October 7, 2022

Guang Dong Kingfa Sci. & Tech.Co., Ltd.
Xiaoge Yu
Director
No. 28 Delong Ave., Shijiao Town, Qingcheng District
Qingyuan, Guangdong 511545
China

Re: K222714
Trade/Device Name: Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs, Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs, Nitrile Patient Examination Gloves Black 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, OPJ, QDO
Dated: August 30, 2022
Received: September 8, 2022

Dear Xiaoge Yu:

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,

Clarence W. Murray, III, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K222714

Device Name

Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs.

Indications for Use *(Describe)*

The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

The Nitrile Patient Examination Gloves Blue Colored were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
The tested chemotherapy drug are as follows:

Bleomycin Sulfate 15 mg/ml >240 min.
Busulfan 6 mg/ml >240 min.
Carboplatin 10 mg/ml >240 min.
Carmustine (BCNU) 3.3 mg/ml 17.2 min.
Cisplatin 1.0 mg/ml >240 min.
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
Cytarabine HCl 100 mg/ml >240 min.
Dacarbazine (DTIC)10.0 mg/ml >240 min.
Daunorubicin 5 mg/mL >240 min.
Docetaxel 10.0 mg/ml >240 min
Doxorubicin HCl 2.0 mg/ml >240 min.
Epirubicin HCl 2.0 mg/ml >240 min.
Etoposide (Toposar) 20.0 mg/ml >240 min.
Fludarabine 25.0 mg/ml >240 min.
Fluorouracil 50.0 mg/ml >240 min.
Gemcitabine 38 mg/ml>240 min.
Idarubicin 1 mg/ml >240 min.
Ifosfamide 50.0 mg/ml >240 min.
Irinotecan 20.0 mg/ml >240 min.
Mechlorethamine HCl 1.0 mg/ml>240 min.
Melphalan 5 mg/ml >240 min.
Methotrexate 25 mg/ml >240 min.
Mitromycin C. 0.5 mg/ml >240
Mitoxantrone 2.0 mg/ml >240 min.
Paclitaxel (Taxol) 6.0 mg/ml >240 min.
Rituximab 10.0 mg/ml >240 min.
Thiotepa 10.0 mg/ml 13.9min.
Trisenox 1.0 mg/ml >240 min.
Vincristine Sulfate 1.0 mg/ml >240 min.
Fentanyl Citrate 100mcg/2ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K222714

Device Name

Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*

The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

The Nitrile Patient Examination Gloves Blue Violet Colored were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.
The tested chemotherapy drug are as follows:

Bleomycin Sulfate 15 mg/ml >240 min.
Busulfan 6 mg/ml >240 min.
Carboplatin 10 mg/ml >240 min.
Carmustine (BCNU) 3.3 mg/ml 65.3 min.
Cisplatin 1.0 mg/ml >240 min.
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
Cytarabine HCl 100 mg/ml >240 min.
Dacarbazine (DTIC)10.0 mg/ml >240 min.
Daunorubicin 5 mg/mL >240 min.
Docetaxel 10.0 mg/ml >240 min
Doxorubicin HCl 2.0 mg/ml >240 min.
Epirubicin HCl 2.0 mg/ml >240 min.
Etoposide (Toposar) 20.0 mg/ml >240 min.
Fludarabine 25.0 mg/ml >240 min.
Fluorouracil 50.0 mg/ml >240 min.
Gemcitabine 38 mg/ml>240 min.
Idarubicin 1 mg/ml >240 min.
Ifosfamide 50.0 mg/ml >240 min.
Irinotecan 20.0 mg/ml >240 min.
Mechlorethamine HCl 1.0 mg/ml>240 min.
Melphalan 5 mg/ml >240 min.
Methotrexate 25 mg/ml >240 min.
Mitromycin C. 0.5 mg/ml >240
Mitoxantrone 2.0 mg/ml >240 min.
Paclitaxel (Taxol) 6.0 mg/ml >240 min.
Rituximab 10.0 mg/ml >240 min.
Thiotepa 10.0 mg/ml 58.3min.
Trisenox 1.0 mg/ml >240 min.
Vincristine Sulfate 1.0 mg/ml >240 min.
Fentanyl Citrate 100mcg/2ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K222714

Device Name

Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*

The nitrile examination glove is intended to be worn on the hands of examiner's to prevent contamination between patient and examiner. This is a single-use, powder-free, non-sterile device.

