October 2, 2023

Isikel Manufacturing LLC
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K232064
Trade/Device Name: Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate)
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: July 10, 2023
Received: July 11, 2023

Dear Yolanda Smith:

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 (the 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 available 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232064

Device Name
Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate)

Indications for Use *(Describe)*
Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with Chemotherapy drugs and Fentanyl Citrate in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to permeation by Chemotherapy Drugs.

Chemotherapy Drug	Concentration	Breakthrough Detection Time
Carmustine	3.3 mg/ml (3,300 ppm)	16.2 (16.2,21.6,21.9) 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.
Etoposide	20 mg/ml (20,000 ppm)	>240 min.
Fluorouracil	50 mg/ml (50,000 ppm)	>240 min.
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.
Paclitaxel	60 mg/ml (6,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	40.6 (70.6,40.6,40.6) min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Fentanyl/Citrate Injection	100 mcg/2mL	>240min.

Please note the following drugs have low permeation times:
Carmustine 3.3 mg/ml (3,300 ppm) 16.2 minutes
Thiotepa 10 mg/ml (10,000 ppm) 40.6 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.

510 (k) Summary K232064

Submitter's Information	
Company:	Isikel Manufacturing LLC.
Address:	28350 West Ten Blvd. Katy, TX 77494
Phone:	832-523-2027
Contact:	Christopher Betts
Email:	chris.betts@isikelmfg.com
Date Prepared:	October 2, 2023

Designated Submission Correspondent	
Name	Yolanda Smith
Company:	Smith Associates
Address:	1468 Harwell Avenue Crofton, MD 21114
Phone	888-729-9674 x 203
Email:	ysmith@fdaconsultants.com

Device Information and Name	
Trade Name:	**Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate)**
Common Name:	Patient Examination Gloves, Specialty
Classification Name:	Polymer Patient Exam Glove, Medical Gloves with Chemotherapy Labeling Claims
Product Code:	LZA- Polymer Patient Examination Glove
Product Code:	LZC- Patient Examination Glove, Specialty
Product Code:	OPJ- Medical Gloves with Chemotherapy Labeling Claims - Test For Use With Chemotherapy Drugs
Product Code	QDO – Fentanyl And Other Opioid Protection Glove
Regulation Number:	21 CFR 880.6250
Device Class:	Class I, Reserved
Reviewing Panel:	General Hospital
Basis for Submission:	New Device 510(k)

Predicate Device K211810	
Manufacturer	PT. Shamrock Manufacturing Corporation
Device Name	Shamrock Powder Free Blue Nitrile Examination Gloves (Tested for use with Chemotherapy Drugs and Fentanyl Citrate)
Regulation No. Regulation Name	21 CFR 880.6250 Non-Powdered Patient Examination Glove
510 (K) Number	K211810
Regulatory Class	1
Product Code	LZA, LZC, OPJ, QDO

1. Device Description

Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate) is a Powder Free Nitrile Examination Glove. The subject device is a patient examination glove manufactured 100% nitrile (Acrylonitrile-Butadiene Copolymer dispersion), Per 21 CFR 880.6250, Product codes LZA, LZC, OPJ, QDO and Class 1, Blue Color, Powder Free and Non-Sterile. The device meets the specifications in ASTM D6319-19. Standard specifications for Nitrile Examination Gloves. The glove sizes provided are Small, Medium, Large, and X-Large. The gloves design features include ambidextrous and textured fingers. The subject device complies with requirements for standard practice for assessment of resistance of medical glove to permeation by chemotherapy drugs as per ASTM D6978-05 (2019).

2. Indications for Use

Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with Chemotherapy drugs and Fentanyl in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to permeation by Chemotherapy Drugs.

Tested Chemotherapy Drug Name	Concentration	Breakthrough Detection Time
Carmustine	3.3 mg/ml (3,300 ppm)	16.2 (16.2.21.6,21.9) min.
Cisplatin	1.0 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.
Etoposide	20 mg/ml (20,000 ppm	>240 min.
Fluorouracil	50 mg/ml (50,000 ppm)	>240 min.
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.
Paclitaxel	60 mg/ml (6,000 ppm)	>240 min.
Thiotepa	10 mg/ml (10,000 ppm)	40.6 (70.6,40.6,40.6) min.
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.
Fentanyl/Citrate Injection	100mcg / 2mL	>240 min.

