February 18, 2025

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

Re: K243792
Trade/Device Name: Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black,White)
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: December 10, 2024
Received: December 10, 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

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)*
K243792

Device Name
Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black)

Indications for Use *(Describe)*
Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black) 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 and Fentanyl using ASTM D6978-05.

| Chemotherapy Drugs | Minimum Breakthrough Detection Time |
|---|---|
| Carmustine (3.3mg/ml) | 14.2 min |
| Cisplatin (1mg/ml) | >240 min |
| Cyclophosphamide (20mg/ml) | >240 min |
| Dacarbazine (10.0 mg/ml) | >240 min |
| Doxorubicin HCl (2 mg/ml) | >240 min |
| Etoposide (20mg/ml) | >240 min |
| Fluorouracil (50mg/ml) | >240 min |
| Paclitaxel (6mg/ml) | >240 min |
| Thiotepa (10mg/ml) | 14.7 min |

| Fentanyl Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2ml | >240 min |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 14.2 minutes, Thiotepa:14.7 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."*

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)*
K243792

Device Name
Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (White)

Indications for Use *(Describe)*
Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (White) 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 and Fentanyl using ASTM D6978-05.

| Chem Drug Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Carmustine (3.3mg/ml) | 16.7 min |
| Cisplatin (1mg/ml) | >240 min |
| Cyclophosphamide (20mg/ml) | >240 min |
| Dacarbazine (10.0 mg/ml) | >240 min |
| Doxorubicin HCl (2 mg/ml) | >240 min |
| Etoposide (20mg/ml) | >240 min |
| Fluorouracil (50mg/ml) | >240 min |
| Paclitaxel (6mg/ml) | >240 min |
| Thiotepa (10mg/ml) | 16.2 min |

| Fentanyl Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2ml | >240 min |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 16.7 minutes, Thiotepa:16.2 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) ☒ 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
K243792

# 510(K) Summary

## 1. Submission Information

Date Prepared: February 18, 2025
Submission Format: Traditional 510(k)
510(K)#: K243792

## 2. Submitter Information

Applicant Name: Basic Medical Technology Inc.
Address: 5300 Concours 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 (Black, White)

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

Shanxi Hongjin Plastic Technology Co., Ltd.

Powder Free Nitrile Examination Gloves (Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (K230779)

Product code: LZA, LZC, QDO, OPJ.

## 5. Device Description:

Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black, White) 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.

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 and Fentanyl Citrate.

**6. Indications for Use:**

Black glove:

Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black) 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 and Fentanyl using ASTM D6978-05.

| Chemotherapy Drugs | Minimum Breakthrough Detection Time |
|---|---|
| Carmustine (3.3mg/ml) | 14.2 min |
| Cisplatin (1mg/ml) | >240 min |
| Cyclophosphamide (20mg/ml) | >240 min |
| Dacarbazine (10.0 mg/ml) | >240 min |
| Doxorubicin HCl (2 mg/ml) | >240 min |
| Etoposide (20mg/ml) | >240 min |
| Fluorouracil (50mg/ml) | >240 min |
| Paclitaxel (6mg/ml) | >240 min |
| Thiotepa (10mg/ml) | 14.7 min |

| Fentanyl Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2ml | >240 min |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 14.2 minutes, Thiotepa:14.7 minutes
Warning: Do not use with Carmustine and Thiotepa.

White glove:

Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (White) 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 and Fentanyl using ASTM D6978-05.

| Chem Drug Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Carmustine (3.3mg/ml) | 16.7 min |
| Cisplatin (1mg/ml) | >240 min |
| Cyclophosphamide (20mg/ml) | >240 min |
| Dacarbazine (10.0 mg/ml) | >240 min |
| Doxorubicin HCl (2 mg/ml) | >240 min |
| Etoposide (20mg/ml) | >240 min |
| Fluorouracil (50mg/ml) | >240 min |
| Paclitaxel (6mg/ml) | >240 min |
| Thiotepa (10mg/ml) | 16.2 min |

| Fentanyl Concentration | Minimum Breakthrough Detection Time |
|---|---|
| Fentanyl Citrate Injection, 100mcg/2ml | >240 min |

*Please note that the following drugs have extremely low permeation times:
Carmustine: 16.7 minutes, Thiotepa:16.2 minutes
Warning: Do not use with Carmustine and Thiotepa.

