May 26, 2022

Grand Work Plastic Products Co., Ltd
℅ Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K220249
Trade/Device Name: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO
Dated: April 18, 2022
Received: April 26, 2022

Dear Kathy 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. 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D
Acting 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220249

Device Name
Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
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. In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978 standards.
Gloves is direct contact and not to be worn for more than 24 hours

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240
Carmustine 3.3 mg/ml (3,300 ppm)	22.4
Chloroquine 50mg/ml (50,000ppm)	>240
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cyclosporin 100 mg/ml (100,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240
Docetaxel HCL, 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	46.3
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade, 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 22.4 minutes, Thiotepa: 46.3 minutes
WARNING: DO NOT USE WITH CARMUSTINE
WARNING: DO NOT USE WITH THIOTEPA

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

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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Grand Work Plastic Products Co., Ltd.

Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR §807.92.

The assigned 510(K) number is: K220249

Date Prepared: April 18, 2022

1. Owner's Identification:

Mrs. Wu Yuli
Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Hebei, 050000, China
Tel: 86-311-66179668

Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Ave., Chino, CA 91710
Tel: 909-590-1611

2. Name of the Device:

Trade Name: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
Classification Regulation: 880.6250
Classification Panel: 880 General Hospital and Personal Use
Product Code: LZA, LZC and QDO
Device Class: Class I

3. Predicate Device Information:

Hartalega SDN.BHD.
Sterile Nitrile Powder Free Examination Glove Tested for use with Chemotherapy Drugs and Fentanyl Citrate (Blue) (K201531)

4. Device Description:

The subject device is Sterile Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs And Fentanyl Citrate (Blue). The subject device is a patient examination glove made from nitrile latex compound, blue color, powder free and sterile (Per 21 CFR 880.6250, class I). The device is direct contact and not to be worn for more than 24 hours. The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves.
Additionally, the gloves have been tested for biocompatibility per 10993-10, 10993-11 and permeability to chemotherapy drugs and Fentanyl Citrate per ASTM D6978-05(2019).

5. Indications for Use:

A patient examination glove is disposable device intended for medical purpose 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 & Fentanyl Citrate and provides protection against following chemotherapy drugs and the minimum breakthrough time are listed as follows.

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin Sulfate 15mg/ml (15000 ppm)	>240
Busulfan 6mg/ml (6,000 ppm)	>240
Carboplatin 10mg/ml (10,000 ppm)	>240

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

Carmustine 3.3 mg/ml (3,300 ppm)	22.4
Chloroquine 50mg/ml (50,000ppm)	>240
Cisplatin 1mg/ml (1,000 ppm)	>240
Cyclophosphamide 20mg/ml (20,000 ppm)	>240
Cyclosporin 100 mg/ml (100,000 ppm)	>240
Cytarabine HCL, 100 mg/ml (100,000 ppm)	>240
Dacarbazine 10 mg/ml (10,000 ppm)	>240
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	>240
Docetaxel HCL, 10 mg/ml (10,000 ppm)	>240
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240
Epirubicin HCL, 2 mg/ml (2,000 ppm)	>240
Etoposide, 20 mg/ml (20,000 ppm)	>240
Fludarabine, 25 mg/ml (25,000 ppm)	>240
Fluorouracil, 50mg/ml (50,000ppm)	>240
Gemcitabine, 38mg/ml (38,000ppm)	>240
Idarubicin HCL, 1mg/ml (1,000ppm)	>240
Ifosfamide, 50mg/ml (50,000ppm)	>240
Irinotecan, 20mg/ml (20,000ppm)	>240
Mechlorethamine HCI, 1mg/ml (1,000ppm)	>240
Melphalan, 5mg/ml (5,000ppm)	>240
Methotrexate, 25mg/ml (25,000ppm)	>240
Mitomycin C, 0.5mg/ml (500ppm)	>240
Mitoxantrone HCL, 2mg/ml (2,000ppm)	>240
Oxaliplatin, 5mg/ml (5,000ppm)	>240
Paclitaxel, 6mg/ml (6,000ppm)	>240
Paraplatin, 10mg/ml (10,000ppm)	>240
Retrovir, 10mg/ml (10,000ppm)	>240
Rituximab, 10mg/ml (10,000ppm)	>240
Thiotepa, 10mg/ml (10,000ppm)	46.3
Topotecan, 1mg/ml (1,000ppm)	>240
Trisenox, 1mg/ml (1,000ppm)	>240
Velcade, 1mg/ml (1,000ppm)	>240
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240
Fentanyl Citrate Injection (100 mcg/2ml)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine: 22.4 minutes, Thiotepa: 46.3 minutes
WARNING: DO NOT USE WITH CARMUSTINE
WARNING: DO NOT USE WITH THIOTEPA