Please note the following drugs have low permeation times:
Carmustine 3.3 mg/ml (3,300 ppm) 16.2 Minutes
Thiotepa 10 mg/ml (10,000 ppm) 40.6 Minutes
Warning: Do Not Use with Carmustine and Thiotepa

3. Summary of the Technological Characteristics of the Device compared to its Predicate

Characteristics	Subject Device	Predicate Device K211810	Comparison
K Number		K211810	
Product Code	LZA, LZC, OPJ, QDO	LZA, LZC, OPJ, QDO	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Class	Class I	Class I	Same
Indications for use	Powder-Free Frost Nitrile Examination Gloves (Blue) (Tested for use with Chemotherapy Drugs and Fentanyl Citrate) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner. In addition, these gloves were tested for use with Chemotherapy drugs and Fentanyl Citrate in accordance with *ASTM D6978-05* Carmustine 3.3 mg/ml (3,300 ppm) 16.2 (16.2.21.6,21.9) min. Cisplatin 1 mg/ml (1,000 ppm) >240 min.	A patient examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner. These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs and Fentanyl. The following chemicals have been tested with these gloves: Chemotherapy Drug and Concentration Breakthrough Detection Time in Minutes Carboplatin (Paraplatin), 10 mg/ml (10,000ppm) > 240 min.	Same for indications for use statement and for all comparative chemotherapy drugs.

Characteristics	Subject Device	Predicate Device K211810	Comparison
	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. Etoposide 20 mg/ml (20,000 ppm) >240 min. Fluorouracil 50 mg/ml (50,000 ppm) >240 min. Mitomycin C 0.5 mg/ml (500 ppm) >240 min. Paclitaxel 60 mg/ml (6,000 ppm) >240 min. Thiotepa 10 mg/ml (10,000 ppm) 40.6 (70.6,40.6,40.6) min. Vincristine Sulfate 1 mg/ml (1,000 ppm) >240 min. Fentanyl/Citrate Injection 100mcg / 2mL >240 min. Please note the following drugs have low permeation times: Carmustine 3.3 mg/ml (3,300 ppm) 16.2(16.2.21.6,21.9) Minutes Thiotepa 10 mg/ml (10,000 ppm) 40.6 (70.6,40.6,40.6) Minutes Warning: Do Not Use with Carmustine and Thiotepa	Carmustine (BCNU), 3.3 mg/ml (3,300ppm) 46.6 min. Chloroquine 50mg/ml (50,000ppm) > 240 min Cisplatin, 1.0 mg/ml (1,000ppm) > 240 min Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm) > 240 min Dacarbazine, 10.0mg/ml (10,000ppm) > 240 min Docetaxel, 10mg/ml (10,000ppm) > 240 min Doxorubicin HCl, 2.0mg/ml (2,000ppm) > 240 min Etoposide, 20.0mg/ml (20,000ppm) > 240 min Fluorouracil, 50.0mg/ml (50,000ppm) > 240 min Ifosfamide, 50 mg/ml (50,000 ppm) > 240 min Methotrexate, 25mg/ml (25,000 ppm) > 240 min Mitomycin C, 0.5 mg/ml (500 ppm) > 240 min Paclitaxel, 6.0 mg/ml (6,000 ppm) > 240 min Thiotepa, 10.0mg/ml (10,000ppm) 64.8 min Vincristine Sulfate, 1 mg/ml (1,000 ppm) > 240 min Fentanyl Citrate Injection 100mcg/2ml (50mcg/1ml) > 240 min Please note that the following drugs that have low permeation time are: Carmustine (BCNU), 3.3 mg/ml 46.6 min Thiotepa, 10.0mg/ml 64.8 min CAUTION: Testing showed an average of breakthrough time of 46.6 min for Carmustine and 64.8 min for Thiotepa.	
Powdered or Powder free	Powder free	Powder free	Same
Material	Nitrile	Nitrile	Same

