



August 27, 2025

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

Re: K251716

Trade/Device Name: Nitrile Powder-Free Exam Gloves 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: LZC, LZA, OPJ, QDO
Dated: June 4, 2025
Received: June 4, 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

Indications for Use

510(k) Number (if known)
K251716

Device Name

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

Indications for Use (Describe)

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 Citrate, Simulated Gastric acid and Xylazine in Fentanyl Citrate 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	15.3min.
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.
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	28.2 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: 15.3 minutes, Thiotepa: 28.2 minutes

Warning: Do not use with Carmustine and Thiotepa.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Basic Medical Technology Inc.

510(K) Summary

K251716

1. Submission Information

Date Prepared: August 27, 2025

Submission Format: Traditional 510(k)

510(K)#: K251716

2. Submitter Information

Applicant Name: Basic Medical Technology Inc.

Address: 5300 Concourse 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 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: Pt. Maja Agung Latexindo

510(k) #: K212408

Trade Name: Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate)

Reference Device :

Applicant: Basic Medical Technology Inc.

510(k) #: K250630

Basic Medical Technology Inc.

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

5. Device Description:

Nitrile Powder-Free Exam Gloves 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 pink color, 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.

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, Gastric Acid and Xylazine in Fentanyl Citrate.

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 Citrate, Simulated Gastric acid and Xylazine in Fentanyl Citrate 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	15.3 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	Ifosfamide, 50 mg/ml	>240 min.
13	Irinotecan HCl, 20 mg/ml	>240 min.
14	Mechlorethamine HCl, 1 mg/ml	>240 min.
15	Melphalan HCl, 5 mg/ml	>240 min.
16	Methotrexate, 25 mg/ml	>240 min.
17	Mitomycin-C, 0.5 mg/ml	>240 min.
18	Mitoxantrone HCl, 2 mg/ml	>240 min.
19	Pacilitaxel, 6 mg/ml	>240 min.
20	Thiotepa, 10 mg/ml	28.2 min.
NO.	Fentanyl, Gastric Acid and Xylazine	Minimum Breakthrough Detection Time

Basic Medical Technology Inc.

1	Fentanyl Citrate Injection, 50mcg/ml	>240 min.
2	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: 15.3 minutes, Thiotepea: 28.2 minutes

Warning: Do not use with Carmustine and Thiotepea.

7. Comparison of Subject Device and Predicate Device:

General Comparison Table:

Device	Proposed Device	Predicate Device	Reference Device	Result
510K #	K251716	K212408	K250630	Different
Applicant Name	Basic Medical Technology Inc.	Pt. Maja Agung Latexindo	Basic Medical Technology Inc.	Same as K250630
Product Name	Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate	Powder Free Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs, Simulated Gastric Acid, and Fentanyl Citrate)	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	Different
Product Code	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	Same
Device Classification	Class I	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 Citrate, Simulated Gastric acid and Xylazine in Fentanyl Citrate in accordance with ASTM D6978-05 Standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.	Powder Free Nitrile 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, Simulated Gastric Acid, and Fentanyl Citrate as per ASTM D6978-05(2019) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.	Nitrile Powder-Free Exam Gloves with Hyaluronic Acid, and tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine 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.	Same
Powder free	Yes	Yes	Yes	Same

Basic Medical Technology Inc.

Material	Nitrile	Nitrile	Nitrile	Same
Color	Pink	Blue	Blue	Different
Size	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	XS, S, M, L, XL, XXL	Same
Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Single Use	Single use	Single use	Single use	Same
Design feature	Ambidextrous	Ambidextrous	Ambidextrous	Same
Other	N/A	N/A	Hyaluronic Acid coated on inside	Different
Chemo Drugs Claim	See below comparison table	See below comparison table	See below comparison table	Different

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

Technological Characteristic Comparison Table:

