



March 18, 2022

Shandong Blue Sail Health Technology Co., Ltd  
Shi Haifeng  
Vice General Manager  
No. 1888 Langgao Road,  
Langshan Advanced Technology Industrial Park  
Weifang, Shandong 262600  
China

Re: K220228

Trade/Device Name: Powder Free Nitrile Examination Gloves, Blue and Violet Blue, Test For Use  
With Chemotherapy Drugs

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I, reserved

Product Code: LZA, LZC, OPJ

Dated: January 20, 2022

Received: January 27, 2022

Dear Shi Haifeng:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K220228

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, Test 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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	22.4
Cisplatin	1.0 mg/ml(1,000 ppm)	>240
Cyclophosphamide (Cytoxan)	20 mg/ml(20,000 ppm)	>240
Dacarbazine	10 mg/ml(10,000 ppm)	>240
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	>240
Etoposide	20.0 mg/ml(20,000 ppm)	>240
Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
Methotrexate	25.0 mg/ml(25,000 ppm)	>240
Mitomycin C	0.5 mg/ml (500 ppm)	>240
Paclitaxel	6.0 mg/ml(6,000 ppm)	>240
*Thio Tapa	10.0 mg/ml(10,000 ppm)	73.1
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	>240

Please note that the following drugs have low permeation times:

Carmustine (BCNU) 3.3mg/ml 22.4 Minutes

Thio Tapa 10.0 mg/ml 73.1 Minutes.

Warning: Don't use with either Carmustine (BCNU) or Thio Tapa

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."*

## Indications for Use

510(k) Number (if known)  
K220228

Device Name

Powder Free Nitrile Examination Gloves, Violet Blue, Tested For Use With Chemotherapy Drugs

Indications for Use (Describe)

The Powder Free Nitrile Examination Gloves, Violet Blue, Test 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. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 (2019) Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
*Carmustine (BCNU)	3.3 mg/ml (3,300 ppm)	23.5
Cisplatin	1.0 mg/ml(1,000 ppm)	>240
Cyclophosphamide (Cytoxan)	20 mg/ml(20,000 ppm)	>240
Dacarbazine	10 mg/ml(10,000 ppm)	>240
Doxorubicin HCl	2.0 mg/ml(2,000 ppm)	>240
Etoposide	20.0 mg/ml(20,000 ppm)	>240
Fluorouracil	50.0 mg/ml(50,000 ppm)	>240
Methotrexate	25.0 mg/ml(25,000 ppm)	>240
Mitomycin C	0.5 mg/ml(500 ppm)	>240
Paclitaxel	6.0 mg/ml(6,000 ppm)	>240
*Thio Tapa	10.0 mg/ml(10,000 ppm)	66.6
Vincristine Sulfate	1.0 mg/ml(1,000 ppm)	>240

Please note that the following drugs have low permeation times:

Carmustine (BCNU) 3.3mg/ml 16.9 Minutes

Thio Tapa 23.5 mg/ml 66.6 Minutes.

Warning: Don't use with either Carmustine (BCNU) or Thio Tapa

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)

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