6. Specification for Nitrile Gloves:

Items	Acceptance Criteria	Results
Length	Minimum 230mm	All size ≥230
Palm Width	XS：70±10mm	76-78mm
	S：80±10mm	86-88 mm
	M:95±10mm	96 -98mm
	L:110±10mm	106-108 mm
	XL：120±10mm	116-118 mm

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

	XXL：130±10mm	126-128 mm
Thickness	Palm: 0.05mm (min)	0.07-0.08mm
	Finger: 0.05mm (min)	0.09-0.11mm
Tensile Strength, Before Aging	14MPa, min	15.7-20.6 MPa
Tensile Strength, After Accelerated Aging	14MPa, min	15.5-19.5 MPa
Ultimate Elongation, Before Aging	500%, min	500-550%
Ultimate Elongation, After Accelerated Aging	400%, min	410-510%
Freedom from holes	G-I, AQL 2.5	Meet and above AQL2.5 requirements
Powder-Content	≤ 2 mg per glove	≤ 2 mg, meet requirements

Gloves meet all the specification listed in ASTM D 6319-19.

7. Comparison of Subject Device and Predicate Device:

Characteristics	Subject Device K220249	Predicate Device K201531	Remark
Trade Name	Sterile Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Nitrile Examination Gloves Sterile Tested for Use with Chemotherapy Drugs claim, White	Similar
Product Code	LZA , LZC and QDO	LZA , LZC and QDO	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	Subject device is a disposable device intended for medical purpose 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.	Predicate device is a disposable device intended for medical purpose 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.	Same
Description	Sterile Examination glove made of Nitrile and color Blue and tested with chemotherapy Drugs	Sterile Examination glove made of Nitrile and color White and tested with chemotherapy Drugs	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Material use	Nitrile Synthetic Latex	Nitrile Synthetic Latex	Same
Color	Blue	Blue	Same
Sterility ISO 11737-2 EN ISO 11137-2	Sterility	Sterility	Same
Single used	Single used	Single used	Same
Non Sterile or Sterile	Sterile	Sterile	Same
10993-10:2010 Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
10993-10:2010 Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
10993-5:2009 In Vitro	Under the conditions of this study,	Under the conditions of this study, the	Same

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

Cytotoxicity Test	the test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systematic toxicity testing.	test article extract showed potential toxicity to L929 cells. Cytotoxicity concern was addressed by acute systematic toxicity testing.	
ISO 10993 Part 11 Acute Systemic Toxicity Test	Under the conditions of this study, there was no evidence of systemic toxicity.	Under the condition of this study, Nitrile Examination glove, sterile shows no adverse biological reaction	Same

Dimensions and Performance Comparison Table:

Technological Characteristics	Subject Device K220249	Predicate Device K201531	Remark
Length	Minimum 230mm	Minimum 230mm	Same
Palm Width (size) (mm)			
XS	70±10	70±10	Same
S	80±10	80±10	Same
M	95±10	95±10	Same
L	110±10	110±10	Same
XL	120±10	120±10	Same
XXL	130±10	/	Different
Thickness(mm)			
Finger	Minimum 0.05	Minimum 0.05	Same
Palm	Minimum 0.05	Minimum 0.05	Same
Tensile Strength, Before Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, Before Aging	500%, min	500%, min	Same
Tensile Strength, After Accelerated Aging	14MPa, min	14MPa, min	Same
Ultimate Elongation, After Accelerated Aging	400%, min	400%, min	Same
Freedom from holes	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	In accordance with ASTM D 5151-19, following ASTM D6319- 19, G-I, AQL 2.5	Same
Residual Powder	≤ 2 mg per glove	≤ 2 mg per glove	Same

Chemotherapy Permeation Comparison Claim:

Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Remark
	Predicate Device	Subject Device	
Bleomycin Sulfate 15mg/ml (15000 ppm)	/	>240	Different
Busulfan 6mg/ml (6,000 ppm)	/	>240	Different
Carboplatin 10mg/ml (10,000 ppm)	/	>240	Different
Carmustine 3.3 mg/ml (3,300 ppm)	26.3	22.4	Similar

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

Chloroquine 50mg/ml (50,000ppm)	/	>240	Different
Cisplatin 1mg/ml (1,000 ppm)	>240	>240	Same
Cyclophosphamide 20mg/ml (20,000 ppm)	>240	>240	Same
Cyclosporin 100 mg/ml (100,000 ppm)	/	>240	Different
Cytarabine HCL, 100 mg/ml (100,000 ppm)	/	>240	Different
Dacarbazine 10 mg/ml (10,000 ppm)	>240	>240	Same
Daunorubicin HCL, 5 mg/ml (5,000 ppm)	/	>240	Different
Docetaxel HCL, 10 mg/ml (10,000 ppm)	/	>240	Different
Doxorubicin HCL, 2 mg/ml (2,000 ppm)	>240	>240	Same
Epirubicin HCL, 2 mg/ml (2,000 ppm)	/	>240	Different
Etoposide, 20 mg/ml (20,000 ppm)	>240	>240	Same
Fludarabine, 25 mg/ml (25,000 ppm)	/	>240	Different
Fluorouracil, 50mg/ml (50,000ppm)	>240	>240	Same
Gemcitabine, 38mg/ml (38,000ppm)	/	>240	Different
Idarubicin HCL, 1mg/ml (1,000ppm)	/	>240	Different
Ifosfamide, 50mg/ml (50,000ppm)	/	>240	Different
Irinotecan, 20mg/ml (20,000ppm)	/	>240	Different
Mechlorethamine HCI, 1mg/ml (1,000ppm)	/	>240	Different
Melphalan, 5mg/ml (5,000ppm)	/	>240	Different
Methotrexate, 25mg/ml (25,000ppm)	>240	>240	Same
Mitomycin C, 0.5mg/ml (500ppm)	>240	>240	Same
Mitoxantrone HCL, 2mg/ml (2,000ppm)	/	>240	Different
Oxaliplatin, 5mg/ml (5,000ppm)	/	>240	Different
Paclitaxel, 6mg/ml (6,000ppm)	>240	>240	Same
Paraplatin, 10mg/ml (10,000ppm)	/	>240	Different
Retrovir, 10mg/ml (10,000ppm)	/	>240	Different
Rituximab, 10mg/ml (10,000ppm)	/	>240	Different
Thiotepa, 10mg/ml (10,000ppm)	97.1	46.3	Similar
Topotecan, 1mg/ml (1,000ppm)	/	>240	Different
Trisenox, 1mg/ml (1,000ppm)	/	>240	Different
Velcade, 1mg/ml (1,000ppm)	/	>240	Different
Vincristine Sulfate, 1mg/ml (1,000ppm)	>240	>240	Same
Fentanyl Citrate Injection (100 mcg/2ml)	>240	>240	Same

8 Summary of Non-Clinical Testing

Non-clinical tests were performed to verify that the subject device will meet the acceptance criteria of the performance test shown below:

Technological Characteristics	Standard / Test /FDA Guidance	Result Summary
Dimensions	ASTM D6319- 19	Meets
Physical Properties	ASTM D6319-19	Meets
Freedom from holes	ASTM D6319- 19 ASTM D5151-19	Meets
Residual Powder	ASTM D 6124-06(2017) ASTM D6319- 19	Meets
Primary Skin Irritation Test	ISO 10993-10:2010	Meets
Dermal Sensitization Assay	ISO 10993-10:2010	Meets
Acute Systemic Toxicity	ISO 10993-11:2017	Meets

Product: Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)

The subject device meets the applicable requirements for patient examination gloves with regards to dimension and sizes, physical properties, freedom from holes and powder Residuals as found in the following standards: ASTM D6139, ASTM D5151, ASTM D6124.The subject device passes biological reactivity testing for dermal sensitization, irritation and acute systemic toxicity with accordance ISO10993-10 and ISO 10993-11.

9. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the Subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.