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

November 21, 2016

Shandong Baisheng Medical Products Co., Ltd.
% John Zhao
Official Correspondence
Basic Medical Industries, Inc.
805 Barrington Ave
Ontario, California 91764

Re: K161944
Trade/Device Name: Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: October 7, 2016
Received: October 19, 2016

Dear John Zhao:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*
K161944

Device Name
Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs

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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
1.	Carmustine (BCNU) (3.3 mg/ml)	13.6
2.	Cisplastin, (1.0 mg/ml)	>240
3.	Cyclophosphamide (20 mg/ml)	>240
4.	Doxorubicin HCl (2.0 mg/ml)	>240
5.	Etoposide (Toposar) (20 mg/ml)	>240
6.	Fluorouracil (50 mg/ml)	>240
7.	Methotrexate (25 mg/ml)	>240
8.	Mitomycin C (0.5 mg/ml)	>240
9.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
10.	Thiotepa (10 mg/ml)	26.9
11.	Vincristine Sulfate (1 mg/ml)	>240

Please note the following drugs, Carmustine and Thiotepa, have extremely low permeation times of 13.6 and 26.9 minutes, respectively.

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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Shandong Baisheng Medical Products Co., Ltd.
11 Longshan Road, Wolong Industry Park
Linqu, Shandong, China
Tel: 0086-536-7510508

510 (K) SUMMARY

K161944

Shandong Baisheng Medical Products Co., Ltd.

Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs

Manufacturer:	Shandong Baisheng Medical Products Co., Ltd. 11 Longshan Road, Wo long Industry Park Linqu, Shandong, China
Regulatory Affairs Contact:	John Zhao, 805 Barrington Ave Ontario, CA 91764
Telephone Number:	(909) 980-1678
Fax Number:	(909) 980-1758
Date Summary Prepared:	November 8, 2016
Product Trade Name:	Shandong Baisheng Medical Products Co., Ltd. Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs
Device Classification Name :	Patient Examination gloves (21 CFR 880.6250).
Device Class :	Class 1.
Product Code :	LZA and LZC.

Shandong Baisheng Medical Products Co., Ltd.
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Predicate Devices:	K141623 - Eco Medi Glove SDN BHD. EMG Blue Nitrile Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs
Reason for 510(k) Submission:	New device
Device Description:	The subject device in this 510(k) Notification is Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs. The subject device is a patient examination glove made from nitrile latex compound, Blue color, powder free and non-sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs. The Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner (product Code LZA) and is used with chemotherapy drugs (Product code LZC). The subject device is substantially equivalent to the legally marketed Nitrile Medical Examination Gloves (product Code LZA and LZC).
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。 **In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.**

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Table 1: Chemotherapy Drug Permeation Time

	Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Minutes)
1.	Carmustine (BCNU) (3.3 mg/ml)	13.6
2.	Cisplastin, (1.0 mg/ml)	>240
3.	Cyclophosphamide (20 mg/ml)	>240
4.	Doxorubicin HCl (2.0 mg/ml)	>240
5.	Etoposide (Toposar) (20 mg/ml)	>240
6.	Fluorouracil (50 mg/ml)	>240
7.	Methotrexate (25 mg/ml)	>240
8.	Mitomycin C (0.5 mg/ml)	>240
9.	Paclitaxel (Taxol) (6.0 mg/ml)	>240
10.	Thiotepa (10 mg/ml)	26.9
11.	Vincristine Sulfate (1 mg/ml)	>240

CAUTION: Please note the following drugs, Carmustine and Thiotepa, have extremely low permeation times of 13.6 and 26. 9 minutes, respectively.

Comparison to Predicate Devices:

Shandong Baisheng Medical Products Co., Ltd. Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs, are substantially equivalent in safety and effectiveness to the ECO MEDI GLOVE SDN. BHD. Powder-Free Nitrile Patient Examination Gloves with Tested for use with Chemotherapy Drugs.

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

The standards used for Shandong Baisheng Medical Products Co., Ltd. glove production are based on ASTM-D-6319-05. All testing passed 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.

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Gloves were tested and meet the "Powder-free" claim (contain no more than 2 mg powder per glove).

Discussion of Clinical Tests Performed:

Not Applicable – There is no hypoallergenic claim.

Substantial Equivalence:

The proposed device is substantially equivalent to the predicate device identified in this 510(k) summary. Substantial equivalence can be established in regard to intended use, physical properties and characteristics, design and product features.

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Table 2: Comparison between the device and predicate device

Characteristics	Acceptance Criteria	Shandong Baisheng Medical Products Co., Ltd. Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs	EMG Blue Nitrile Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs
K-Number		K161944	K141623
Product Code	LZA, LZC	LZA, LZC	LZA, LZC
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger 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 finger to prevent contamination between patient and examiner.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.
Material used	Nitrile	Nitrile	Nitrile
Color	Blue	Blue	Blue
Single use	Single Use	Yes	Yes
Non Sterile	Non Sterile	Non Sterile	Non Sterile
Dimensions	Overall Length (mm) Min 270mm Width (± 5mm) Size S = 85mm Size M = 95mm Size L = 105mm Size XL = 115mm Thickness at Palm (mm) Min; 0.10mm Thickness at Finger	Meets ASTM D6319-10	Meets ASTM D6319-10

	Tip (mm) Min 0.10 mm		
Physical properties	Before Ageing Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min After Aging at 70°C for 168 hrs @ 100°C for 22 hrs Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06
Residual Powder	< 2.0 mg/pc	Meets ASTM D5151-06	Meets ASTM D5151-06
Biological Evaluation on Medical Device - -Primary Skin Irritation Test		Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.
Biological Evaluation on Medical Device - Dermal Sensitization Assay		Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.

Resistance against Chemotherapy Drugs	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-05(2013)	1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 13.6 min. 2)Cisplastin (1.0mg/ml or 10,000ppm) Breakthrough time : >240 min. 3)Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 4) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : >240 min. 5) Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 6) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 7) Flourouracil (50mg/ml or 50,000ppm), Breakthrough time : >240 min.	1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 1.3 min. 2)Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 3) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : >240 min. 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 min. 7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min.

		8) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min. 9) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min. 10) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 26.9 min 11)Vincristine Sulfate (1mg/ml or1000ppm) Breakthrough time : >240 min.	8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min. 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 63.9 min

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that Shandong Baisheng Medical Product Co., Ltd. Synthetic Nitrile Patient Examination Gloves, Powder Free, Blue Color, and Tested for Use with Chemotherapy Drugs (K161944) is as safe, as effective, and performs as well as the legally marketed predicate device K141623, EMG Blue Nitrile Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs.