May 22, 2025

Basic Medical Technology Inc.
John Zhao
General Manager
5300 Concours Street
Ontario, California 91764

Re: K250630
Trade/Device Name: Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in 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: March 3, 2025
Received: March 3, 2025

Dear John Zhao:

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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250630

Device Name
Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate

Indications for Use *(Describe)*
Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
Gloves were tested for use with Chemotherapy drugs, Fentanyl, Gastric acid and Xylazine in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drugs	Minimum Breakthrough Detection Time
Carboplatin, 10 mg/ml	>240 min.
Carmustine, 3.3 mg/ml	11.6 min.
Cisplatin, 1 mg/ml	>240 min.
Cyclophosphamide, 20 mg/ml	>240 min.
Cytarabine HCl 100 mg/ml	>240 min.
Dacarbazine, 10 mg/ml	>240 min.
Daunorubicin HCl, 5 mg/ml	>240 min.
Doxorubicin HCl, 2 mg/ml	>240 min.
Etoposide, 20 mg/ml	>240 min.
5-Fluorouracil, 50 mg/ml	>240 min.
Gemcitabine HCl, 38 mg/ml	>240 min.
Idarubicin HCl, 1 mg/ml	>240 min.
Ifosfamide, 50 mg/ml	>240 min.
Irinotecan HCl, 20 mg/ml	>240 min.
Mechlorethamine HCl, 1 mg/ml	>240 min.
Melphalan HCl, 5 mg/ml	>240 min.
Methotrexate, 25 mg/ml	>240 min.
Mitomycin-C, 0.5 mg/ml	>240 min.
Mitoxantrone HCl,, 2 mg/ml	>240 min.
Pacilitaxel, 6 mg/ml	>240 min.
Thiotepa, 10 mg/ml	25.3 min.
Vincrinstine Sulfate,1 mg/ml	>240 min.

Fentanyl, Gastric Acid and Xylazine	Minimum Breakthrough Detection Time
Fentanyl Citrate Injection, 50mcg/ml	>240 min.
Simulated Gastric Acid	>240 min.
Fentanyl Citrate (50mcg/ml): Xylazine HCl(100mg/ml), 50:50	>240 min.

*Please note that the following drugs have extremely low permeation times:
Carmustine: 11.6 minutes, Thiotepa:25.3 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.

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510(k) Summary

1. Submission Information

Date Prepared: May 21, 2025
Submission Format: Traditional 510(k)
510(K)#: K250630

2. Submitter Information

Applicant Name: Basic Medical Technology Inc.
Address: 5300 Concours Ontario, CA 91764
Contact Person: John Zhao
Tel： (909) 980-1678
Email: hotmailtojohn@yahoo.com

3. Device Information

Trade Name: Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate

Common Name: Nitrile Powder-Free Exam Gloves
Classification Name: Non-Powdered Patient Examination Glove
Regulation: 21 CFR 880.6250
Product Code: LZA, LZC, QDO, OPJ
Classification Panel: General Hospital
Device Class: Class I

4. Predicate Device Information

Primary Predicate Device:

Applicant: Anhui Intco Medical Products Co., Ltd.

510(k) #: K231365

Trade Name: Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate. Aka Synguard C+ Nitrile Exam Gloves

Reference Device 1:

Applicant: Basic Medical Technology Inc.

510(k) #: K243441

Trade Name: Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid (Light blue, Dark blue)

Reference Device 2:

Applicant: Ever Global (Vietnam) Enterprise Corporation

510(k) #: K244034

Trade Name: Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine

5. Device Description:

Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate is a Class I patient examination glove and specialty chemotherapy gloves, that made from synthetic nitrile latex. They are non-sterile, powder-free, fingertip textured, ambidextrous with beaded cuff, blue colored nitrile gloves featuring an inner coating of hyaluronic acid and single use only. There are six different sizes- XS, S, M, L, XL and XXL.

