August 28, 2023

Kimberly-Clark Corporation
% Amy Fowler
Consultant
Pathmaker FDA Law PLLC
1415 Lilac Drive N, Suite 270
Minneapolis, Minnesota 55422

Re: K231435
Trade/Device Name: KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA, LZC, QDO, OPJ
Dated: May 17, 2023
Received: May 17, 2023

Dear Amy Fowler:

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 -S

Bifeng Qian, M.D., 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

Indications for Use

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

510(k) Number *(if known)*

K231435

Device Name

KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid.

Indications for Use (Describe)

The nitrile powder free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
In addition to routine examination glove's intended use, the gloves are Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid.

Table 1. Chemotherapy Drugs, Concentrations, and Minimum Breakthrough Detection Times

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Avastin	25 mg/mL (25,000 ppm)	>240 min.
Cabazitaxel	60 mg/1.5mL (40,000 ppm)	>240 min.
Capecitabine	26 mg/mL (26,000 ppm)	>240 min.
Carmustine	3.3 mg/mL (3,300 ppm)	78.1 min.
Cisplatin	1 mg/mL (1,000 ppm)	>240 min.
Cyclophosphamide	20 mg/mL (20,000 ppm)	>240 min.
Dacarbazine	10 mg/mL (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mg/mL (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/mL (500 ppm)	>240 min.
Etoposide	20 mg/mL (20,000 ppm)	>240 min.
Floxuridine	100 mg/mL (100,000 ppm)	>240 min.
Fluorouracil	50 mg/mL (50,000 ppm)	>240 min.
Ifosfamide	50 mg/mL (50,000 ppm)	>240 min.
Lenvatinib	20 mg/mL (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/mL (2,000 ppm)	>240 min.
Oxaliplatin	5 mg/mL (5,000 ppm)	>240 min.
Paclitaxel	6 mg/mL (6,000 ppm)	>240 min.
Pemetrexed	25 mg/mL (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/mL (200,000 ppm)	>240 min.
Tamoxifen	2 mg/mL (2,000 ppm)	>240 min.
ThioTEPA	10 mg/mL (10,000 ppm)	>240 min.
Vinblastine Sulfate	1 mg/mL (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/mL (1,000 ppm)	>240 min.
Vinorelbine	10 mg/mL (10,000 ppm)	>240 min.

Caution: The following chemotherapy drug has low permeation time: Carmustine (3.3mg/ml): 78.1 minutes**.**

Tested in accordance to ASTM D6978-05 (2019)

Indications for Use

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

510(k) Number *(if known)*

K231435

Table 2. Fentanyl Citrate, Simulated Gastric Acid, and Simulated Gastric Acid with Fentanyl Citrate Mix Minimum Breakthrough Detection Times

Fentanyl/Gastric Acid	Concentration	Minimum Breakthrough Detection Time
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid Fluid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix	50/50 mix solution	>240 min.

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 (K231435)
(As required by 21 CFR 807.92)

1. Submission Information

KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid

Date Prepared:	<August 28, 2023>
Submission Format:	Traditional 510(k)
510(k) #:	K231435

2. Submitter Information

Applicant:	Kimberly-Clark Corporation
Address:	1400 Holcomb Bridge Road Roswell, Georgia 30076
Phone:	+1 770 587 8000

Contact person:	Kimberly Tempas Associate Director, Regulatory Affairs
	2100 Winchester Road Neenah, WI 54956
Phone:	+1 (920) 721-4084
Email:	Kimberly.Tempas@kcc.com

3. Device Information

Trade Name:	KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid
Common Name:	Nitrile powder-free patient exam glove for use with chemotherapy drugs and fentanyl
Classification Name:	Non-powered Patient Examination Glove
Regulation:	21 CFR 880.6250

Regulatory Class:	Class I
Panel:	General Hospital
Product Codes:	LZA, LZC, QDO, OPJ

Table 5.1. *Product codes*

Product codes	
LZA	Polymer Patient Examination Glove
LZC	Patient Examination Glove, Specialty
QDO	Fentanyl and other opioid protection gloves
OPJ	Medical Gloves with Chemotherapy Labeling Claims

4. Predicate Device Information

K200072 Powder-free Nitrile Exam Glove for use with Chemotherapy drugs and Fentanyl Product Code: LZC, LZA, QDO.

5. Device Description

KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid are dark magenta in color, and are single use only, non-sterile, disposable gloves. The powder-free gloves are made of synthetic copolymers of acrylonitrile and butadiene. The product will be sold as a disposable and non-sterile product in extra-small, small, medium, large, and extra-large sizes.

6. Indications for Use

The nitrile powder-free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition to routine examination glove's intended use, the gloves are Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid.