Characteristics	Subject Device	Predicate Device K211810	Comparison
Design Feature	Ambidextrous	Ambidextrous	Same
Sterility	Non-sterile	Non-sterile	Same
Color	Light Blue	Blue	Similar
Size	Small, Medium, Large, Extra Large	X-Small, Small, Medium, Large, X-Large, XX-large	Similar
Single Use vs Reusable	Single use	Single use	Same
Residual Powder	Powder Free ≤2 mg/glove Complies with ASTM D6319-19	Powder Free ≤2 mg/glove Complies with ASTM D6319-19	Same
Detection of Holes ASTM D5151-2019	AQL 2.5 Complies with ASTM D6319-19	AQL 2.5 Complies with ASTM D6319-19	Same
Dimensions (Length, Width, Thickness)	Complies with ASTM D6319-19	Complies with ASTM D6319-19	Same
Physical Properties (Unaged)	Elongation: 500% min. Tensile Strength: 14MPa min. Complies with ASTM D6319-19	Elongation: 500% min. Tensile Strength: 14MPa min. Complies with ASTM D6319-19	Same
Physical Properties (Aged)	Elongation: 400% min. Tensile Strength: 14MPa min. Complies with ASTM D6319-19	Elongation: 400% min. Tensile Strength: 14MPa min. Complies with ASTM D6319-19	Same
Labeling Information FDA Label Requirements	Meets FDA's Requirements	Meets FDA's Requirements	Same

Test Method		ASTM D6319-19					Comparison of Test results
Purpose		**To Determine the Length of Gloves**					
Acceptance Criteria		Min 220 mm for all Size Small & Min 230 mm for all other sizes					
Designation-Length		S	M	L	XL	Tolerance	
Subject Device	Length, mm	220mm	230mm	230mm	230mm	min.	Met Standard
Predicate K211810	Length, mm	220mm	230mm	230mm	230mm	min.	Met Standard

Test Method		ASTM D6319-19					Comparison of Test results
Purpose		**To Determine the Width of Gloves**					
Acceptance Criteria		Small: 80+/110 mm Medium: 95+/- 10mm Large: 110+/- 10mm X Large: 115+/1 10mm					
Designation- Width		S	M	L	XL	Tolerance	
Subject Device	Width, mm	80mm	95mm	110mm	115mm	± 10	Met Standard
Predicate K211810	Width, mm	80mm	95mm	110mm	115mm	± 10	Met Standard

Test Method		ASTM D6319-2019				Comparison of Test results
Purpose		**To Determine the Palm Thickness of the Glove**				
Acceptance Criteria		Palm 0.05 mm min for all sizes				
Designation- Palm		S	M	L	XL	
Subject	Palm	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard
Predicate K211810	Palm	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard
Purpose		**To Determine the Finger Thickness of the Glove**				
Acceptance Criteria		Finger 0.05 mm min for all sizes				
Designation - Finger		S	M	L	XL	
Subject	Finger	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard
Predicate K211810	Finger	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard

Test Method	ASTM D412		Comparison of Test results
Purpose	**Test Method for Vulcanized Rubber and Thermoplastic Elastomers- Tension**		
Acceptance Criteria Before Aging	Tensile Strength- Before Aging 14 MPa, min	Ultimate Elongation- Before Aging 500 % min	
Subject	≥ 14 MPa	500%	Same
Predicate K211810	≥ 14 MPa	500%	Same
Test Method	ASTM D412		Comparison of Test results

Purpose	**Test Method for Vulcanized Rubber and Thermoplastic Elastomers-Tension**		
Acceptance Criteria After Aging	Tensile Strength- After Aging 14 MPa, min	Ultimate Elongation- After Aging 400% min	
Subject	≥ 14 MPa	400%	Same
Predicate K211810	≥ 14 MPa	400%	Same

