



January 31, 2025

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

Re: K243441

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

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: November 6, 2024

Received: November 6, 2024

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

Indications for Use

Submission Number (if known)

K243441

Device Name

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

Indications for Use (Describe)

The glove is 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 and Gastric acid in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

Light Blue glove:

Chemotherapy Drugs	Minimum Breakthrough Detection Time (minutes)
Bendamustine HCl, 5 mg/ml	>240
Bortezomib, 1 mg/ml	>240
Busulfan, 6 mg/ml	>240
Carboplatin, 10 mg/ml	>240
Carmustine, 3.3 mg/ml	16.6
Carfilzomib, 2 mg/ml	>240
Cetuximab (Erbix) 2 mg/ml	>240
Chloroquine, 50mg/ml	>240
Cisplatin, 1 mg/ml	>240
Cladribine, 1.0 mg/ml	>240
Cyclophosphamide, 20 mg/ml	>240
Cyclosporin A, 100mg/ml	>240
Cytarabine HCl, 100 mg/ml	>240
Cytovene, 10 mg/ml	>240
Dacarbazine, 10 mg/ml	>240
Daunorubicin HCl, 5 mg/ml	>240
Decitabine, 5 mg/ml	>240
Docetaxel, 10 mg/ml	>240
Doxorubicin HCl, 2 mg/ml	>240
Epirubicin HCl, 2 mg/ml	>240
Etoposide, 20 mg/ml	>240
Fludarabine, 25 mg/ml	>240
Fluorouracil, 50 mg/ml	>240
Gemcitabine HCl, 38 mg/ml	>240
Idarubicin HCl, 1 mg/ml	>240
Ifosfamide, 50 mg/ml	>240
Irinotecan, 20 mg/ml	>240
Mechlorethamine HCl, 1 mg/ml	>240
Melphalan HCl, 5 mg/ml	>240
Methotrexate, 25 mg/ml	>240
Mitomycin-C, 0.5 mg/ml	>240
Mitoxantrone HCl, 2 mg/ml	>240
Oxaliplatin, 2 mg/ml	>240
Paclitaxel, 6 mg/ml	>240

Retrovir, 10 mg/ml	>240
ThioTEPA, 10 mg/ml	44.9
Trisenox, 1 mg/ml	>240
Vidaza (Azacitidine), 25 mg/ml	>240
Vincristine Sulfate, 1 mg/ml	>240

Fentanyl Citrate and Gastric Acid	Minimum Breakthrough Detection Time, minutes
Fentanyl Citrate Injection, 100mcg/2ml	>240
Simulated Gastric Acid	>240

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

Carmustine: 16.6 minutes, Thio Tapa: 44.9 minutes

Warning: Do not use with Carmustine and Thio Tapa.

Dark Blue glove:

Chemotherapy Drugs	Minimum Breakthrough Detection Time (minutes)
Bendamustine HCl, 5 mg/ml	>240
Bortezomib, 1 mg/ml	>240
Busulfan, 6 mg/ml	>240
Carboplatin, 10 mg/ml	>240
Carmustine, 3.3 mg/ml	21.5
Carfilzomib, 2 mg/ml	>240
Cetuximab (Erbix) 2 mg/ml	>240
Chloroquine, 50mg/ml	>240
Cisplatin, 1 mg/ml	>240
Cladribine, 1.0 mg/ml	>240
Cyclophosphamide, 20 mg/ml	>240
Cyclosporin A, 100mg/ml	>240
Cytarabine HCl, 100 mg/ml	>240
Cytovene, 10 mg/ml	>240
Dacarbazine, 10 mg/ml	>240
Daunorubicin HCl, 5 mg/ml	>240
Decitabine, 5 mg/ml	>240
Docetaxel, 10 mg/ml	>240
Doxorubicin HCl, 2 mg/ml	>240
Epirubicin HCl, 2 mg/ml	>240
Etoposide, 20 mg/ml	>240
Fludarabine, 25 mg/ml	>240
Fluorouracil, 50 mg/ml	>240
Gemcitabine HCl, 38 mg/ml	>240
Idarubicin HCl, 1 mg/ml	>240
Ifosfamide, 50 mg/ml	>240
Irinotecan, 20 mg/ml	>240
Mechlorethamine HCl, 1 mg/ml	>240
Melphalan HCl, 5 mg/ml	>240
Methotrexate, 25 mg/ml	>240
Mitomycin-C, 0.5 mg/ml	>240
Mitoxantrone HCl, 2 mg/ml	>240
Oxaliplatin, 2 mg/ml	>240
Paclitaxel, 6 mg/ml	>240
Retrovir, 10 mg/ml	>240
ThioTEPA, 10 mg/ml	17.9

Trisenox, 1 mg/ml	>240
Vidaza (Azacitidine), 25 mg/ml	>240
Vincristine Sulfate, 1 mg/ml	>240
Fentanyl Citrate and Gastric Acid	Minimum Breakthrough Detection Time, minutes
Fentanyl Citrate Injection, 100mcg/2ml	>240
Simulated Gastric Acid	>240

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

Carmustine: 21.5 minutes, Thio Tepa: 17.9 minutes

Warning: Do not use with Carmustine and Thio Tepa.