**7. Comparison of Subject Device and Predicate Device:**

General Comparison Table:

| | Subject Device | Predicate Device K230779 | Result |
|---|---|---|---|
| Trade Name | Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black, White) | Powder Free Nitrile Examination Gloves (Black), Tested for Use with Chemotherapy Drugs and Fentanyl Citrate | - |
| Product Code | LZA, LZC, QDO, OPJ | LZA, LZC, QDO, OPJ | Same |
| Regulation Number | 21 CFR 880.6250 | 21 CFR 880.6250 | Same |
| Class | Class I | Class I | Same |
| Indications for use (Chemotherapy drug permeation testing results compared below) | Nitrile Powder-Free Exam Gloves Tested for Use with Chemotherapy Drugs, Opioid Fentanyl Citrate (Black/White) is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.<br>Gloves have been tested for use with Chemotherapy drugs and Fentanyl using ASTM D6978-05. | Powder Free Nitrile Examination Gloves (Black), Tested for Use with Chemotherapy Drugs and 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.<br>Gloves have been tested for use with chemotherapy drugs and Fentanyl Citrate using ASTM D6978 | Similar |
| Powder free | Yes | Yes | Same |
| Material | Nitrile | Nitrile | Same |
| Color | Black, White | Black | Different |
| 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** | | **Subject Device** | **Predicate Device K230779** | **Result** |
|---|---|---|---|---|
| **Dimension**<br><br>ASTM D6319-19 | Length | Min 230mm | Min 230mm | Same |
| | Width | XS: 70±10 mm<br>S: 80±10 mm<br>M: 95±10 mm<br>L： 110±10 mm<br>XL：120±10 mm<br>XXL：130±10 mm | XS: 70±10 mm<br>S: 80±10 mm<br>M: 95±10 mm<br>L： 110±10 mm<br>XL：120±10 mm<br>XXL：130±10 mm | Same |
| | Thickness | Palm: Min 0.05 mm<br>Finger: Min 0.05 mm | Palm: Min 0.05 mm<br>Finger: Min 0.05 mm | Same |
| **Physical properties**<br><br>ASTM D6319-19<br>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**<br>ASTM D6319-19<br>ASTM D5151-19 | | G-I, AQL2.5 | G-I, AQL2.5 | Same |
| **Residual Powder**<br>ASTM D6319-19<br>ASTM D6124-06 | | ≤ 2 mg per glove | ≤ 2 mg per glove | Same |
| **Biocompatibility** | Irritation<br>ISO 10993-23 | Under the conditions of the study, not an irritant | Under the conditions of the study, not an irritant | Same |
| | Sensitization<br>ISO 10993-10 | Under the conditions of the study, not a sensitizer | Under the conditions of the study, not a sensitizer | Same |
| | Acute Systemic Toxicity Test<br>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 |

**Chemotherapy Drugs Comparison Claim:**

| NO. | Chemotherapy Drugs | Minimum Breakthrough Detection Time, minutes | | | Result of comparison |
|---|---|---|---|---|---|
| | | **Subject device** | | **Predicate Device K230779** | |
| | | Black | White | | |
| 1 | Carmustine (3.3mg/ml) | 14.2 | 16.7 | 11.3 | Different |
| 2 | Cisplatin (1mg/ml) | >240 | >240 | >240 | Same |
| 3 | Cyclophosphamide (20mg/ml) | >240 | >240 | >240 | Same |
| 4 | Dacarbazine (10.0 mg/ml) | >240 | >240 | >240 | Same |
| 5 | Doxorubicin HCl (2 mg/ml) | >240 | >240 | >240 | Same |
| 6 | Etoposide (20mg/ml) | >240 | >240 | >240 | Same |
| 7 | Fluorouracil (50mg/ml) | >240 | >240 | >240 | Same |
| 8 | Paclitaxel (6mg/ml) | >240 | >240 | >240 | Same |
| 9 | Thiotepa (10mg/ml) | 14.7 | 16.2 | 24.7 | Different |
| NO. | Fentanyl Citrate | Minimum Breakthrough Detection Time, minutes | | | Result of comparison |
| | | **Subject device** | | **Predicate device K230779** | |
| | | Black | White | | |
| 1 | Fentanyl Citrate Injection, 100mcg/2ml | >240 | >240 | >240 | Same |

** 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 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<br>ASTM D5151-19 | Meet requirement inspection level G- 1, AQL 2.5 (ISO2859-1) | Pass |
| Dimension-Length | ASTM D6319-19 | Minimum 230mm for all the size | Pass |
| Dimension-Width | ASTM D6319-19 | XS: 70±10mm<br>S: 80±10mm<br>M: 95±10mm<br>L: 110±10mm<br>XL: 120±10mm<br>XXL: 130±10mm | Pass |
| Dimension-Thickness | ASTM D6319-19 | Finger: 0.05mm (Min)<br>Palm: 0.05mm (Min) | Pass |

| | | | |
|---|---|---|---|
| Physical properties | ASTM D6319-19<br>ASTM D412-16 | Tensile Strength (Min14 Mpa)<br>Elongation (Before Aging 500% and after aging 400%) Min | Pass |
| Powder Residue | ASTM D6319-19<br>ASTM D6124-06 | Not more than 2 mg per glove | Pass |
| Permeation by Chemotherapy Drugs and Fentanyl Citrate | ASTM D6978-05 | Refer the above table | Pass |
| Skin Irritation | ISO10993-23:2021 | Not a primary skin irritant | Pass |
| Skin Sensitization | ISO10993-10:2021 | Not a contact sensitizer | Pass |
| Acute Systemic Toxicity | ISO 10993-11:2017 | No acute systemic toxicity | 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), 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.
- 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 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K230779.