The gloves are designed and manufactured in accordance with the ASTM D6319-19 standard and are tested for use with chemotherapy drugs, opioid Fentanyl Citrate, simulated Gastric Acid and Xylazine per ASTM D6978-05.

6. Indications for Use:

Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

Gloves were tested for use with Chemotherapy drugs, Fentanyl, Gastric acid and Xylazine in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

NO.	Chemotherapy Drugs	Minimum Breakthrough Detection Time
1	Carboplatin, 10 mg/ml	>240 min
2	Carmustine, 3.3 mg/ml	11.6 min
3	Cisplatin, 1 mg/ml	>240 min
4	Cyclophosphamide, 20 mg/ml	>240 min
5	Cytarabine HCl, 100 mg/ml	>240 min
6	Dacarbazine, 10 mg/ml	>240 min
7	Daunorubicin HCl, 5 mg/ml	>240 min
8	Doxorubicin HCl, 2 mg/ml	>240 min
9	Etoposide, 20 mg/ml	>240 min
10	5-Fluorouracil, 50 mg/ml	>240 min
11	Gemcitabine HCl, 38 mg/ml	>240 min
12	Idarubicin HCl, 1 mg/ml	>240 min
13	Ifosfamide, 50 mg/ml	>240 min
14	Irinotecan HCl, 20 mg/ml	>240 min
15	Mechlorethamine HCl, 1 mg/ml	>240 min

16	Melphalan HCl, 5 mg/ml	>240 min
17	Methotrexate, 25 mg/ml	>240 min
18	Mitomycin-C, 0.5 mg/ml	>240 min
19	Mitoxantrone HCl, 2 mg/ml	>240 min
20	Pacilitaxel, 6 mg/ml	>240 min
21	Thiotepa, 10 mg/ml	25.3 min
22	Vincristine Sulfate, 1 mg/ml	>240 min
NO.	Fentanyl, Gastric Acid and Xylazine	Minimum Breakthrough Detection Time
1	Fentanyl Citrate Injection, 50mcg/ml	>240 min.
2	Simulated Gastric Acid	>240 min.
3	Fentanyl Citrate (50mcg/ml): Xylazine HCl(100mg/ml), 50:50	>240 min.

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

Carmustine: 11.6 minutes, Thiotepa: 25.3 minutes
Warning: Do not use with Carmustine and Thiotepa.

7. Comparison of Subject Device and Predicate Device:

General Comparison Table:

Device	**Proposed Device**	**Predicate Device**	Reference Device	Reference Device	**Result**
510K #	K250630	K231365	K243441	K244034	-
Applicant Name	Basic Medical Technology Inc.	Anhui Intco Medical Products Co., Ltd.	Basic Medical Technology Inc.	Ever Global (Vietnam) Enterprise Corporation	**Same as** K243441
Product Name	Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate	Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl citrate. Aka Synguard C+ Nitrile Exam Gloves	Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid (Light blue, Dark blue)	Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs And Fentanyl Citrate And Xylazine	-
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	21 CFR 880.6250	Same
Device Classification	Class I	Class I	Class I	Class I	Same
Indications for use	Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate is a disposable device intended for medical purposes that is worn on the examiner's	A powder-free 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.	The glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner. Gloves were tested for use with	A patient examination gloves is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were	Similar

	hand to prevent contamination between patient and examiner. Gloves were tested for use with Chemotherapy drugs, Fentanyl, Gastric acid and Xylazine in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.	The glove was tested for use with Chemotherapy Drugs and Fentanyl Citrate as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Chemotherapy drugs, Fentanyl and Gastric acid in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs	tested for use with chemotherapy drugs, fentanyl citrate and xylazine in accordance with ASTM D6978-05 standard practice for assessment of Resistance of medical gloves to permeation by chemotherapy drugs.	
Powder free	Yes	Yes	Yes	Yes	Same
Material	Nitrile	Nitrile	Nitrile	Nitrile	Same
Color	Blue	Blue	Light blue, Dark blue	Blue	Similar
Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	XS, S, M, L, XL	Similar
Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use	Single use	Single use	Single use	Single use	Same
Design feature	Ambidextrous	Ambidextrous	Ambidextrous	Ambidextrous	Same
Other	Hyaluronic Acid coated on inside	Hyaluronic Acid coated on inside	NA	NA	Same as K231365
Chemo Drugs Claim	See below comparison table	See below comparison table	See below comparison table	See below comparison table	/

