January 23, 2026

Basic Medical Technology, Inc.
Amy Gao
RA Engineer
5300 Concours St.
Ontario, California 91764

Re: K253160
Trade/Device Name: Syntex Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: December 29, 2025
Received: December 29, 2025

Dear Amy Gao:

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)*
K253160

Device Name
Syntex Exam Gloves

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.

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.

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Basic Medical Technology Inc.

510(K) Summary

1. **Submission Information**

Date Prepared: Jan 22, 2026

Submission Format: Traditional 510(k)

510(K)#: K253160

2. **Submitter Information**

Applicant Name: Basic Medical Technology Inc.

Address: 5300 Concours Ontario, CA 91764

Contact Person: Amy Gao

Tel：(909) 980-1678

Email: amygao@basicmedical.com

3. **Device Information**

Trade Name: Syntex Exam Gloves

Common Name: Synthetic Butadiene-acrylonitrile latex Powder-Free Exam Gloves

Classification Name: Non-Powdered Patient Examination Glove

Regulation: 21 CFR 880.6250

Product Code: LZA

Classification Panel: General Hospital

Device Class: Class I

4. **Predicate Device Information**

Predicate Device:

Applicant: Tianjin Aoshang Outdoor Equipment Co.,Ltd.

510(k) #: K220442

Trade Name: Synguard Nitrile Exam Glove

5. **Device Description:**

Syntex Exam Gloves is a Class I patient examination glove, that made from synthetic Butadiene-acrylonitrile latex. They are natural latex color, non-sterile, powder-free, 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.

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.

7. Comparison of Subject Device and Predicate Device:

General Comparison Table:

Device	Proposed Device	Predicate Device	Result
510K #	K253160	K220442	-
Applicant Name	Basic Medical Technology Inc.	Tianjin Aoshang Outdoor Equipment Co.,Ltd.	-
Product Name	Syntex Exam Gloves	Synguard Nitrile Exam Glove	-
Product Code	LZA	LZA	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.	Synguard Nitrile Exam Glove is a disposable device intended for medical purposes that is worn on the examiner' s hand or finger to prevent contamination between patient and examiner	Same
Powder free	Yes	Yes	Same
Material	synthetic Butadiene-acrylonitrile latex	Acrylonitrile, Butadiene	Same
Color	Natural latex color	Blue	Different
Size	XS, S, M, L, XL, XXL	S, M, L, XL	Different
Sterile	Non-Sterile	Non-Sterile	Same
Single Use	Single use	Single use	Same
Design feature	Ambidextrous	Ambidextrous	Same

*Different 1- Color
The color of the proposed device is different from the predicate device. However, the biocompatibility and specification performance tests have been performed on each of the proposed devices and the test results show no significant concerns. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

*Different 2- Size
The size of the proposed device is not exactly same as the predicate device. However, the size of the proposed device has been covered by ASTM D6319-19. The user can select appropriate model depended on size of user' s hand. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Technological Characteristic Comparison Table:

Characteristics	Proposed device	Predicate device	Result

		K253160	K220442	
Dimension **Reference standard** ASTM D6319-19	Length	Min 220mm for XS, S Min 230mm for M, L, XL, XXL	Min 230mm for S, M Min 240mm for L, XL	Different
	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	S: 84±5 mm M: 94±5 mm L: 110±10 mm XL: 120±10 mm	Different
	Thickness	Palm: Min 0.05 mm Finger: Min 0.05 mm	Palm: Min 0.05 mm Finger: Min 0.05 mm	Same
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		No water leakage occurs G-I, AQL2.5	No water leakage occurs G-I, AQL2.5	Same
Residual Powder ASTM D6319-19 ASTM D6124-06		≤ 2 mg per glove	≤ 2 mg per glove	Same
Biocompatibility	Skin Irritation	No Irritation	No Irritation	Same
	Sensitization	No Sensitization	No Sensitization	Same
	Acute Systemic Toxicity	No Acute Systemic Toxicity	No Acute Systemic Toxicity	Same

8. <u>Summary of Non-Clinical Performance Data</u>

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

- 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, Standard Test Method for Residual Powder on Medical Gloves
- ASTM D412-16, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension
- 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

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

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.