Type of Use (Select one or both, as applicable)

☐

Prescription Use (Part 21 CFR 801 Subpart D)

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Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Basic Medical Technology Inc.
5300 Concours Ontario, CA 91764

510(K) Summary
K243441

1. Submission Information

Date Prepared: January 31, 2025
Submission Format: Traditional 510(k)
510(K)#: K243441

2. Submitter Information

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

3. Device Information

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

Lingshi Hongruida Health Protection Technology Co., Ltd.
Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, and select other drugs (K240051)
Product code: LZA, LZC, QDO, OPJ.

5. Device Description:

Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid (Light blue, Dark blue) 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, and single use only, and come in different sizes- XS, S, M, L, XL and XXL.

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The device meets all the specifications in ASTM D6319-19, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs, Fentanyl Citrate and Gastric Acid.

6. Indications for Use:

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

Light Blue glove:

NO.	Chemotherapy drug	Minimum Breakthrough Detection Time, minutes
1	Bendamustine HCl, 5 mg/ml	>240
2	Bortezomib, 1 mg/ml	>240
3	Busulfan, 6 mg/ml	>240
4	Carboplatin, 10 mg/ml	>240
5	Carmustine, 3.3 mg/ml	16.6
6	Carfilzomib, 2 mg/ml	>240
7	Cetuximab (Erbix), 2 mg/ml	>240
8	Chloroquine, 50mg/ml	>240
9	Cisplatin, 1 mg/ml	>240
10	Cladribine, 1.0 mg/ml	>240
11	Cyclophosphamide, 20 mg/ml	>240
12	Cyclosporin A, 100mg/ml	>240
13	Cytarabine HCl, 100 mg/ml	>240
14	Cytovene, 10 mg/ml	>240
15	Dacarbazine, 10 mg/ml	>240
16	Daunorubicin HCl, 5 mg/ml	>240
17	Decitabine, 5 mg/ml	>240
18	Docetaxel, 10 mg/ml	>240
19	Doxorubicin HCl, 2 mg/ml	>240
20	Epirubicin HCl, 2 mg/ml	>240
21	Etoposide, 20 mg/ml	>240
22	Fludarabine, 25 mg/ml	>240
23	Fluorouracil, 50 mg/ml	>240
24	Gemcitabine HCl, 38 mg/ml	>240
25	Idarubicin HCl, 1 mg/ml	>240
26	Ifosfamide, 50 mg/ml	>240
27	Irinotecan HCl, 20 mg/ml	>240
28	Mechlorethamine HCL, 1 mg/ml	>240
29	Melphalan HCl, 5 mg/ml	>240
30	Methotrexate, 25 mg/ml	>240
31	Mitomycin-C, 0.5 mg/ml	>240
32	Mitoxantrone HCl, 2 mg/ml	>240

Basic Medical Technology Inc.

5300 Concourse Ontario, CA 91764

33	Oxaliplatin, 2 mg/ml	>240
34	Paclitaxel, 6 mg/ml	>240
35	Retrovir, 10 mg/ml	>240
36	ThioTEPA, 10 mg/ml	44.9
37	Trisenox, 1 mg/ml	>240
38	Vidaza (Azacitidine), 25 mg/ml	>240
39	Vincristine Sulfate, 1 mg/ml	>240
NO.	Fentanyl Citrate and Gastric Acid	Minimum Breakthrough Detection Time, minutes
1	Fentanyl Citrate Injection, 100mcg/2ml	>240
2	Simulated Gastric Acid	>240

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

Carmustine: 16.6 minutes, Thio Tapa: 44.9 minutes

Warning: Do not use with Carmustine and Thio Tapa.

