DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 5, 2016

Zibo Huiying Medical Products, Co. Ltd.
% Sophie Hao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Ave
Chino, California 91710

Re: K153028
Trade/Device Name: Synmax Synthetic Patient Examination Vinyl Gloves, Powder Free, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: December 18, 2015
Received: December 18, 2015

Dear Sophie 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division 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)*
K153028

Device Name
Synmax Synthetic Patient Examination Vinyl Gloves, Powder Free, Blue

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.

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"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

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

1. **Submitter's Identification:**
   Zibo Huiying Medical Products, Co. Ltd.
   No. 3, Da Wu Road
   Linzi, Shandong
   China
   Tel: 86-18953386552

   Contact Person
   Sophie Hao
   Tel: 909-548-4828, Fax: 909-548-4808
   Sophiehao@basicmedical.com

Date summary prepared: Jan 7, 2016

2. **Name of the Device:**
   Synmax Synthetic Patient Examination Vinyl Gloves,
   Powder Free, Blue

3. **Common Name:**
   Patient Examination Gloves

4. **Predicate Device Information:**
   Grand Work Plastic Products Co., Ltd.
   Vinyl Nitrile Co-Polymer Powder Free Exam Blue Gloves (K051662)

5. **Device Description:**
   Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Vinyl Patient Examination Gloves, LYZ, and meets all requirements of ASTM D5250-06.

6. **Intended 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.(21 CFR 880.6250)

7. **Comparison to Predicate Devices on Indication for Use:**
   Zibo Huiying Medical Products, Co. Ltd. Synmax Synthetic Patient Examination Vinyl Gloves, Powder Free, Blue is substantially equivalent in safety, and effectiveness to Grand Work Plastics Product Vinyl Nitrile Co-Polymer Powder Free Exam Blue Glove (K051662).

8. **Discussion of Non-Clinical Test Performed for Determination of Substantial Equivalence are as Follows:**
The standards used for Zibo Huiying Medical Products, Co. Ltd.'s gloves product are based on ASTM D-5250. 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 based on ASTM-D5151-06 was also conducted samplings of AQL 2.5 inspection level G-1, meeting these requirements. Primary Skin Irritation and Skin Sensitization (allergic contact dermatitis) testing was conducted in accordance with ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization with results showing no primary skin irritation or sensitization reactions under the conditions tested.

There are no special labeling claims and we do not claim our gloves as hypoallergenic on our labels.

A Residual Powder Test that based on ASTM D-6124 for start to finish inspection is conducted to insure that our gloves meet our "powder-free" claims (contains no more then 2 mg powder per glove).

9. **Patient Contact**
The glove is available for surface-contacting with less than 24 hours duration.

10. **Sterilization**
The subject device is non-sterile.

11. **Discussion of Clinical Tests Performed:**
Not Applicable – There is no hypoallergenic Claim.

12. **Device Comparison Table**
Please see below for detailed updated comparison between our device and predicate device.

13. **Conclusions:**
The Synmax Synthetic Patient Examination Vinyl Glove, Powder Free (Blue) is substantially equivalent to the Grand Works Plastics Vinyl Nitrile Co-Polymer Powder Free Exam Gloves (Blue). Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Grand Works Plastics Vinyl Nitrile Co-Polymer Powder Free Exam Gloves (Blue) cleared under K051662.

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

	Proposed Device	Predicate Device (K051662)
Description	Zibo Huiying Medical Products, Co. Ltd. Synmax Synthetic Examination Vinyl Gloves, Powder Free, Blue	Grand Work Plastics Product Vinyl Nitrile Co-Polymer Powder Free Exam Blue Gloves
Indication for use	Cover the hand and wrist area. It is a disposable device which is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.	Cover the hand and wrist area. It is a disposable device which is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.
Labeling: Labels on the carton	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.
Device Materials	Poly Vinyl Chloride Polyurethane Diisononyl Phthalate (DINP)	Poly Vinyl Chloride Nitrile Polyurethane Diisononyl Phthalate (DINP)
Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 16.9 Average Ultimate Elongations: 550%	Substantially Equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. Tensile Strength: 16 mpa min Elongation: 500 % min
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 14.4 Average Ultimate Elongations: 500%	Substantially equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. Tensile Strength: 14 mpa min, Elongation: 400 % min
Overall Length on Medium Size	Average over 234mm	Substantially equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. 230 min
Width of Palm on Medium Size	Average 96mm	Substantially equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. 95 ± 10 mm
Palm Thickness	Average 0.096 mm	Substantially equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. 0.05 mm min

Finger Thickness	Average 0.98 mm	Substantially equivalent Conforms to ASTM D5250 and ASTM D6319 -00al. 0.05 mm min
Residual Powder	According to ASTM D6124-06 Standard Test Method for Residual Powder on Medical gloves for the determination of residual powder content. Testing result indicates the weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found according to ASTM D6124-06.	Substantially equivalent Conforms to ASTMD6124-06 The weight of all types of residual or powder on finished powder-free gloves as < 2 mg per glove and there is no defect glove found
Pinhole Results	According to ASTM D5151-06, Testing result indicates pinhole were found less than two pieces gloves out of 125 pieces gloves. AQL 2.5 is met.	Substantially equivalent Conforms to ASTM D5151-06 AQL 2.5
Biocompatibility Result: Primary Skin Irritation	Under the conditions tested, the subject device was not an irritant	Substantially equivalent The subject device was not an irritant
Dermal Sensitization	Under the conditions tested, the subject device was not a sensitizer	Substantially equivalent The subject device was not a sensitizer
Summary of comparison	The Synmax Synthetic Patient Examination Vinyl Glove, Powder Free (Blue) is substantially equivalent to the Grand Works Plastics Vinyl Nitrile Co-Polymer Powder Free Exam Gloves (Blue). Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Grand Works Plastics Vinyl Nitrile Co-Polymer Powder Free Exam Gloves (Blue) cleared under K051662.	