Table 5.2. *Permeation Times for Chemotherapy Drugs*

Chemotherapy Drug	Concentration	Minimum Breakthrough Detection Time
Avastin	25 mg/mL (25,000 ppm)	>240 min.
Cabazitaxel	60 mg/1.5mL (40,000 ppm)	>240 min.
Capecitabine	26 mg/mL (26,000 ppm)	>240 min.
Carmustine	3.3 mg/mL (3,300 ppm)	78.1 minutes
Cisplatin	1 mg/mL (1,000 ppm)	>240 min.
Cyclophosphamide	20 mg/mL (20,000 ppm)	>240 min.
Dacarbazine	10 mg/mL (10,000 ppm)	>240 min.
Doxorubicin HCL	2 mg/mL (2,000 ppm)	>240 min.
Eribulin Mesylate	0.5 mg/mL (500 ppm)	>240 min.
Etoposide	20 mg/mL (20,000 ppm)	>240 min.
Floxuridine	100 mg/mL (100,000 ppm)	>240 min.
Fluorouracil	50 mg/mL (50,000 ppm)	>240 min.
Ifosfamide	50 mg/mL (50,000 ppm)	>240 min.
Lenvatinib	20 mg/mL (20,000 ppm)	>240 min.
Mitoxantrone	2 mg/mL (2,000 ppm)	>240 min.
Oxaliplatin	5 mg/mL (5,000 ppm)	>240 min.
Paclitaxel	6 mg/mL (6,000 ppm)	>240 min.
Pemetrexed	25 mg/mL (25,000 ppm)	>240 min.
Sorafenib Tosylate	200 mg/mL (200,000 ppm)	>240 min.
Tamoxifen	2 mg/mL (2,000 ppm)	>240 min.
ThioTEPA	10 mg/mL (10,000 ppm)	>240 min.
Vinblastine Sulfate	1 mg/mL (1,000 ppm)	>240 min.
Vincristine Sulfate	1 mg/mL (1,000 ppm)	>240 min.
Vinorelbine	10 mg/mL (10,000 ppm)	>240 min.
Fentanyl/Gastric Acid	**Concentration**	**Minimum Breakthrough Detection Time**
Fentanyl Citrate	100mcg/2mL	>240 min.
Simulated Gastric Acid Fluid	0.2% (w/v) NaCl in 0.7% (v/v) HCL acid	>240 min.
Simulated Gastric Acid Fluid/Fentanyl Citrate Injection Mix	50/50 mix solution	>240 min.

Caution: **The following chemotherapy drug has a low permeation time: Carmustine** (3.3mg/ml): 78.1 minutes**.**

7. Predicate & Subject Technological Characteristics Comparison Table

Table 5.3. *Comparison between Subject and Predicate Devices*

Attributes	Standard Where Limits Test Limits Set	Purple K200072 (Predicate)	Polaris (Subject Device)	Comparison
Device Regulation	NA	21 CFR 880.6250	21 CFR 880.6250	**Same**
Product Codes	NA	LZA, LZC, QDO	LZA, LZC, QDO, OPJ	**Same**
Common Name	NA	Examination glove	Examination glove	**Same**
Sizes	NA	Five sizes: XS, S, M, L, XL	Five sizes: XS, S, M, L, XL	**Same**
Base Material	NA	Nitrile	Nitrile	**Same**
Color	NA	Purple	Dark Magenta	**Similar:** Biocompatibility & physical attributes testing show that the difference in color does not alter glove safety or performance.
Glove formulation	NA	KC Purple Nitrile 9.5 Chemo Formulation	Proprietary formula	**Similar:** Formulations share similar materials and physical characteristics; biocompatibility and physical properties testing show that the subject device's formulation does not reduce glove safety or performance.

Attributes	Standard Where Limits Test Limits Set	Purple K200072 (Predicate)	Polaris (Subject Device)	Comparison
Glove layers	NA	Single layer	Single layer	**Same**
Sterile or Non- Sterile	NA	Non-Sterile	Non-Sterile	**Same**
Prescription or OTC	NA	OTC	OTC	**Same**
Single Use Disposable	NA	Yes	Yes	**Same**
Intended Use/ Indications for Use	NA	The device is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patients and examiner. KIMTECH™ Purple Nitrile™ Powder free Examination Gloves are Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid, and Fentanyl in Simulated Gastric Acid.	The nitrile powder-free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. In addition to routine examination glove's intended use, the gloves are tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid.	**Similar:** The subject device removed "or finger" because it is intended to be worn on the hand, not the finger.