Tested Chemotherapy Drug Name	Concentration	Subject Device	Predicate Device 211810	Comparison
Carmustine	3.3 mg/ml (3,300 ppm)	16.2 min (16.2. 21.6, 21.9)	46.6 Minutes	Different
Cisplatin	1 mg/ml (1,000 ppm)	>240 min.	>240 Minutes	Same
Cyclophosphamide	20 mg/ml (20,000 ppm)	>240 min.	>240 Minutes	Same
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.	>240 Minutes	Same
Doxorubicin HCL	2 mg/ml (2,000 ppm)	>240 min.	>240 Minutes	Same
Etoposide	20 mg/ml (20,000 ppm)	>240 min.	>240 Minutes	Same
Fluorouracil	50 mg/ml (50,000 ppm)	>240 min.	>240 Minutes	Same
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.	>240 Minutes	Same
Paclitaxel	60 mg/ml (6,000 ppm)	>240 min.	>240 Minutes	Same
Thiotepa	10 mg/ml (10,000 ppm)	40.6 min (70.6,40.6,40.6)	64.8 Minutes	Different
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.	>240 Minutes	Same
Fentanyl/Citrate Injection	100mcg / 2mL	>240 Minutes	>240 Minutes	Same

Test Method	Purpose of Test	Subject Device	Predicate	Comparison of Test results
ASTM D6319-19	Physical Dimensions To determine the Length and Width of Gloves	Complies with: ASTM D6319-19	Complies with: ASTM D6319-19	Same

Test Method	Purpose of Test	Subject Device	Predicate	Comparison of Test results
ASTM D5151	Watertightness Test for Detection of Holes	Meets the requirement when tested in accordance with ASTM D5151 AQL = 2.5	Complies with: ASTM D6319-19 ASTM D5151 AQL 2.5	Same
ASTM D6124-06	To determine the residual powder in gloves	Meets the requirement of ASTM D6124 ≤2 mg glove	Complies with: ASTM D6319-19 < 2 mg per glove	Same

Test Performed	Subject Device	Predicate Device K211820	Comparison
ISO 10993-10:2010 Skin Sensitization Test	Non-Sensitizer	Under the conditions of study, not a sensitizer	Same
ISO 10993-23:2021 Intracutaneous Reactivity Test	Non-Irritant	Under the conditions of study, not an irritant	Same
ISO 10993-5:2009 In vitro Cytotoxicity Test	Under the conditions of the study, cytotoxic.	Under the conditions of the study, cytotoxic	Same
ISO 10993-11:2017 Acute Systemic Toxicity Test	Pass	Under the conditions of study, does not induce any acute systemic toxicity concern	Same

Analysis: Some of the sizes are different with that of the predicate, but they all meet the requirements of ASTM D6319-19. The differences do not raise any new safety or performance issues. Differences in breakthrough detection times are addressed through labeling.

4. Discussion of Non-Clinical Performance Testing

Non-Clinical test were conducted to verify that the proposed device met all design specifications.

Biocompatibility Testing

ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for in vitro Cytotoxicity

ISO 10993-10:2010 Biological Evaluation of Medical Devices. Part 10- Test for Irritation and Skin Sensitization.

ISO 10993-11 ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

ISO 10993-23:2021 Biological Evaluation of Medical Devices, Part 23: Tests for Irritation-Primary

Performance Testing (Bench)
Physical performance qualities of the proposed device were evaluated per ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.

Permeation testing was conducted to support the addition of the label claim: Tested for use with Chemotherapy drugs and Fentanyl Citrate. The proposed device was tested according to ASTM D6978-05 (Reapproved 2019), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs, in which minimum breakthrough times were determined for a wide range of chemotherapy drugs.

In summary, the performance testing of the subject device was conducted in accordance with the following test methods:

- ASTM D6319-19 Standard Specifications for Nitrile Examination Gloves for Medical Application.
    - ASTM D412-Test methods for Vulcanized Rubber and Thermoplastic Elastomers- Tension.
    - ASTM D573-Test Method for Rubber-Deterioration in an Air Oven.
    - ASTM D3767- Practice Rubber Examination Gloves
    - ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves
    - ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D6978-05- Standard Practice for Assessment of Resistance of Medical Gloves to Permeations by Chemotherapy Drugs.