The Nitrile Patient Examination Gloves Black Colored were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

The tested chemotherapy drug are as follows:

Carmustine (BCNU) 3.3 mg/ml 49.2 min.
Cisplatin 1.0 mg/ml >240 min.
Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
Dacarbazine (DTIC)10.0 mg/ml >240 min.
Doxorubicin HCl 2.0 mg/ml >240 min.
Etoposide (Toposar) 20.0 mg/ml >240 min.
Fluorouracil 50.0 mg/ml >240 min.
Fentanyl Citrate 100mcg/2ml >240 minutes
Paclitaxel (Taxol) 6.0 mg/ml >240 min.
Thiotepa 10.0 mg/ml 87.1min.

Warning: Do not use with Carmustine and Thiotepa.

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.

510(k) Summary – K222714

I. Submitter

GUANG DONG KINGFA SCI. & TECH.CO., LTD.
No. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province 511545, China

Contact person: Xiaoge Yu
Position: Manager
Tel.: +86-13570952157
E-mail: yuxiaoge@kingfa.com.cn

Preparation date: August. 30, 2022

II. Proposed Device

Device Trade Name	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs
Common name:	Patient Examination Glove (Tested For Use With Chemotherapy Drugs)
Regulation Number:	21 CFR 880.6250
Regulatory Class:	Class I
Product code:	LZA, LZC, OPJ, QDO
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K213040
Trade name:	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs
Common name:	Patient Examination Glove
Classification:	Class I

Product Code: LZA, LZC,OPJ, QDO

IV. Device description

Powder-Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs) are non-sterile, single use, disposable gloves intended for medical purposes to be worn on the hands of examiners to prevent contamination between a patient and an examiner. The gloves are offered in six sizes, extra-small, small, medium, large, extra-large, extra-extra-large. Three colors are available for all size, includes blue, blue violet and black.

The gloves are designed and manufactured in accordance with the ASTM D6319-10 standard and are tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2019).

V. Indication for use

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (2019) *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.*

The Nitrile Patient Examination Gloves Blue Tested Chemotherapy Drugs are as follows:

- Bleomycin Sulfate 15 mg/ml >240 min.
- Busulfan 6 mg/ml >240 min.
- Carboplatin 10 mg/ml >240 min.
- Carmustine (BCNU) 3.3 mg/ml 17.2 min.
- Cisplatin 1.0 mg/ml >240 min.
- Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
- Cytarabine HCl 100 mg/ml >240 min.
- Dacarbazine (DTIC)10.0 mg/ml >240 min.
- Daunorubicin 5 mg/mL>240 min.
- Docetaxel 10.0 mg/ml >240 min
- Doxorubicin HCl 2.0 mg/ml >240 min.
- Epirubicin HCl 2.0 mg/ml >240 min.
- Etoposide (Toposar) 20.0 mg/ml >240 min.

- Fludarabine 25.0 mg/ml >240 min.
- Fluorouracil 50.0 mg/ml >240 min.
- Gemcitabine 38 mg/ml>240 min.
- Idarubicin 1 mg/ml >240 min.
- Ifosfamide 50.0 mg/ml >240 min.
- Irinotecan 20.0 mg/ml >240 min.
- Mechlorethamine HCl 1.0 mg/ml>240 min.
- Melphalan 5 mg/ml >240 min.
- Methotrexate 25 mg/ml >240 min.
- Mitromycin C. 0.5 mg/ml >240
- Mitoxantrone 2.0 mg/ml >240 min.
- Paclitaxel (Taxol) 6.0 mg/ml >240 min.
- Rituximab 10.0 mg/ml >240 min.
- Thiotepa 10.0 mg/ml 13.9min.
- Trisenox 1.0 mg/ml >240 min.
- Vincristine Sulfate 1.0 mg/ml >240 min.
- Fentanyl Citrate 100mcg/2ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa.