Attributes	Standard Where Limits Test Limits Set	Purple K200072 (Predicate)	Polaris (Subject Device)	Comparison
Indications for Use Claims:	Chemotherapy drugs tested for permeation and degradation in accordance with ASTM D6978-05 (2019)	**Chemotherapy Drugs Tested:** **1. Carmustine** **2. Cyclophosphamide** **3. Doxorubicin HCL** **4. Etoposide** **5. Fluorouracil** **6. Mitoxantrone** **7. Paclitaxel** **8. ThioTEPA** **9. Dacarbazine** **10. Ifosfamide** **11. Vincristine Sulfate** 12. Bleomycin Sulfate 13. Busulfan 14. Cytarabine 15. Dacarbazine 16. Daunorubicin 17. Docetaxel 18. Epirubicin 19. Fludarabine 20. Gemcitabine 21. Idarubicin 22. Mechlorethamine HCL 23. Melphalan 24. Methotrexate 25. Mitomycin C 26. Osplaten 27. Paraplatin 28. Rituximab 29. Trisenox	**Chemotherapy Drugs Tested:** 1. Avastin 2. Cabazitaxel 3. Capecitabine **4. Carmustine** 5. Cisplatin **6. Cyclophosphamide** **7. Dacarbazine** **8. Doxorubicin HCL** 9. Eribulin Mesylate **10. Etoposide** 11. Floxuridine **12. Fluorouracil** **13. Ifosfamide** 14. Lenvatinib **15. Mitoxantrone** 16. Oxaliplatin **17. Paclitaxel** 18. Pemetrexed 19. Sorafenib Tosylate 20. Tamoxifen **21. ThioTEPA** **22. Vinblastine Sulfate** 23. Vincristine Sulfate 24. Vinorelbine	**Similar:** Both have been tested with a common list of chemotherapy drugs in accordance with the same test method, but the subject glove has been tested for some different chemotherapy drugs to better meet current user and chemotherapy treatment needs.

Attributes	Standard Where Limits Test Limits Set	Purple K200072(Predicate)	Polaris (Subject Device)	Comparison
Permeation and Degradation Tests of Other Substances	ASTM D6978-05 (2019)	Passed permeation testing for: Fentanyl citrate Simulated gastric acid 50/50 mix of fentanyl and gastric acid	Passed permeation testing for: Fentanyl citrate Simulated gastric acid 50/50 mix of fentanyl and gastric acid	**Same**
Carmustine and ThioTEPA Permeation Time	ASTM D6978-05 (2019)	Carmustine: 3.6 minutes ThioTEPA: 15.9 minutes	Carmustine: 78.1 minutes ThioTEPA: >240 minutes	**Different:** The predicate was below minimum permeation time of 240 minutes specified in the standard for Carmustine and ThioTEPA while the subject device is only below the minimum permeation time of 240 minutes specified in the standard for Carmustine.
Carmustine and ThioTEPA Caution/ Warning Statements	NA	WARNING: Not for use with: Carmustine, ThioTEPA	Caution: The following chemotherapy drug has a low permeation time: Carmustine (3.3mg/ml): 78.1 minutes	**Different:** The predicate has a warning due to extremely low permeation times while the subject device has lesser "Caution Statement" based on permeation times >70 minutes.
Dimensions: Overall Length	ASTM D6319 Minimum: 230 mm	All sizes comply with length dimensions	All sizes comply with length dimensions	**Same**
Dimensions: Width (mean)	ASTM D6319 Minimum: 70 +10mm	All sizes comply with width dimensions	All sizes comply with width dimensions	**Same**
Dimensions: Palm & Finger Thickness	ASTM D6319 Minimum Palm: 0.05mm Minimum Finger: 0.05mm	All sizes comply with Palm & Finger Thickness dimensions	All sizes comply with Palm & Finger Thickness dimensions	**Same**

Attributes	Standard Where Limits Test Limits Set	Purple K200072(Predicate)	Polaris (Subject Device)	Comparison
Tensile Strength: Before & After Aging	ASTM D6319 Min Before: 14MPa After: 14Mpa	Complies both before and after accelerated aging.	Complies both before and after accelerated aging.	**Same**
Ultimate Elongation Before & After aging	ASTM D6319 Minimum: Before: 500% After:400%	Complies both before and after accelerated aging.	Complies both before and after accelerated aging.	**Same**
Freedom from Pinholes	ASTM D6319 G1, AQL 2.5 7 Accept 8 Reject	Pass (AQL 1.5)	Pass (AQL 0.65)	**Same:** Both gloves pass the tests. The subject glove AQL is tighter and allows fewer pinhole defects.
Powder-Free	ASTM D6319-19 (2019) Maximum <2mg/glove	Passed at <2mg / glove in accordance with the standard	Passed at <2mg / glove in accordance with the standard	**Same**
Biocompatibility Acute Systemic Toxicity	ISO 10993-11:2017(E) – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Pass	Pass	**Same**
Biocompatibility Skin Irritation	ANSI/AAMI/ISO 10993-23:2021(E) - Biological evaluation of medical devices - Part 23: Tests for irritation	Pass	Pass	**Same**