Technological Characteristic Comparison Table:

Characteristics		**Proposed device**	**Predicate device** K231365	**Reference Device** K243441	**Reference Device** K244034	**Result**
Dimension **Reference standard** ASTM D6319-19	Length	Min 220mm for XS, S Min 230mm for M, L, XL, XXL	Min 220mm for XS, S Min 230mm for M, L, XL, XXL	Min 220mm for XS, S Min 230mm for M, L, XL, XXL	Length: Short cuff: ⩾ 230mm Long cuff: ⩾300mm	Similar
	Width	XS: 70±10 mm S: 80±10 mm M: 95±10 mm L： 110±10 mm XL：120±10 mm XXL：130±10 mm	XS: 70±10 mm S: 80±10 mm M: 95±10 mm L： 110±10 mm XL：120±10 mm XXL：130±10 mm	XS: 70±10 mm S: 80±10 mm M: 95±10 mm L： 110±10 mm XL：120±10 mm XXL：130±10 mm	XS: 70±10 mm S: 80±10 mm M: 95±10 mm L：110±10 mm XL：120±10 mm	
	Thickness	Palm: Min 0.05 mm Finger: Min 0.05 mm	Palm: Min 0.05 mm Finger: Min 0.05 mm	Palm: Min 0.05 mm Finger: Min 0.05 mm	Palm: Min 0.05 mm Finger: Min0.05 mm Cuff: Min 0.05 mm	
Physical properties	**Before aging**					Same
	Tensile strength	Min 14MPa	Min 14MPa	Min 14MPa	Min 14MPa	

ASTM D6319-19 ASTM D412-16	Ultimate elongation	Min 500%	Min 500%	Min 500%	Min 500%	
	After aging					
	Tensile strength	Min 14MPa	Min 14MPa	Min 14MPa	Min 14MPa	
	Ultimate elongation	Min 400%	Min 400%	Min 400%	Min 400%	
Freedom from holes ASTM D6319-19; ASTM D5151-19		G-I, AQL2.5	G-I, AQL2.5	G-I, AQL2.5	G-I, AQL2.5	Same
Residual Powder ASTM D6319-19; ASTM D6124-06		≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	Same
Biocompatibility	Skin Irritation ISO 10993-23	Under the conditions of the study, not an irritant	*Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Similar
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same
	Acute Systemic Toxicity Test ISO 10993-11	Under the conditions of this study, no evidence of acute systemic toxicity.	Under the conditions of this study, no evidence of acute systemic toxicity.	Under the conditions of this study, no evidence of acute systemic toxicity.	Not Performed	Different as K244034
	Cytotoxicity ISO 10993-5	Not Performed	Not Performed	Not Performed	Under the conditions of the study, test article is non-cytotoxic	Different as K244034

*The new version of standard for Skin Irritation we refer is ISO 10993-23:2021, the test method and process is the same as the old version ISO 10993-10:2010.

Chemotherapy Drugs Comparison Claim:

NO.	Chemotherapy Drugs	Minimum Breakthrough Detection Time					Result of comparison
		Proposed device	**Predicate device** K231365 ①	**Reference Device** K243441②		**Reference Device** K244034③	
				Light blue	Dark blue		
1	Carboplatin, 10 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
2	Carmustine, 3.3 mg/ml	11.6 min	12.1 min	16.6 min	21.5 min	21.5 min	Different
3	Cisplatin, 1 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
4	Cyclophosphamide, 20 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same