The Nitrile Patient Examination Gloves Blue Violet Tested Chemotherapy Drugs are as follows:

- Bleomycin Sulfate 15 mg/ml >240 min.
- Busulfan 6 mg/ml >240 min.
- Carboplatin 10 mg/ml >240 min.
- Carmustine (BCNU) 3.3 mg/ml 65.3 min.
- Cisplatin 1.0 mg/ml >240 min.
- Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
- Cytarabine HCl 100 mg/ml >240 min.
- Dacarbazine (DTIC)10.0 mg/ml >240 min.
- Daunorubicin 5 mg/mL>240 min.
- Docetaxel 10.0 mg/ml >240 min
- Doxorubicin HCl 2.0 mg/ml >240 min.
- Epirubicin HCl 2.0 mg/ml >240 min.
- Etoposide (Toposar) 20.0 mg/ml >240 min.

- Fludarabine 25.0 mg/ml >240 min.
- Fluorouracil 50.0 mg/ml >240 min.
- Gemcitabine 38 mg/ml>240 min.
- Idarubicin 1 mg/ml >240 min.
- Ifosfamide 50.0 mg/ml >240 min.
- Irinotecan 20.0 mg/ml >240 min.
- Mechlorethamine HCl 1.0 mg/ml>240 min.
- Melphalan 5 mg/ml >240 min.
- Methotrexate 25 mg/ml >240 min.
- Mitromycin C. 0.5 mg/ml >240
- Mitoxantrone 2.0 mg/ml >240 min.
- Paclitaxel (Taxol) 6.0 mg/ml >240 min.
- Rituximab 10.0 mg/ml >240 min.
- Thiotepa 10.0 mg/ml 58.3min.
- Trisenox 1.0 mg/ml >240 min.
- Vincristine Sulfate 1.0 mg/ml >240 min.
- Fentanyl Citrate 100mcg/2ml >240 minutes

Warning: Do not use with Carmustine and Thiotepa.

The Nitrile Patient Examination Gloves Black Tested Chemotherapy Drugs are as follows:

- Carmustine (BCNU) 3.3 mg/ml 49.2 min.
- Cisplatin 1.0 mg/ml >240 min.
- Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.
- Dacarbazine (DTIC)10.0 mg/ml >240 min.
- Doxorubicin HCl 2.0 mg/ml >240 min.
- Etoposide (Toposar) 20.0 mg/ml >240 min.
- Fluorouracil 50.0 mg/ml >240 min.
- Fentanyl Citrate 100mcg/2ml >240 minutes
- Paclitaxel (Taxol) 6.0 mg/ml >240 min.
- Thiotepa 10.0 mg/ml 87.1min.

Warning: Do not use with Carmustine and Thiotepa.

VI. Comparison of technological characteristics with the predicate devices

Table 1 Comparison of Nitrile Examination Gloves

Item	Proposed device (K222714)	Predicate device (K213040)	Discussion
Product name	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs. Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs. Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs.	Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs. Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs. Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs.	-
Product Code	LZA, LZC,OPJ, QDO	LZA, LZC,OPJ, QDO	Same
Regulation No.	21 CFR 880.6250	21 CFR 880.6250	Same
Classification	Class I	Class I	Same
Powder free	Yes	Yes	Same
Indication for use	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05	Same

