October 27, 2021

Shanxi Hongjin Plastic Technology Co., Ltd.
Kathy Liu
Project Manager
Hongray USA Medical Products Inc.
3973 Schaefer Avenue
Chino, California 91710

Re: K211604
Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue), Tested 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
Dated: July 23, 2021
Received: September 22, 2021

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,

For 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

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

510(k) Number *(if known)*
K211604

Device Name
Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
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 to prevent contamination between patient and examiner.
Gloves have been tested for use with chemotherapy drugs using ASTM D6978 and will be labeled with a statement of compliance and a summary of the testing results.
Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves:

* Please note that the following drugs have extremely low permeation times:

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin (15.0mg/ml)	>240
Bortezomib (Velcade) 1mg/ml	>240
Busulfan (6.0mg/ml)	>240
Carboplatin, (10.0mg/ml)	>240
Carmustine(BCNU) (3.3 mg/ml)	7.0
Chloroquine, (50.0mg/ml)	>240
Cisplatin (1mg/ml)	>240
Cyclophosphamide (Cytoxan) (20mg/ml)	>240
Cyclosporin, (100.0mg/ml)	>240
Cytarabine, (100.0mg/ml)	>240
Dacarbazine (10mg/ml)	>240
Daunorubicin, HCL (5.0mg/ml)	>240
Docetaxel, (10.0mg/ml)	>240
Doxorubicin HCL (2mg/ml)	>240
Epirubicin HCL (Ellence), (2.0mg/ml)	>240
Etoposide (20mg/ml)	>240
Fludarabine, (25.0mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Gemcitabine (38.0mg/ml)	>240
Idarubicin HCL (1.0mg/ml)	>240
Ifosfamide, (50.0mg/ml)	>240
Irinotecan, (20.0mg/ml)	>240
Mechlorethamine HCI, (1.0mg/ml)	>240
Melphalan, (5.0mg/ml)	>240
Methotrexate (25mg/ml)	>240
Mitomycin C, (0.5mg/ml)	>240
Mitoxantrone, (2.0mg/ml)	>240
Oxaliplatin, (5.0mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Paraplatin, (10.0mg/ml)	>240
Retrovir, (10.0mg/ml)	>240
Rituximab, (10.0mg/ml)	>240
Thio Tepa (10mg/ml)	23.0
Topotecan HCL, (1.0mg/ml)	>240

Trisonex, (1.0mg/ml)	>240
Vincristine, (1.0mg/ml)	>240

Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU): 7.0 minutes, Thio Tepa: 23 minutes,
Warning: Do not use with Carmustine (BCNU) and Thio Tepa.

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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Shanxi Hongjin Plastic Technology Co., Ltd.

Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, Shanxi Province

510(K) SUMMARY

The assigned 510(K) numbers: K211604

Date Prepared: October 27, 2021

1. Owner's Identification:

Mr. Wu Zhigang
Shanxi Hongjin Plastic Technology Co., Ltd.
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, Shanxi Province

Tel: 86-311-66766067
Contact: Ms. Kathy Liu, Project Manager
Address: 3973 Schaefer Avenue, Chino, CA 91710, USA
Tel: 909-590-1611
Email: kathyliu@hongrayusa.com or fdareg@126.com

2. Name of the Device:

Trade / Product Name: Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs
Common Name: Examination Gloves
Classification Name: Patient Examination Glove Specialty
Classification Regulation: 21 CFR 880.6250
Product Code: LZA LZC
Classification Panel: General Hospital
Device Class: Class I

3. Predicate Device Information:

Better Care Plastic Technology Co., Ltd
Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) (K182600)

4. Device Description:

Powder Free Nitrile Examination Gloves(Blue), Tested for Use with Chemotherapy Drugs are Class I Patient Examination Gloves and Specialty Chemotherapy Gloves. They are ambidextrous and come in different sizes—Extra Small, Small, Medium, Large and Extra Large.
Gloves meet the specification of ASTM D6319-19 and have been tested for resistance to permeation by chemotherapy drugs as per ASTM D6978-05(2019).

