tensile strength) 480% average (elongated rate) Meet requirement under ASTM D5250-06	14.92 average (Tensile strength) 480% average (elongated rate) Meet requirement under ASTM D5250-06	Similar
Pinhole Results	AQL 2.5, met per ASTM D5151-06	AQL 2.5	Similar
Primary Skin Irritation Per ISO-10993-10	Not an irritant under the condition of study	Not an irritant under the condition of study	Similar
Dermal Sensitization	Not a sensitizer under the condition of study	Not a sensitizer under the condition of study	Similar
Labeling	Labels include: Product name; Non-sterile; color; "single use Only" size, Quantity, ambidextrous, lot number, distributor name, indication for use and manufacturer address.	Labels include: Product name; Non-sterile; color; "single use" size, Quantity, ambidextrous, distributor name, indication for use and manufacturer address.	Similar
Substantially equivalent comparison	Powder-free Vinyl Patient Examination Glove, the subject device in K161390, has similar intended use and is substantially equivalent to the predicate device (K022091).		

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

The standards used for Zibo Hongchin Plastic and Rubber Co.,Ltd glove production are based on ASTM-D-5250-06. All testing meets requirements for dimensions, physical properties, barrier properties and powder under ASTM-D-5250-06. Physical property test conducted on gloves meets Inspection Level S-2, AQL 2.5.

The FDA 1000 ml. Water Fill Test was also conducted with samplings of AQL 2.5, Inspection Level I, meeting these requirements.

Biocompatibility test results showing no primary skin irritation or sensitization under the conditions of study.

10. **Patient Contact**

The glove is available for surface-contacting with less than 24 hours duration.

11. **Sterilization**

Subject device is non-sterile examination gloves for single use.

12. **Discussion of Clinical Tests Performed:**

Not Applicable

13. **Conclusions:**

The Zibo Hongchin Plastic and Rubber Co., Ltd Vinyl Exam Gloves, Powder Free, Clear are substantially equivalent to the predicate Vinyl Powder Free Examination Glove cleared under K022091.