	(Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	(Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs	
Main Material	Powder-Free Nitrile	Powder-Free Nitrile	Same
Color	Blue, Blue violet, Black	Blue, Blue violet, Black	Same
Size	x-small, small, medium, large, x-large, XX-large	x-small, small, medium, large, x-large, XX-large	Same
Dimensions – Length	Complies with ASTM D6319-10 XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min)	Complies with ASTM D6319-10 XS (220mm min) S (220mm min) M (230mm min) L (230mm min) XL (230mm min) XXL (230mm min)	Same
Dimensions – Width	Complies with ASTM D6319-10 XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm) XXL (≥120mm)	Complies with ASTM D6319-10 XS (70±10mm) S (80±10mm) M (95±10mm) L (110±10mm) XL (120±10mm) XXL (≥120mm)	Same
Dimensions – Thickness	Complies with: ASTM D6319-10 Palm: 0.05mm min Finger: 0.11mm min	Complies with: ASTM D6319-10 Palm: 0.05mm min Finger: 0.11mm min	Same
Physical Properties	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ⩾14 MPa, min. After Aging ⩾14 MPa, min.	Complies with: ASTM D6319-10 minimum: Tensile Strength: Before Aging ⩾14 MPa, min. After Aging ⩾14 MPa, min.	Same
	Elongation: Before Aging 500%, min.	Elongation: Before Aging 500%, min.	Same

	After Aging 400%, min.	After Aging 400%, min.	
Freedom from Holes	Complies with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Complies with ASTM D6319-10 and ASTM D5151-06 G-1, AQL 1.5	Same
Residual Powder	Complies with: ASTM D6319-10 <2mg per glove	Complies with: ASTM D6319-10 <2mg per glove	Same
Contact Durations	Limited <24 hours	Limited <24 hours	Same
Biocompatibility	ISO 10993-10: Not a skin irritant Not a skin sensitizer At the neat extraction, the test article is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect.	ISO 10993-10: Not a skin irritant Not a skin sensitizer At the neat extraction, the test article is considered cytotoxic, but the acute systemic toxicity results demonstrate the device will not cause a systemic effect.	Same
Sterility	Non-sterile	Non-sterile	Same
Rx Only or OTC	Over the Counter	Over the Counter	Same
Tested Chemotherapy Drugs	Nitrile Patient Examination Gloves Blue Colored Tested For Use With Chemotherapy Drugs	Nitrile Patient Examination Gloves Blue Colored Tested For Use With Chemotherapy Drugs	/
	Bleomycin Sulfate 15 mg/ml >240 min.	Bleomycin Sulfate 15 mg/ml >240 min.	Similar[1]
	Busulfan 6 mg/ml >240 min.	NA	
	Carboplatin 10 mg/ml >240 min.	Carboplatin 10 mg/ml >240 min.	
	Carmustine (BCNU) 3.3 mg/ml 17.2 min.	Carmustine (BCNU) 3.3 mg/ml 17.2 min.	
	Cisplatin 1.0 mg/ml >240 min.	Cisplatin 1.0 mg/ml >240 min.	

	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	
	Cytarabine HCl 100 mg/ml >240 min.	Cytarabine HCl 100 mg/ml >240 min.	
	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Dacarbazine (DTIC)10.0 mg/ml >240 min.	
	Daunorubicin 5 mg/mL>240 min.	Daunorubicin 5 mg/mL>240 min.	
	Docetaxel 10.0 mg/ml >240 min	Docetaxel 10.0 mg/ml >240 min	
	Doxorubicin HCl 2.0 mg/ml >240 min.	Doxorubicin HCl 2.0 mg/ml >240 min.	
	Epirubicin HCl 2.0 mg/ml >240 min.	NA	
	Etoposide (Toposar) 20.0 mg/ml >240 min.	Etoposide (Toposar) 20.0 mg/ml >240 min.	
	Fludarabine 25.0 mg/ml >240 min.	NA	
	Fluorouracil 50.0 mg/ml >240 min.	Fluorouracil 50.0 mg/ml >240 min.	
	Gemcitabine 38 mg/ml>240 min.	Gemcitabine 38 mg/ml>240 min.	
	Idarubicin 1 mg/ml >240 min.	Idarubicin 1 mg/ml >240 min.	
	Ifosfamide 50.0 mg/ml >240 min.	Ifosfamide 50.0 mg/ml >240 min.	
	Irinotecan 20.0 mg/ml >240 min.	Irinotecan 20.0 mg/ml >240 min.	
	Mechlorethamine HCl 1.0 mg/ml>240 min.	Mechlorethamine HCl 1.0 mg/ml>240 min.	
	Melphalan 5 mg/ml >240 min.	Melphalan 5 mg/ml >240 min.	
	Methotrexate 25 mg/ml >240 min.	Methotrexate 25 mg/ml >240 min.	
	Mitromycin C. 0.5 mg/ml >240	Mitromycin C. 0.5 mg/ml >240	
	Mitoxantrone 2.0 mg/ml	Mitoxantrone 2.0 mg/ml	