Characteristics		Proposed device	Predicate device K212408	Reference Device K250630	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	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	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	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	Min 14MPa	
	Ultimate elongation	Min 500%	Min 500%	Min 500%	
	After aging				
	Tensile strength	Min 14MPa	Min 14MPa	Min 14MPa	
Ultimate elongation	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	Same	
Residual Powder ASTM D6319-19 ASTM D6124-06	≤ 2 mg per glove	≤ 2 mg per glove	≤ 2 mg per glove	Same	
Biocompatibility	Irritation	Not a primary skin	Not a primary skin	Not a primary skin	Same

Basic Medical Technology Inc.

		irritant	irritant	irritant	
	Sensitization	Not a primary skin sensitizer	Not a primary skin sensitizer	Not a primary skin sensitizer	Same
	Acute Systemic Toxicity Test	Not toxic	Not toxic	Not toxic	Same

Chemotherapy Drugs Comparison Claim:

Chemotherapy Drugs	Minimum Breakthrough Detection Time			Result of comparison
	Proposed device	Predicate device K212408	Reference Device K250630	
Carboplatin, 10 mg/ml	>240 min.	>240 min	>240 min	Same
Carmustine, 3.3 mg/ml	15.3 min.	58.3 min	11.6 min	Different
Cisplatin, 1 mg/ml	>240 min.	>240 min	>240 min	Same
Cyclophosphamide, 20 mg/ml	>240 min.	>240 min	>240 min	Same
Cytarabine HCl, 100 mg/ml	>240 min.	/	>240 min	Same as K250630
Dacarbazine, 10 mg/ml	>240 min.	>240 min	>240 min	Same
Daunorubicin HCl, 5 mg/ml	>240 min.	/	>240 min	Same as K250630
Docetaxel, 10 mg/ml	/	>240 min	/	Different
Doxorubicin HCl, 2 mg/ml	>240 min.	>240 min	>240 min	Same
Etoposide, 20 mg/ml	>240 min.	>240 min	>240 min	Same
5-Fluorouracil, 50 mg/ml	>240 min.	>240 min	>240 min	Same
Gemcitabine HCl, 38 mg/ml	>240 min.	/	>240 min	Same as K250630
Idarubicin HCl, 1 mg/ml	/	/	>240 min	Different
Ifosfamide, 50 mg/ml	>240 min.	>240 min	>240 min	Same
Irinotecan HCl, 20 mg/ml	>240 min.	/	>240 min	Same as K250630
Mechlorethamine HCl, 1 mg/ml	>240 min.	/	>240 min	Same as K250630
Melphalan HCl, 5 mg/ml	>240 min.	/	>240 min	Same as K250630
Methotrexate, 25 mg/ml	>240 min.	>240 min	>240 min	Same
Mitomycin-C, 0.5 mg/ml	>240 min.	>240 min	>240 min	Same
Mitoxantrone HCl, 2 mg/ml	>240 min.	/	>240 min	Same as K250630
Pacitaxel, 6 mg/ml	>240 min.	>240 min	>240 min	Same
Thiotepa, 10 mg/ml	28.2 min.	119min	25.3 min	Different
Vincristine Sulfate,1 mg/ml	/	>240 min	>240 min	Different
Fentanyl, Gastric Acid and Xylazine	Minimum Breakthrough Detection Time			Result of comparison
	Proposed device	Predicate device K212408	Reference Device K250630	
Fentanyl Citrate Injection,50mg/ml	>240 min.	>240 min	>240 min.	Same
Simulated Gastric Acid	>240 min.	>240 min	>240 min.	Same
Fentanyl Citrate (50mcg/ml): Xylazine HCl(100mg/ml), 50:50	>240 min.	/	>240 min.	Same as K250630

* 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

Basic Medical Technology Inc.

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 (Min14 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	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

- 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), Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Basic Medical Technology Inc.

- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- ISO10993-23:2021 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, Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate, Simulated Gastric Acid and Xylazine in Fentanyl Citrate, is as safe, as effective, and performs as well as or better than the legally marketed predicate device.