



August 28, 2025

Basic Medical Technology Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K252505

Trade/Device Name: Powder-Free Vinyl Exam Gloves, clear
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: August 8, 2025
Received: August 8, 2025

Dear Prithul Bom:

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)
K252505

Device Name
Powder-Free Vinyl Exam Gloves, clear

Indications for Use (Describe)

Powder-Free Vinyl Exam Gloves, clear is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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.

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510(K) Summary K252505

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1. Submitter's Information:

Company Name: Basic Medical Technology Inc.

Address: 5300 Concours Ontario, CA 91764

Contact Person: John Zhao

Tel: (909) 980-1678

Date of Preparation: July 28, 2025

2. Device information:

Trade / Product Name: Powder-Free Vinyl Exam Gloves, clear

Common Name: Vinyl Patient Examination Glove

Classification Name: Non-Powdered Patient Examination Glove

Model(s): S, M, L, XL

Regulation: 21 CFR 880.6250

Product Code: LYZ

Classification Panel: General Hospital

Device Class: Class I

3. Predicate Device Information:

Manufacturer: CHIFENG HUAWEI MEDICAL SCIENCE & TECHNOLOGY CO., LTD.

Device: Disposable Vinyl Examination Glove

Product code: LYZ

510(k) number: K220469

4. Device Description:

The subject device is a powder free vinyl patient examination glove, provided as non-sterile and disposable device. It is provided with clear color. Available in four sizes—small, medium, large, and extra - large—users can choose the most suitable option.

5. Indications for Use:

Powder-Free Vinyl Exam Gloves, clear is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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6. Technological Characteristic Comparison Table:

Table 1: General Comparison

Item		Subject Device		Predicate Device(K220469)		Remark
Product Name		Powder-Free Vinyl Exam Gloves, clear		Disposable Vinyl Examination Glove		-
Product Code		LYZ		LYZ		Same
Regulation Number		21 CFR 880.6250		21 CFR 880.6250		Same
Indications for use		Powder-Free Vinyl Exam Gloves, clear is a disposable device intended for medical purposes that is worn on the examiner’s hand to prevent contamination between patient and examiner.		The Disposable Vinyl Examination Glove is a disposable device intended for medical purposes that is worn on the examiner’s hands to prevent contamination between patient and examiner.		Same
Material		Vinyl		Vinyl		Same
Powder free		Yes		Yes		Same
Design feature		Ambidextrous		Ambidextrous		Same
Color		Clear		Clear		Same
Size		S, M, L, XL		S, M, L, XL		Same
Sterile		Non-Sterile		Non-Sterile		Same
For singe use		Yes		Yes		Same
Dimension(mm)		Length: S/M/L/XL: ≥ 230 Width: S: 85±5 M: 95±5 L: 105±5 XL: 115±5		Length: S/M/L/XL: ≥ 230 Width: S: 85±5 M: 95±5 L: 105±5 XL: 115±5		Same
Thickness(mm)		Palm: ≥ 0.08 Finger: ≥ 0.08		Palm: ≥ 0.08 Finger: ≥ 0.08		Same
Physical properties	Before aging	Tensile strength	11MPa, min	Tensile strength	11MPa, min	Same
		Ultimate elongation	300%, min	Ultimate elongation	300%, min	Same
	After aging	Tensile strength	11MPa, min	Tensile strength	11MPa, min	Same
		Ultimate elongation	300%, min	Ultimate elongation	300%, min	Same
Freedom from holes		Be free from holes when tested in accordance with ASTMD5151 G-I AQL=2.5		Be free from holes when tested in accordance with ASTMD5151 G-I AQL=2.5		Same

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Item	Subject Device	Predicate Device(K220469)	Remark
Residual Powder	Meet the requirements of ASTM D6124 ≤ 2 mg per glove	Meet the requirements of ASTM D6124 ≤ 2 mg per glove	Same
Biocompatibility	ISO10993-23 Under the conditions of this study, the test article did not induce skin irritation.	ISO 10993-10; Under the conditions of the study, not an irritant or a sensitizer	Similar ^①
	ISO10993-10 Under the conditions of this test, the test article did not cause skin sensitization reaction, and the sensitization positive rate was 0%.		Same
	ISO10993-5 Under the conditions of this study, the test article did not show potential toxicity to L-929 cells.	Under conditions of the study, did not show potential toxicity to L-929 cells. Complies with ISO 10993-5	Same

① 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

7. 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:

ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

ASTM D6124-06 Standard Test Method for Residual Powder on Medical Gloves

ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

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Table 2 - Summary of non-clinical performance testing

Methodology	Test Performed	Acceptance Criteria	Results
ASTM D5250-19 ASTM D3767-03	Physical Dimensions	Length(mm) S/M/L/XL: ≥ 230	>230 / Pass
		Width(mm) S: 85 ± 5 mm M: 95 ± 5 mm L: 105 ± 5 mm XL: 115 ± 5 mm	S: 85-86 / Pass M: 95-96 / Pass L: 104-106 / Pass XL: 115-116 / Pass
		Thickness(mm) Finger: ≥ 0.08 mm Palm: ≥ 0.08 mm	Finger: 0.09-0.12 / Pass Palm: 0.08-0.10 / Pass
ASTM D5250-19 ASTM D412- 16	Physical Properties	Before aging: 11MPa, min 300%, min	14 - 22 MPa / Pass 302 – 419 % / Pass
		After aging: 11MPa, min 300%, min	14 - 21 MPa / Pass 303 – 433 % / Pass
ASTM D5250-19 ASTM D5151-19	Water leak test	G-I, AQL 2.5 (ISO 2859- 1)	Pass
ASTM D5250-19 ASTM D6124-06	Powder Residue	Max 2mg/glove	0.37-0.53mg / Pass
ISO 10993-10:2021	Sensitization	Non-sensitizing	Under conditions of the study, not a sensitizer. /Pass
ISO 10993-23:2021	Irritation	Non-irritating	Under the conditions of the study, not an irritant/ Pass
ISO 10993-5:2009	Cytotoxicity	Non-Cytotoxicity	Under conditions of the study, device is not cytotoxic. /Pass

8. Summary of Clinical Testing:

Clinical testing is not needed for this device.

9. 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 K220469, Disposable Vinyl Examination Glove.