5	Cytarabine HCl, 100 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
6	Dacarbazine, 10 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
7	Daunorubicin HCl, 5 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
8	Doxorubicin HCl, 2 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
9	Etoposide, 20 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
10	5-Fluorouracil, 50 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
11	Gemcitabine HCl, 38 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
12	Idarubicin HCl, 1 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
13	Ifosfamide, 50 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
14	Irinotecan HCl, 20 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
15	Mechlorethamine HCl, 1 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
16	Melphalan HCl, 5 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
17	Methotrexate, 25 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
18	Mitomycin-C, 0.5 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
19	Mitoxantrone HCl, 2 mg/ml	>240 min	/	>240 min	>240 min	>240 min	Same as ②and ③
20	Pacilitaxel, 6 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
20	Thiotepa, 10 mg/ml	25.3 min	10.1 min	44.9 min	17.9 min	13.6 min	Different
22	Vincristine Sulfate, 1 mg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
23	Arsenic Trioxide,1.0 mg/ml	/	/	/	/	>240 min	Different
24	Bendamustine HCl, 5 mg/ml	/	/	>240 min	>240 min	>240 min	Different
25	Bleomycin Sulfate,15.0 mg/ml	/	/	/	/	>240 min	Different
26	Bortezomib,1 mg/ml	/	/	>240 min	>240 min	>240 min	Different
27	Busulfan, 6 mg/ml	/	/	>240 min	>240 min	>240 min	Different
28	Carfilzomib, 2 mg/ml	/	/	>240 min	>240 min	>240 min	Different
29	Cetuximab (Erbitux), 2 mg/ml	/	/	>240 min	>240 min	>240 min	Different
30	Chloroquine, 50mg/ml	/	/	>240 min	>240 min	>240 min	Different
31	Cladribine, 1.0 mg/ml	/	/	>240 min	>240 min	>240 min	Different
32	Cyclosporin A,100mg/ml	/	/	>240 min	>240 min	>240 min	Different
33	Cytovene, 10 mg/ml	/	/	>240 min	>240 min	>240 min	Different
34	Decitabine, 5 mg/ml	/	/	>240 min	>240 min	>240 min	Different
35	Docetaxel, 10 mg/ml	/	/	>240 min	>240 min	>240 min	Different
36	Epirubicin HCl, 2 mg/ml	/	/	>240 min	>240 min	>240 min	Different
37	Fludarabine, 25 mg/ml	/	/	>240 min	>240 min	>240 min	Different
38	Fulvestrant, 50.0 mg/ml	/	/	/	/	>240 min	Different
39	Mesna, 100 mg/ml	/	/	/	/	>240 min	Different
40	Oxaliplatin, 2 mg/ml	/	/	>240 min	>240 min	>240 min	Different

41	Paraplatin,10.0 mg/ml	/	/	/	/	>240 min	Different
42	Pemetrexed, 25.0 mg/ml	/	/	/	/	>240 min	Different
43	Pertuzumab,30.0 mg/ml	/	/	/	/	>240 min	Different
44	Raltitrexed, 0.5 mg/ml	/	/	/	/	>240 min	Different
45	Retrovir, 10 mg/ml	/	/	>240 min	>240 min	>240 min	Different
46	Rituximab, 10.0 mg/ml	/	/	/	/	>240 min	Different
47	Temsirolimus, 25.0 mg/ml	/	/	/	/	>240 min	Different
48	Topotecan HCl,1.0 mg/ml	/	/	/	/	>240 min	Different
49	Trastuzumab,21.0 mg/ml	/	/	/	/	>240 min	Different
50	Triclosan,2.0 mg/ml	/	/	/	/	>240 min	Different
51	Trisenox,1.0 mg/ml	/	/	>240 min	>240 min	>240 min	Different
52	Vidaza (Azacitidine),25 mg/ml	/	/	>240 min	>240 min	>240 min	Different
53	Vinblastine, 1.0 mg/ml	/	/	/	/	>240 min	Different
54	Vinorelbine,10.0 mg/ml	/	/	/	/	>240 min	Different
55	Zoledronic Acid, 0.8 mg/ml	/	/	/	/	>240 min	Different