510(K) SUMMARY

5. Indications for Use:

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 to prevent contamination between patient and examiner.
Gloves have been tested for use with chemotherapy drugs using ASTM D6978-05(2019) and will be labeled with a statement of compliance and a summary of the testing results.
Chemotherapy Drug Permeation

The following chemicals have been tested with these gloves:

Chemotherapy Drug	Minimum BDT (Minutes)
Bleomycin (15.0mg/ml)	>240
Bortezomib (Velcade) 1mg/ml	>240
Busulfan (6.0mg/ml)	>240
Carboplatin, (10.0mg/ml)	>240
Carmustine(BCNU) (3.3 mg/ml)	7.0
Chloroquine, (50.0mg/ml)	>240
Cisplatin (1mg/ml)	>240
Cyclophosphamide (Cytoxan) (20mg/ml)	>240
Cyclosporin, (100.0mg/ml)	>240
Cytarabine, (100.0mg/ml)	>240
Dacarbazine (10mg/ml)	>240
Daunorubicin, HCL (5.0mg/ml)	>240
Docetaxel, (10.0mg/ml)	>240
Doxorubicin HCL (2mg/ml)	>240
Epirubicin HCL (Ellence), (2.0mg/ml)	>240
Etoposide (20mg/ml)	>240
Fludarabine, (25.0mg/ml)	>240
Fluorouracil (50mg/ml)	>240
Gemcitabine (38.0mg/ml)	>240
Idarubicin HCL (1.0mg/ml)	>240
Ifosfamide, (50.0mg/ml)	>240
Irinotecan, (20.0mg/ml)	>240
Mechlorethamine HCI, (1.0mg/ml)	>240
Melphalan, (5.0mg/ml)	>240
Methotrexate (25mg/ml)	>240
Mitomycin C, (0.5mg/ml)	>240
Mitoxantrone, (2.0mg/ml)	>240
Oxaliplatin, (5.0mg/ml)	>240
Paclitaxel (Taxol) (6mg/ml)	>240
Paraplatin, (10.0mg/ml)	>240
Retrovir, (10.0mg/ml)	>240
Rituximab, (10.0mg/ml)	>240

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Thio Tepa (10mg/ml)	23.0
Topotecan HCL, (1.0mg/ml)	>240
Trisonex, (1.0mg/ml)	>240
Vincristine, (1.0mg/ml)	>240

* Please note that the following drugs have extremely low permeation times:
Carmustine (BCNU): 7.0 minutes, Thio Tepa: 23 minutes

6. Comparison of Subject Device and Predicate Device:

The proposed device will be known as Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs.

The following tables are summaries of the technological characteristics, biocompatibility and testing for use with chemotherapy drugs of the proposed and predicate devices.

General Comparison Table:

	Proposed Device K211604	Predicate Device K182600	Remark
Trade Name	Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs	Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue)	Same
Product Code	LZA, LZC	LZA, LZC	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	I	I	Same
Indications for Use	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 to prevent contamination between patient and examiner.	Powder Free Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Powder or Powder Free	Powder Free	Powder Free	Same
Design Feature	Ambidextrous	Ambidextrous	Same
Color	Blue	Blue	Similar
Labeling Information	Single-use, powder free glove size, quantity, Nitrile Examination Gloves, Non Sterile	Single-use, powder free glove size, quantity, Nitrile Examination Gloves, Non Sterile	Same

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Chemotherapy Drug Permeation Claim	See below comparison table	See below comparison table	Same

Dimensions and Performance Comparison Table:

Technological Characteristics	Proposed Device K211604	Predicate Device K182600	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
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
Powder-Content	≤ 2 mg per glove	≤ 2 mg per glove	Similar
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 Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity	Under the conditions of this study, no cytotoxic potential	Same
ISO 10993 Part 11 Systemic toxicity	Under the conditions of this study, there was no evidence of systemic toxicity.	/	/

Chemotherapy Permeation Comparison Claim:

