DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 18, 2016

Shandong Feiyang Professional Gloves Company Limited
% Sophie Hao
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Ave
Chino, CA 91710

Re: K152517
Trade/Device Name: Nitrile Examination Gloves, Powder Free, (White)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: February 25, 2016
Received: February 29, 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,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
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)*
K152517

Device Name
Nitrile Examination Gloves, Powder Free, (White)

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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 Feiyang Professional Gloves Company Limited
338 Huaqing Drive, Qixin Chemical Industry Zone,
Qinzhou, China

Contact Person: Sophie Hao
Tel: 909-548-4828
Fax: 909-548-4807
Email: sophiehao@basicmedical.com

Date summary prepared: March 18, 2016

2. **Name of the Device:**

Nitrile Examination Gloves, Powder Free, (White)

3. **Proprietary/trade name of the Device:**

Nitrile Examination Gloves, Powder Free, (White)

4. **Common name of the Device:**

Nitrile Examination Gloves, Powder Free, (White)

5. **Classification name of the Device:**

Nitrile Examination Gloves, Powder Free, (White)
Class I, Non-Sterile Powder-Free Patient Examination Gloves.

6. **Predicate Device Information:**

Tangshan Zhonghong Pulin Group Co., Ltd.
Powder Free Nitrile Patient Examination Gloves (K082598)

7. **Device Description:**

Subject device: Nitrile Examination Gloves, Powder Free, (White)
Device Class: Class I
Regulation number: 21 CFR 880.6250
Product code: LZA

Length: 230 mm min
Width: 75 mm min
Palm Thickness: 0.05 mm min
Fingertip Thickness: 0.097 mm min
Tensile Strength (Mpa)
Before aging 15Mpa min
After aging 14Mpa min
Ultimate Elongations
Before aging 480% min
After aging 400% min

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

Significant physical and performance characteristics of the device: The subject device is manufactured based on ASTM D6319-10. All testing meets requirements for physical properties and dimension testing conducted on gloves. The water leak testing meets Inspection Level I, AQL 2.5. Primary Skin irritation and Skin Sensitization testing, based on ISO 10993-10, was conducted with results showing no primary skin irritant or sensitization reactions under the conditions of the studies. Residual powder on finished powder-free glove was <2 mg per glove, determined by ASTM D6124.

8. Intended 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)

9. Comparison to Predicate Devices:

Shandong Feiyang Professional Gloves Company Limited Nitrile Examination Gloves, Powder Free, (White) are substantially equivalent in safety and effectiveness to the Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves.

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

	Proposed Device	Predicate Device (K082598)
Description	Shandong Feiyang Professional Gloves Company Limited Nitrile Examination Gloves, Powder Free, (White)	Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves
Indication for Use	Disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner
Basic Design	A garment covering the hand and wrist area. Have separate sheaths or openings for each finger and the thumb.	A garment covering the hand and wrist area. Have separate sheaths or openings for each finger and the thumb.
Materials Used	Nitrile Sulfur Accelerator, ZDBC	Nitrile Sulfur Accelerator, ZDBC
Product Code:	LZA	LZA
Regulation #	21 CFR 880.6250	21 CFR 880.6250
Device Class	Class I	Class I
Labeling	Labels include: Product name; color; "single use Only" size, piece count, lot number, distributor name, and manufacturer address.	Substantially equivalent
Single Use	Yes	Yes
Size	XS,S,M,L,XL	Substantially equivalent
Non-Clinical results: Residual Powder	<2 mg per glove Meet the requirement of ASTM D6124-06.	Meet ASTM D6124-06
Sterile	Not sterile	Not sterile
Physical Properties: Length (mm)	XS ≥ 230 S ≥ 230 M ≥ 230 L ≥ 230 XL ≥ 230	230 min Substantially equivalent Confirmed with ASTM D5250-06

Physical Properties: Width of Palm (mm)	XS 80±5 S 87±5 M 97±5 L 107±5 XL 117±5	75 min Substantially equivalent Confirmed with ASTM D5250-06
Physical Properties: Palm Thickness (mm)	XS 0.07±0.02 S 0.07±0.02 M 0.07±0.02 L 0.07±0.02 XL 0.07±0.02	0.05 min Substantially equivalent Confirmed with ASTM D5250-06
Physical Properties: Fingertip Thickness (mm)	XS 0.10±0.03 S 0.10±0.03 M 0.10±0.03 L 0.10±0.03 XL 0.10±0.03	0.070min Substantially equivalent Confirmed with ASTM D5250-06
Dimensions with Tolerances (All sizes): Before Aging: Tensile Strength(Mpa) and Ultimate Elongations	≥ 14mpa 500%	⩾ 14mpa 500% Substantially equivalent Meet ASTM D5250-06
Dimensions with Tolerances (All sizes): After Aging: Tensile Strength(Mpa) and Ultimate Elongations	≥14mpa 500%	⩾ 14mpa 500% Substantially equivalent Meet ASTM D5250-06
Primary Skin Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant
Dermal Sensitization	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer
Summary of comparison	Based on the performance characteristics of Shandong Feiyang Professional Gloves Company Limited Synthetic, Nitrile Examination Gloves, Powder Free, (White), Shandong Feiyang Professional Gloves Company Limited Synthetic, Nitrile Examination Gloves, Powder Free, (White) is as safe, as effective, and perform as well as the Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves. Therefore, your device is substantially equivalent to the predicate.	

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

The standards used for Shandong Feiyang Professional Gloves Company Limited glove production are based on ASTM-D6319-10. 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 AQL 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.

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

Not Applicable

12. **Conclusions:**

Shandong Feiyang Professional Gloves Company Limited Nitrile Examination Gloves, Powder Free, (White) conform fully to ASTM-D6319-10 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims. The conclusions drawn from the nonclinical tests demonstrate that the device is as safe and as effective, and performs as well as the legally marketed device.