NO.	Fentanyl, Gastric Acid and Xylazine	Minimum Breakthrough Detection Time					Result of comparison
		Proposed device	**Predicate device** K231365 ①	**Reference Device** K243441②		**Reference Device** K244034③	
				Light blue	Dark blue		
1	Fentanyl Citrate Injection,50mcg/ml	>240 min	>240 min	>240 min	>240 min	>240 min	Same
2	Gastric Acid	>240 min	/	>240 min	>240 min	/	Same as ②
3	Xylazine HCl Injection (100 mg/ml)	/	/	/	/	>240 min	Different
4	Fentanyl Citrate (50mcg/ml): Xylazine HCl (100mg/ml), 50:50	>240 min	/	/	/	/	Different

** Chemotherapy drugs and the minimum breakthrough time of subject device will be listed on labeling, so this different does not raise questions of safety and effectiveness.*

8. Summary of Non-Clinical Testing

Biocompatibility

Biocompatibility Testing according to ISO 10993-1:2018, the nature of body contact for the proposed device is Surface and External Communicating Device and duration of contact is A-Limited (≤24h). The following tests for the proposed device were conducted to evaluate the biocompatibility of Nitrile Disposable Examination Gloves as per Guidance for Industry and FDA Staff - Medical Glove Guidance Manual issued on January 22, 2008:

- ISO 10993-23: Primary Skin Irritation
- ISO 10993-10: Dermal Sensitization
- ISO 10993-11: Systemic Toxicity*

*Similar to the predicate, Acute Systemic Toxicity was performed in lieu of Cytotoxicity testing.

Performance Testing

Physical Performance testing of the proposed device was conducted as per ASTM D6319-19 *Standard Specification for Nitrile Examination Gloves for Medical Application*. Permeation testing was conducted to support the addition of the labeling claim. The proposed device was also tested according to ASTM D6978-05 (2023) *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 and fentanyl citrate, simulated gastric acid, and fentanyl citrate: xylazine HCL.
To summarize, the performance testing of the subject device was conducted to adequately demonstrate the effectiveness of the device in accordance to the relevant test methods cited below:

- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
- ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves
- ASTM D5151-06 Standard Test Method for Detection of Holes in Medical Gloves
- ASTM D6978-05 Standard Practice for Assessment of resistance of Medical Gloves to Permeation by Chemotherapy Drugs

From the test result, we find that the product can meet the requirements as its intended use indicates.

Test performed	Methodology	Acceptance Criteria	Result
Freedom From Holes	ASTM D6319-19 ASTM D5151-19	Meet requirement inspection level G- 1, AQL 2.5 (ISO2859-1)	Pass
Dimension-Length	ASTM D6319-19	Minimum 220mm for size XS-S Minimum 230mm for size M-XXL	Pass
Dimension-Width	ASTM D6319-19	XS: 70±10mm S: 80±10mm M: 95±10mm L:110±10mm XL: 120±10mm XXL: 130±10mm	Pass
Dimension-Thickness	ASTM D6319-19	Finger: 0.05mm (min) Palm: 0.05mm (min)	Pass
Physical properties	ASTM D6319-19 ASTM D412-16	Tensile Strength (Before and After Aging 14 Mpa Min) Elongation (Before Aging 500% and after aging 400% Min)	Pass
Powder Residue	ASTM D6319-19 ASTM D6124-06	Not more than 2 mg per glove	Pass
Skin Irritation	ISO10993-23:2021	Under the conditions of the study, not a primary skin irritant	Pass
Skin Sensitization	ISO10993-10:2021	Under the conditions of the study, not a contact sensitizer	Pass
Acute Systemic Toxicity	ISO 10993-11:2017	Under the conditions of the study, no signs of acute systemic toxicity were observed	Pass
Chemotherapy Drug	ASTM D6978-05	Refer to the above table	Pass

9. Summary of Clinical Testing:

Not applicable.

10. Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.