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Tested Chemotherapy Drug and Concentration	Minimum BDT (Minutes)		Remark
	Proposed Device K211604	Predicate Device K182600	
Bleomycin (15.0mg/ml)	>240	>240	Same
Bortezomib (Velcade) 1mg/ml	>240	>240	Same
Busulfan (6.0mg/ml)	>240	>240	Same
Carboplatin, (10.0mg/ml)	>240	>240	Same
Carmustine(BCNU) (3.3 mg/ml)	7.0	11.0	similar
Chloroquine, (50.0mg/ml)	>240	>240	Same
Cisplatin (1mg/ml)	>240	>240	Same
Cyclophosphamide (Cytoxan) (20mg/ml)	>240	>240	Same
Cyclosporin, (100.0mg/ml)	>240	>240	Same
Cytarabine, (100.0mg/ml)	>240	>240	Same
Dacarbazine (10mg/ml)	>240	>240	Same
Daunorubicin, HCL (5.0mg/ml)	>240	>240	Same
Docetaxel, (10.0mg/ml)	>240	>240	Same
Doxorubicin HCL (2mg/ml)	>240	>240	Same
Epirubicin HCL (Ellence), (2.0mg/ml)	>240	>240	Same
Etoposide (20mg/ml)	>240	>240	Same
Fludarabine, (25.0mg/ml)	>240	>240	Same
Fluorouracil (50mg/ml)	>240	>240	Same
Gemcitabine (38.0mg/ml)	>240	>240	Same
Idarubicin HCL (1.0mg/ml)	>240	>240	Same
Ifosfamide, (50.0mg/ml)	>240	>240	Same
Irinotecan, (20.0mg/ml)	>240	>240	Same
Mechlorethamine HCI, (1.0mg/ml)	>240	>240	Same
Melphalan, (5.0mg/ml)	>240	>240	Same
Methotrexate (25mg/ml)	>240	>240	Same
Mitomycin C, (0.5mg/ml)	>240	>240	Same
Mitoxantrone, (2.0mg/ml)	>240	>240	Same
Oxaliplatin, (5.0mg/ml)	>240	>240	Same
Paclitaxel (Taxol) (6mg/ml)	>240	>240	Same
Paraplatin, (10.0mg/ml)	>240	>240	Same
Retrovir, (10.0mg/ml)	>240	>240	Same
Rituximab, (10.0mg/ml)	>240	>240	Same
Thio Tepa (10mg/ml)	23.0	28.8	similar
Topotecan HCL, (1.0mg/ml)	>240	>240	Same
Trisonex, (1.0mg/ml)	>240	>240	Same
Vincristine, (1.0mg/ml)	>240	>240	Same

510(K) SUMMARY

7. Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
- ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves.
- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- ASTM D6978-05 (Reapproved 2019), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.

Test method	Purpose	Acceptance Criteria	Results
ASTM D6319- 19	Length	Minimum 230mm	All size ≥230
ASTM D6319- 19	Palm Width	XS：70±10mm	77-78mm
		S：80±10mm	86-88 mm
		M:95±10mm	96 -98mm
		L:110±10mm	108-110 mm
		XL：120±10mm	116-117 mm
ASTM D6319- 19	Thickness	Finger: 0.05mm (min)	≥0.05mm
		Palm: 0.05mm (min)	≥0.05mm
ASTM D6319-19 ASTN D412-16	Tensile Strength, Before Aging	14MPa, min	≥14 MPa
ASTM D6319-19 ASTN D412-16	Tensile Strength, After Accelerated Aging	14MPa, min	≥14 MPa
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, Before Aging	500%, min	≥500%
ASTM D6319-19 ASTN D412-16	Ultimate Elongation, After Accelerated Aging	400%, min	≥400%
ASTM D 5151-19 ASTM D6319- 19	Freedom from holes	G-I, AQL 2.5	Meet and above AQL2.5 requirements
ASTM D 6124-06(2017) ASTM D6319- 19	Powder-Content	≤ 2 mg per glove	≤ 2 mg, meet requirements

510(K) SUMMARY

ISO 10993-10:2010	Skin Irritation Study	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant
ISO 10993-10:2010	Maximization Sensitization Study	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer
ISO 10993-5:2009	Cytotoxicity Test	Under the conditions of this study, the test article extract showed potential toxicity	Under the conditions of this study, the test article extract showed potential toxicity
ISO 10993-11:2017	Systemic toxicity	Under the conditions of this study, there was no evidence of systemic toxicity.	Under the conditions of this study, there was no evidence of systemic toxicity.
ASTM D6978-05 (2019)	Tested for Use with Chemotherapy Drugs	/	Details refer to the above 5.0 result

8. Clinical Performance Data

N/A

9. Conclusion:

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