Attributes	Standard Where Limits Test Limits Set	Purple K200072(Predicate)	Polaris (Subject Device)	Comparison
Biocompatibility Skin Sensitization	ISO 10993-23:2021(E) – Biological evaluation of medical devices – Part 10: Tests for skin sensitization	Pass	Pass	**Same**

9. Summary of Non-Clinical Performance Tests:

The subject 510(k) device has undergone a series of safety and performance tests. The test results demonstrated that the proposed device met the performance criteria as specified utilizing the following test methods, standards, and specifications:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application (FDA Recognition number 6-446)
- ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves (FDA Recognition number 6-424)
- ASTM D6124-06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves (FDA Recognition number 6-178)
- ASTM D6978-05 (Reapproved 2019) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (FDA Recognition number 6-147)
- ISO 2859-1:1999 Sampling Procedures and Tables for Inspection by Attributes. (FDA Recognition number 5-88)
- ASTM D412-2006a (Reapproved 2013) Standard Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension (FDA Recognition number 8-596)
- ASTM D573-2004 (Reapproved 2010) Standard Test Method for Rubber-Deterioration in an Air Oven (No FDA Recognition number)
- ASTM D3767-03 (2020) Standard Practice for Rubber Measurement of Dimensions (No FDA Recognition number)
- ASTM D7103-19 Standard guide for assessment of medical gloves (FDA Recognition number 6-444)
- ANSI/AAMI/ISO 10993-23:2021(E) - Biological evaluation of medical devices -Part 23: Tests for irritation (FDA Recognition number 2-291)
- ANSI/AAMI/ISO 10993-10:2021(E)- Biological evaluation of medical devices —Part 10: Tests for skin sensitization (FDA Recognition number 2-296)
- ANSI/AAMI/ISO 10993-11:2017(E) – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity. (FDA Recognition number 2-255)

- ANSI/AAMI/ISO 10993-12:2021(E) – Biological evaluation of medical devices – Part 12: Sample preparation and reference material. (FDA Recognition number 2-289)
- ANSI/AAMI/ISO 10993-2:2022(E) - Biological evaluation of medical devices -Part 2: Animal welfare requirements (FDA Recognition number 2-222)

Table 5.4 *Description of Non-Clinical Tests*

Brief description of non-clinical tests:	Test	Standard	Acceptance Criteria	Results
	Dimensions	ASTM D 6319		Meets Requirements
		Length	220 mm minimum (XS, S) 230 mm minimum (M, L, XL)	
		Width (mean)	70 mm minimum (XS) 80 mm minimum (S) 95 mm minimum (M) 110 mm minimum (L) 120 mm minimum (XL)	
		Finger Thickness Palm Thickness	0.05 mm minimum 0.05 mm minimum	
	Physical Properties	ASTM D 6319	AQL 4 Before Tensile Strength: ≥14 MPa Ultimate elongation: ≥500% After Tensile Strength: ≥14 MPa Ultimate elongation: 400%	Meets Requirements
	Freedom from Pinholes	ASTM D 6319 ASTM D 5151	AQL 2.5 No leakage	Meets Requirements
	Power - Free	ASTM D 6124	≤ 2 mg / glove	Meets Requirements
	ISO Irritation Study	ISO 10993, Part 23	No irritation	Under the conditions of the study the device is not an irritant.
	ISO Acute Systemic	ISO 10993, Part 11	No systemic toxicity	No evidence of

	Toxicity Study			Acute systemic toxicity
	ISO Dermal Sensitization	ISO 10993, Part 10	No sensitization	Under the conditions of the study the device is not a sensitizer
	Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	ASTM D6978-05	No signs of breakthrough for the subject device up to 240 minutes. Any drugs performing at less than 240 minutes are specified as such. Refer to Table 5.2 for Minimum breakthrough detection times	Breakthrough was measured for up to 240 minutes for each of the 24 chemotherapy drugs and opioid drug listed above. Refer to Table 5.2 for minimum breakthrough detection times.

10. Summary of Clinical Performance Testing: Not applicable.

11. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that, the KIMTECH™ Polaris™ Xtra Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Fentanyl in Simulated Gastric Acid, is as safe, as effective, and performs as well as or better than the predicate device, the KIMTECH™ Purple Nitrile Powder-Free Exam Glove cleared in K200072.