



Food and Drug Administration
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August 8, 2014

Shandong Xinshi Medical Products Co, Ltd.
Mr. Ray Zhou
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Avenue
Chino, CA 91710

Re: K133325
Trade/Device Name: Blue Nitrile Powder-Free Exam Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: June 30, 2014
Received: July 7, 2014

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,

 **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

Indications for Use

510(k) Number (if known)

K133325

Device Name

Blue Nitrile Powder-Free Exam Glove

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)

Sreekanth
Gutala -S



Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
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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 Xinshi Medical Products Co., Ltd.
No. 566 Baiyun Road, Hanting Development Zone,
Weifang, Shandong,
China

Contact Person: Ray Zhou

Tel: 909-548-4828

Fax: 909-548-4807

Email: rayzhou@basicmedical.com

Date summary prepared: August 7, 2014

2. **Name of the Device:**

Blue Nitrile Powder-Free Exam Glove

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

Blue Nitrile Powder-Free Exam Glove

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

Blue Nitrile Powder-Free Exam Glove

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

Blue Nitrile Patient Exam glove: Class I, Non-Sterile Powder-Free Patient Examination Gloves.

6. **Predicate Device Information:**

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

7. **Device Description:**

Classified by FDA's General and Plastic Surgery Device panel as Class I, 21 CFR 880.6250, Powder-Free Nitrile Patient Examination Glove, 80LZA, and meets all requirement of ASTM Standard D6319-10.

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 Xinshi Medical Products Co., Ltd. Blue Nitrile Powder-Free Exam Glove are substantially equivalent in safety and effectiveness to the Tangshan Zhonghong Pulin Group Co., Ltd. Powder-Free Nitrile Patient Examination Gloves.

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

The standards used for Shandong Xinshi Medical Products Co., Ltd. glove production are based on ASTM-D-6319-10. 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.

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).

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

Not Applicable – There is no hypoallergenic claim.

12. **Conclusions:**

Shandong Xinshi Medical Products Co., Ltd. Blue Nitrile Powder-Free Exam Glove conform fully to ASTM-D-6319-10 standard as well as applicable 21 CFR references, and, meets pinhole FDA requirements, biocompatibility requirements and labeling claims. The conclusion drawn from the nonclinical test demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.

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

	Proposed Device	Predicate Device (K082598)
Description	Shandong Xinshi Medical Products Co., Ltd. Synthetic, Blue Nitrile Powder-Free Exam Glove	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 or finger to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand or finger 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 Latex (NBR) Sulfur Accelerator, ZDBC	Nitrile Latex (NBR) Sulfur Accelerator, ZDBC
Single Use	Yes	Yes
Size	S,M,L,XL	Information Unavailable
Sterile	Not sterile	Not sterile
Before Aging: Tensile, Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 28.77 Average Ultimate Elongations: 759.23%	Substantially equivalent
After Aging: Tensile Strength(Mpa) and Ultimate Elongations	Average Tensile Strength (Mpa): 24.00 Average Ultimate Elongations: 712.31%	Substantially equivalent
Overall Length on Medium Size	Average 231 mm	Substantially equivalent
Width of Palm on Medium Size	Average 95.15 mm	Substantially equivalent
Palm Thickness	Average 0.08 mm	Substantially equivalent
Finger Thickness	Average 0.09 mm	Substantially equivalent
Free of Pinhole	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.	Meets ASTM D5151-06

Residue 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.	Meets ASTM D6124-06
Primary Skin Irritation	under the conditions of the study, not an irritant	under the conditions of the study, not an irritant
Dermal Sensitization	under conditions of the study, not a sensitizer	under conditions of the study, not a sensitizer
Summary of comparison	Shandong Xinshi Medical Products Co., Ltd. Synthetic, Blue Nitrile Powder-Free Exam Glove (subject device) and Tangshan Zhonghong Pulin Group Co., Ltd. Powder Free Nitrile Patient Examination Gloves (predicate device) are substantially equivalent in all technological characteristics, including tensile strength, ultimate elongations size, thickness, residual powder and pinhole.	