Physical Properties -Tensile Strength Before and After Aging	**Acceptance Criteria- For all Sizes Before and After Aging 14Mpa**		
Test Method - Applicable Standard	Before Aging	After Aging	Unexpected Results – Significant Deviations

ASTM D412	19.0 min (MPa)	22.6 min (MPa)	None
Physical Properties-Ultimate Elongation Before and After Aging	**Acceptance Criteria- For All Sizes Before Aging 500% - After Aging 400%**		
Test Method - Applicable Standard	Before Aging	After Aging	Unexpected Results – Significant Deviations
ASTM D573	610 min (%)	486 min (%)	None

Test Method		ASTM D6319-19					f Test results
Purpose		**To Determine the Length of Gloves**					
Acceptance Criteria		Min 220 mm for all Size Small & Min 230 mm for all other sizes					
Designation-Length		S	M	L	XL	Tolerance	
Subject Device	Length, mm	220mm	230mm	230mm	230mm	min.	Met Standard
Test Method		ASTM D6319-19					Comparison of Test results
Purpose		**To Determine the Width of Gloves**					
Acceptance Criteria		Small: 80+/110 mm Medium: 95+/- 10mm Large: 110+/- 10mm X Large: 115+/1 10mm					
Designation- Width		S	M	L	XL	Tolerance	
Subject Device	Width, mm	80mm	95mm	110mm	115mm	± 10	Met Standard

Test Method		ASTM D6319-2019				Test Results
Purpose		**To Determine the Palm Thickness of the Glove**				
Acceptance Criteria		Palm 0.05 mm min for all sizes				
Designation- Palm		S	M	L	XL	
Subject	Palm	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard
Purpose		**To Determine the Finger Thickness of the Glove**				
Acceptance Criteria		Finger 0.05 mm min for all sizes				
Designation - Finger		S	M	L	XL	

Subject	Finger	0.05 mm min.	0.05 mm min.	0.05 mm min.	0.05 mm min.	Meets standard

Test Performed	**Test Method**	**Acceptance Criteria**	**Results**
Residual Powder on Medical Gloves	ASTM D6124-06	Limit: ≤ 2.0 mg	0.54 mg/Glove

Chemotherapy Drug	**Concentration**	**Breakthrough Time In Minutes**	**Observations**
Carmustine	3.3 mg/ml (3,300 ppm	16.2 (16.2.21.6,21.9)	Slight swelling and no degradation
Cisplatin	1 mg/ml (1,000 ppm)	>240 min.	Slight swelling and no degradation
Cyclophosphamide	20 mg/ml (20,000 ppm)	>240 min.	Slight swelling and no degradation
Dacarbazine	10 mg/ml (10,000 ppm)	>240 min.	Slight swelling and no degradation
Doxorubicin HCL	2 mg/ml (2,000 ppm)	>240 min.	Slight swelling and no degradation
Etoposide	20 mg/ml (20,000 ppm)	>240 min.	Slight swelling and no degradation
Fluorouracil	50 mg/ml (50,000 ppm)	>240 min.	Slight swelling and no degradation
Mitomycin C	0.5 mg/ml (500 ppm)	>240 min.	Slight swelling and no degradation
Paclitaxel	60 mg/ml (6,000 ppm)	>240 min.	Slight swelling and no degradation
Thiotepa	10 mg/ml (10,000 ppm)	40.6 min	Slight swelling and no degradation
Vincristine Sulfate	1 mg/ml (1,000 ppm)	>240 min.	Slight swelling and no degradation
Fentanyl/Citrate Injection	100mcg / 2mL	>240 Minutes	Slight swelling and degradation

Test Performed	Acceptance Criteria	Results
ISO 10993-10:2010 Skin Sensitization Test	Under the conditions of the study, not a sensitizer	Pass (Non- Sensitizer)

Test Performed	Acceptance Criteria	Results
ISO 10993-23:2021 Intracutaneous Reactivity Test	Under the conditions of the study, not an irritant	Pass (Non-Irritant)
ISO 10993-5:2009 In vitro Cytotoxicity Test	Under the conditions of the study, non-cytotoxic	Was considered Cytotoxic
ISO 10993-11:2017 Acute Systemic Toxicity Test	Under the conditions of the study, the device extracts do not pose an acute systemic toxicity concern.	Pass

5. Discussion of Clinical Testing

Clinical testing is not needed for this device.

6. Conclusion

The conclusions from the non-clinical tests demonstrate that the **Powder-Free Frost Nitrile Examination Gloves (Blue) Tested for use with Chemotherapy Drugs and Fentanyl Citrate** is as safe, as effective, and performs as well as or better than the predicate device that was cleared under K211280.