Dark Blue glove:

NO.	Chemotherapy drug	Minimum Breakthrough Detection Time, minutes
1	Bendamustine HCl, 5 mg/ml	>240
2	Bortezomib, 1 mg/ml	>240
3	Busulfan, 6 mg/ml	>240
4	Carboplatin, 10 mg/ml	>240
5	Carmustine, 3.3 mg/ml	21.5
6	Carfilzomib, 2 mg/ml	>240
7	Cetuximab (Erbix), 2 mg/ml	>240
8	Chloroquine, 50mg/ml	>240
9	Cisplatin, 1 mg/ml	>240
10	Cladribine, 1.0 mg/ml	>240
11	Cyclophosphamide, 20 mg/ml	>240
12	Cyclosporin A, 100mg/ml	>240
13	Cytarabine HCl, 100 mg/ml	>240
14	Cytovene, 10 mg/ml	>240
15	Dacarbazine, 10 mg/ml	>240
16	Daunorubicin HCl, 5 mg/ml	>240
17	Decitabine, 5 mg/ml	>240
18	Docetaxel, 10 mg/ml	>240
19	Doxorubicin HCl, 2 mg/ml	>240
20	Epirubicin HCl, 2 mg/ml	>240
21	Etoposide, 20 mg/ml	>240
22	Fludarabine, 25 mg/ml	>240
23	Fluorouracil, 50 mg/ml	>240
24	Gemcitabine HCl, 38 mg/ml	>240
25	Idarubicin HCl, 1 mg/ml	>240
26	Ifosfamide, 50 mg/ml	>240
27	Irinotecan HCl, 20 mg/ml	>240
28	Mechlorethamine HCL, 1 mg/ml	>240
29	Melphalan HCl, 5 mg/ml	>240

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30	Methotrexate, 25 mg/ml	>240
31	Mitomycin-C, 0.5 mg/ml	>240
32	Mitoxantrone HCl, 2 mg/ml	>240
33	Oxaliplatin, 2 mg/ml	>240
34	Paclitaxel, 6 mg/ml	>240
35	Retrovir, 10 mg/ml	>240
36	ThioTEPA, 10 mg/ml	17.9
37	Trisenox, 1 mg/ml	>240
38	Vidaza (Azacitidine), 25 mg/ml	>240
39	Vincristine Sulfate, 1 mg/ml	>240
NO.	Fentanyl Citrate and Gastric Acid	Minimum Breakthrough Detection Time, minutes
1	Fentanyl Citrate Injection, 100mcg/2ml	>240
2	Simulated Gastric Acid	>240

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

Carmustine: 21.5 minutes, Thio TEPA: 17.9 minutes

Warning: Do not use with Carmustine and Thio TEPA.

7. Comparison of Subject Device and Predicate Device:

General Comparison Table:

	Proposed Device	Predicate Device K240051	Result
Product Name	Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid (Light blue, Dark blue)	Powder Free Nitrile Examination Gloves (Blue), Tested for Use with Chemotherapy Drugs. Fentanyl Citrate, and select other drugs	-
Product Code	LZA, LZC, QDO, OPJ	LZA, LZC, QDO, OPJ	Same
Regulation Number	21 CFR 880.6250	21 CFR 880.6250	Same
Device Classification	Class I	Class I	Same
Indications for use	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 Chemotherapy drugs, Fentanyl and Gastric acid in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs	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 have been tested for use with chemotherapy drugs, Fentanyl Citrate, and select other drugs using ASTM D6978-05(2019)	Same
Powder free	Yes	Yes	Same
Material	Nitrile	Nitrile	Same
Color	Light Blue, Dark blue	Blue	Different

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Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	Same
Sterile	Non-Sterile	Non-Sterile	Same
Single Use	Single use	Single use	Same
Design feature	Ambidextrous	Ambidextrous	Same
Chemo Drugs Claim	See below comparison table	See below comparison table	

Analysis: * The finished subject device has been tested with performance and Biocompatibility, all the test results meet the requirements, so the difference of color does not raise questions of safety and effectiveness.

Technological Characteristic Comparison Table:

Characteristics		Proposed device	Predicate device K240051	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	Same
	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	
	Thickness	Palm: Min 0.05 mm Finger: Min 0.05 mm	Palm: Min 0.05 mm Finger: Min 0.05 mm	
Physical properties ASTM D6319-19 ASTM D412-16	Before aging			Same
	Tensile strength	Min 14MPa	Min 14MPa	
	Ultimate elongation	Min 500%	Min 500%	
	After aging			
	Tensile strength	Min 14MPa	Min 14MPa	
	Ultimate elongation	Min 400%	Min 400%	
Freedom from holes ASTM D6319-19; ASTM D5151-19		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	Same
Biocompatibility	Irritation ISO 10993-23	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
	Sensitization ISO 10993-10	Under the conditions of the study, not a sensitizer	Under the conditions of the study, not a sensitizer	Same