	>240 min.	>240 min.	
	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	
	Rituximab 10.0 mg/ml >240 min.	NA	
	Thiotepa 10.0 mg/ml 58.3min.	Thiotepa 10.0 mg/ml 58.3min.	
	Trisenox 1.0 mg/ml >240 min.	NA	
	Vincristine Sulfate 1.0 mg/ml >240 min.	Vincristine Sulfate 1.0 mg/ml >240 min.	
	Fentanyl Citrate 100mcg/2ml >240 minutes	NA	
	Nitrile Patient Examination Gloves Blue Violet Colored Tested For Use With Chemotherapy Drugs	Nitrile Patient Examination Gloves Blue Violet Colored Tested For Use With Chemotherapy Drugs	/
	Bleomycin Sulfate 15 mg/ml >240 min.	NA	Similar[1]
	Busulfan 6 mg/ml >240 min.	NA	
	Carboplatin 10 mg/ml >240 min.	NA	
	Carmustine (BCNU) 3.3 mg/ml 65.3 min.	Carmustine (BCNU) 3.3 mg/ml 65.3 min.	
	Cisplatin 1.0 mg/ml >240 min.	Cisplatin 1.0 mg/ml >240 min.	
	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	
	Cytarabine HCl 100 mg/ml >240 min.	NA	
	Dacarbazine (DTIC)10.0 mg/ml >240 min.	Dacarbazine (DTIC)10.0 mg/ml >240 min.	
	Daunorubicin 5 mg/mL>240 min.	NA	

	Docetaxel 10.0 mg/ml >240 min	NA	
	Doxorubicin HCl 2.0 mg/ml >240 min.	Doxorubicin HCl 2.0 mg/ml >240 min.	
	Epirubicin HCl 2.0 mg/ml >240 min.	NA	
	Etoposide (Toposar) 20.0 mg/ml >240 min.	Etoposide (Toposar) 20.0 mg/ml >240 min.	
	Fludarabine 25.0 mg/ml >240 min.	NA	
	Fluorouracil 50.0 mg/ml >240 min.	Fluorouracil 50.0 mg/ml >240 min.	
	Gemcitabine 38 mg/ml>240 min.	NA	
	Idarubicin 1 mg/ml >240 min.	NA	
	Ifosfamide 50.0 mg/ml >240 min.	NA	
	Irinotecan 20.0 mg/ml >240 min.	NA	
	Mechlorethamine HCl 1.0 mg/ml>240 min.	NA	
	Melphalan 5 mg/ml >240 min.	NA	
	Methotrexate 25 mg/ml >240 min.	Methotrexate 25 mg/ml >240 min.	
	Mitromycin C. 0.5 mg/ml >240.	NA	
	Mitoxantrone 2.0 mg/ml >240 min.	NA	
	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	
	Rituximab 10.0 mg/ml >240 min.	NA	
	Thiotepa 10.0 mg/ml 58.3min.	Thiotepa 10.0 mg/ml 58.3min.	
	Trisenox 1.0 mg/ml >240 min.	NA	

