



October 12, 2017

Blue Sail Medical Co.,Ltd  
Robin Liu  
RA/QA Department Manger  
No. 21 Qingtian Road, Qilu Chemical Industrial Park  
Zibo, 255414 CN

Re: K171782

Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue, Tested for Use with  
Chemotherapy drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA, LZC

Dated: July 31, 2017

Received: August 10, 2017

Dear Robin Liu:

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 (DICE) 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 (DICE) 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

## Indications for Use

510(k) Number (if known)

**K171782**

Device Name

Powder Free Nitrile Examination Gloves, Blue, Tested for Use with Chemotherapy Drugs

Indications for Use (Describe)

The Powder Free Nitrile Examination Gloves, Blue, 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.

The proposed device was tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The following chemicals have been tested with proposed device.

Test Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	35.3
Cisplatin	1.0 mg/ml(1,000 ppm)	>240
Cyclophosphamide (Cytoxan)	20 mg/ml(20,000 ppm)	>240
Doxorubicin Hydrochloride	2.0 mg/ml(2,000 ppm)	>240
Eotosome (Toposar)	20.0 mg/ml(20,000 ppm)	>240
Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
Mechlorethamine HCl	1.0 mg/ml(1,000 ppm)	>240
Methotrexate	25.0 mg/ml(25,000 ppm)	>240
Mitomycin C	0.5 mg/ml(500 ppm)	>240
Paclitaxel (Taxol)	6.0 mg/ml(6,000 ppm)	>240
*Thiotepa	10.0 mg/ml(10,000 ppm)	29.2
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	>240

Please note that the following drugs have lower permeation times:

Carmustine (BCNU): 35.3 minutes and Thiotepa: 29.2 minutes.

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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