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	Acute Systemic Toxicity Test ISO 10993 -11	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Under the conditions of this study, there was no evidence of acute systemic toxicity.	Same
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Chemotherapy Drugs Comparison Claim:

NO.	Chemotherapy Drugs	Minimum Breakthrough Detection Time, minutes			Result of comparison
		Proposed device		Predicate device K240051	
		Light Blue	Dark Blue		
1	Bendamustine HCl, 5 mg/ml	>240	>240		Different
2	Bortezomib, 1 mg/ml	>240	>240	>240	Same
3	Busulfan, 6 mg/ml	>240	>240	>240	Same
4	Carboplatin, 10 mg/ml	>240	>240	>240	Same
5	Carmustine, 3.3 mg/ml	16.6	21.5	29.1	Different
6	Carfilzomib, 2 mg/ml	>240	>240		Different
7	Cetuximab (Erbitux), 2 mg/ml	>240	>240		Different
8	Chloroquine, 50mg/ml	>240	>240	>240	Same
9	Cisplatin, 1 mg/ml	>240	>240	>240	Same
10	Cladribine, 1.0 mg/ml	>240	>240		Different
11	Cyclophosphamide, 20 mg/ml	>240	>240	>240	Same
12	Cyclosporin A,100mg/ml	>240	>240	>240	Same
13	Cytarabine HCl, 100 mg/ml	>240	>240	>240	Same
14	Cytovene, 10 mg/ml	>240	>240		Different
15	Dacarbazine, 10 mg/ml	>240	>240	>240	Same
16	Daunorubicin HCl, 5 mg/ml	>240	>240	>240	Same
17	Decitabine, 5 mg/ml	>240	>240		Different
18	Docetaxel, 10 mg/ml	>240	>240	>240	Same
19	Doxorubicin HCl, 2 mg/ml	>240	>240	>240	Same
20	Epirubicin HCl, 2 mg/ml	>240	>240	>240	Same
21	Etoposide, 20 mg/ml	>240	>240	>240	Same
22	Fludarabine, 25 mg/ml	>240	>240	>240	Same
23	Fluorouracil, 50 mg/ml	>240	>240	>240	Same
24	Gemcitabine HCl, 38 mg/ml	>240	>240	>240	Same
25	Idarubicin HCl, 1 mg/ml	>240	>240	>240	Same
26	Ifosfamide, 50 mg/ml	>240	>240	>240	Same
27	Irinotecan HCl, 20 mg/ml	>240	>240	>240	Same
28	Mechlorethamine HCL, 1 mg/ml	>240	>240	>240	Same
29	Melphalan HCl, 5 mg/ml	>240	>240	>240	Same
30	Methotrexate, 25 mg/ml	>240	>240	>240	Same
31	Mitomycin-C, 0.5 mg/ml	>240	>240	>240	Same
32	Mitoxantrone HCl, 2 mg/ml	>240	>240	>240	Same
33	Oxaliplatin, 2 mg/ml	>240	>240	>240	Same
34	Paclitaxel, 6 mg/ml	>240	>240	>240	Same
35	Retrovir, 10 mg/ml	>240	>240	>240	Same

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36	ThioTEPA, 10 mg/ml	44.9	17.9	78.3	Different
37	Trisenox, 1 mg/ml	>240	>240	>240	Same
38	Vidaza (Azacitidine),25 mg/ml	>240	>240		Different
39	Vincristine Sulfate,1 mg/ml	>240	>240	>240	Same
NO.	Fentanyl Citrate and Gastric Acid	Minimum Breakthrough Detection Time, minutes			Result of comparison
		Proposed device		Predicate device K240051	
		Light Blue	Light Blue		
1	Fentanyl Citrate Injection,100mcg/2ml	>240	>240	>240	Same
2	Simulated Gastric Acid	>240	>240		Different

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

8. Summary of Non-Clinical Performance Data

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

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 (Min 14 Mpa) 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	Not a primary skin irritant	Pass
Skin Sensitization	ISO10993-10:2021	Not a contact sensitizer	Pass

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Acute Systemic Toxicity	ISO 10993-11:2017	No acute systemic toxicity	Pass
Chemotherapy Drug, Fentanyl, and Gastric Acid	ASTM D6978-05	Minimum Breakthrough Detection Time (minutes)	Remark

- ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application.
- 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 D412-16 (2021), Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- ASTM D6978-05(2023), Assessment of Reissuance of Medical Gloves to Permeation by Chemotherapy Drugs.
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation.
- ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

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, K240051.