	Vincristine Sulfate 1.0 mg/ml >240 min.	NA	
	Fentanyl Citrate 100mcg/2ml >240 minutes	NA	
	Nitrile Patient Examination Gloves Black Colored Tested For Use With Chemotherapy Drugs	Nitrile Patient Examination Gloves Blue Violet Colored Tested For Use With Chemotherapy Drugs	/
	Cisplatin 1.0 mg/mL>240 min.	NA	Similar[1]
	Carmustine (BCNU) 3.3 mg/ml 49.2 min.	NA	
	Cyclophosphamide (Cytoxan) 20.0 mg/ml >240 min.	NA	
	Dacarbazine (DTIC)10.0 mg/ml >240 min.	NA	
	Doxorubicin HCl 2.0 mg/ml >240 min.	NA	
	Etoposide (Toposar) 20.0 mg/ml >240 min.	NA	
	Fluorouracil 50.0 mg/ml >240 min.	NA	
	Paclitaxel (Taxol) 6.0 mg/ml >240 min.	NA	
	Thiotepa 10.0 mg/ml 87.1min.	NA	
	Fentanyl Citrate 100mcg/2ml >240 minutes	Fentanyl Citrate 100mcg/2ml >240 minutes	

[1] Add new kinds of the chemotherapy label claim to the previous cleared under K213040. The permeation testing was conducted per ASTM D6978-05 (Reapproved 2019) to support the addition of the labeling claim.

VII. Non-Clinical Testing

Non-clinical tests were leveraged from the predicate submission. Additional testing per

ASTM D6978-05 (2019) was performed to support inclusion of additional chemotherapy drugs to the indications for use.

Table 2 Summary of Non-Clinical Performance Testing

Test Methodology	Purpose	Acceptance Criteria			Results
ASTM D6319	Physical Dimensions Test	Extra-Small: Length：≥ 220mm Width: 70±10 mm; Small: Length：≥ 220mm Width: 80±10mm; Medium: Length：≥ 230mm Width: 95±10mm Large: Length：≥ 230mm Width: 110±10mm Extra- Large: Length：≥ 230mm Width: 120±10mm Extra- Extra- Large: Length：≥ 230mm Width: ≥120mm			Pass
		Thickness (mm): Finger:≥0.05 Palm: ≥0.08			Pass
	Physical properties	Before Aging	Tensile Strength	≥14MPa	Pass
			Ultimate Elongation	≥500%	
		After Aging	Tensile Strength	≥14MPa	Pass
			Ultimate Elongation	≥500%	
ASTM D5151	Freedom from pinholes	Meet the requirements of ASTM D5151Test for AQL 2.5			Pass
ASTM D6124	Powder Residue	Meet the requirements of ASTM D6124< 2.0mg			Pass
ISO 10993-10	To determine if the finished device material is an irritant	Non-irritating			Under the conditions of the study not an irritant/ Pass
ISO 10993-10	To determine if the finished device material is a sensitizer	Non- sensitizing			Under conditions of the study, not a sensitizer. / Pass
ISO 10993-11	To determine if the finished device material extracts pose a systemic toxicity concern	Non-acute systemic toxicity			Under conditions of the study, did not show acute systemic toxicity in vivo / Pass

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D3767-03(2020), Practice for rubber-Measurement of Dimensions
- ASTM D5151-19, Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6124-06(2017), Standard Test Method for Residual Powder on Medical Gloves
- ASTM D573-04(2019), Standard Test Method for Rubber—Deterioration in an Air Oven
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05(2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017, Biological evaluation of medical devices - Part11:Tests for Systemic Toxicity

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the subject device, Nitrile Patient Examination Gloves Blue Tested For Use With Chemotherapy Drugs; Nitrile Patient Examination Gloves Blue Violet Tested For Use With Chemotherapy Drugs; Nitrile Patient Examination Gloves Black Tested For Use With Chemotherapy Drugs, are as safe, as effective, and performs as well as or better than the legally marketed predicate device (K213040).