October 17, 2025

Program insite LLC
Emnet Menyahil
CEO
2224 Victoria Place
Olney, Maryland 20832

Re: K252075
Trade/Device Name: Program insite® Powder-Free, Disposable Nitrile Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: September 10, 2025
Received: September 11, 2025

Dear Emnet Menyahil:

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)*
K252075

Device Name
Program insite® Powder-Free, Disposable Nitrile Exam Gloves

Indications for Use *(Describe)*
A powder-free patient examination 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.

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."

Program insite LLC
18450 Showalter Rd,
Unit 10A,
Hagerstown, MD 21742
emnet.menyahil@programinsite.com
+1 301 633 1218

October 17, 2025

510(k) Summary (per 21 CFR 807.92) - K252075
Type of 510(k) Submission: Abbreviated

Submitter Information:

Program insite LLC 2224 Victoria Place
Olney, Maryland 20832

Device Name & Classification

Trade Name:	**Program insite® Powder-Free, Disposable Nitrile Exam Gloves**
Common Name:	Nitrile Examination Gloves
Classification Name:	Non-Powdered Patient Examination Gloves
Product Code:	LZA
Review Panel:	General Hospital
Regulatory Class:	Class I (Reserved)
Regulation Number	21 CFR 880.6250

Predicate Device

Device Name:	Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Gloves
510(k) Number:	K190159
510(k) Owner:	Showa Best Glove, Inc.

Device Description:

The powder-free nitrile exam gloves are non-sterile, single-use, ambidextrous medical examination gloves made from nitrile butadiene rubber (NBR). They are blue, feature a beaded cuff, and are available in sizes S–XL. The gloves are not made with natural rubber latex.

Their physical and performance characteristics meet all requirements of ASTM D6319-19. The gloves are powder-free and meet the requirements of ASTM D6124-06. Powder is not used during any stage of manufacturing. Rather, the gloves are manufactured using a non-chlorinated polyurethane (PU) inner coating to reduce surface friction and facilitate donning. More specifically, following the dipping phase, the gloves pass through gelling and pre-curing ovens to stabilize the film and control

thickness and tactile responsiveness. The PU coating is applied to the inner (donning) surface and then dried and cured, producing a smooth, low-friction finish. Residual processing aids are removed through rinsing/drying steps, resulting in a stable, non-reactive donning surface. Automated cuff beading is then performed to enhance edge durability and ease of application.

Indications for Use:

A powder-free patient examination 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..

Summary of Technological Characteristics:

The technological characteristics of the Program insite® Powder-Free, Disposable Nitrile Exam Gloves are summarized within the following table comparing subject gloves to the predicate device under ASTM or equivalent standards.

Device Characteristic	**Proposed Device K252075**	**Predicate Device K190159**	**Comparison**
Product Name	Program insite® Powder-Free, Disposable Nitrile Exam Gloves	Showa® Medical Exam Glove (Green) Powder-Free Nitrile	Similar
Device Description / Regulation	Patient examination glove / 21 CFR 880.6250	Patient examination glove / 21 CFR 880.6250	Same
Product Code	LZA	LZA	Same
Indications for Use	A powder-free patient examination 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.	The Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove is a disposable device intended for medical purposes that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner	Similar
Material Composition	Nitrile Butadiene Rubber (NBR)	Nitrile Butadiene Rubber (NBR)	
Color	Blue	Green	Different
Sterile	Non-sterile	Non-sterile	Same
Single-Use	Yes	Yes	Same
Residual Powder	Meets ASTM D6124-06 (2022)	Meets ASTM D6124	Similar
Watertight Integrity	ASTM D5151 (AQL 1.5)	ASTM D5151	Similar

Physical Properties (ASTM D6319 key criteria)	Meets ASTM D6319 requirements.	Meets ASTM D6319 requirements.	Similar
Biocompatibility Irritation	ISO 10993-23:2021 Skin Irritation Study Pass	ISO 10993-10 Skin Irritation Study Pass	Similar
Biocompatibility Sensitization	ISO 10993-10:2010 Skin Sensitization Study Pass	ISO 10993-10 Skin Sensitization Study Pass	Same
Biocompatibility Acute Systemic Toxicity	ISO 10993-11 Acute Systemic Toxicity Study Pass	ISO 10993-11 Acute Systemic Toxicity Study Pass	Same
Biocompatibility Cytotoxicity	ISO 10993-5 Cytotoxicity Study Pass	Not reported	Same
Biodegradation Properties	Not included in the Study	Biodegradable	Different

Summary of Differences and Comparison of Technological Characteristics:

The Program insite® Powder-Free, Disposable Nitrile Examination Gloves (K252075) and the predicate Showa® Medical Exam Glove (Green) Powder-Free, Disposable Nitrile Glove (K190159) have the same intended use (patient examination glove), regulation (21 CFR 880.6250), product code (LZA), material (nitrile butadiene rubber), non-sterile configuration, powder-free claim, and ambidextrous beaded-cuff design. The only design difference is color (subject: blue; predicate: green).

The predicate's 510(k) summary also references a biodegradable attribute (ASTM D5526) that is non-medical and not reviewed by FDA; the subject device makes no biodegradability claim. These differences do not affect intended use, safety, or performance.

Non-Clinical Performance Testing

Testing was conducted in accordance with the standards below. Dimensional measurements were made per D3767 and evaluated against D6319 limits; mechanical properties per D412 with heat aging per D573; watertight integrity per D5151; residual powder per D6124; and biocompatibility per ISO 10993, as applicable.

- **ASTM D6319-19 (Reapproved 2023)** - Standard Specification for Nitrile Examination Gloves for Medical Application
- **ASTM D3767** - Measurement of Dimensions (evaluation against D6319 limits)
- **ASTM D412 (Method A)** -Tension (tensile strength and ultimate elongation)
- **ASTM D573** - Heat Aging, for post-aging properties
- **ASTM D5151-19** - Detection of Holes (watertight integrity; AQL per sampling plan)
- **ASTM D6124-06 (Reaffirmed 2022)** - Residual Powder on Medical Gloves
- **ISO 10993-5:2009 / ISO 10993-23:2021 / ISO 10993-10:2010 / ISO 10993-11:2017** — Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity (as applicable)

Non-Clinical Performance Summary - Program insite® Powder-Free, Disposable Nitrile Exam Gloves

Physical Characteristics	Standard / Test Method	Acceptance Criteria	Result Summary
PHYSICAL CHARACTERISTICS			
Dimensions (Length / Width / Thickness)	ASTM D3767 measurement; evaluated against ASTM D6319-19 (Reapproved 2023) limits	Meets ASTM D6319 size-specific length, palm width, and minimum single-wall thickness requirements.	PASS — All sizes (S–XL) meet dimensional requirements.
Overall Length	ASTM D3767 / D6319-19	Minimum: S ≥ 220 mm; M ≥ 230 mm; L ≥ 230 mm; XL ≥ 230 mm	S: 231–238 mm; M: 233–243 mm; L: 233–240 mm; XL: 238–252 mm - Pass
Palm Width	ASTM D3767 / D6319-19	S: 80 ± 10 mm; M: 95 ± 10 mm; L: 110 ± 10 mm; XL: 120 ± 10 mm	S: 82–85 mm; M: 94–96 mm; L: 107–112 mm; XL: 111–114 mm - Pass
Single-Wall Thickness (Finger / Palm)	ASTM D3767 / D6319-19	Minimums: Finger ≥ 0.05 mm; Palm ≥ 0.05 mm	Finger 0.087 - 0.116 mm; Palm 0.062 - 0.079 mm - Pass
Tension Properties (pre/post aging)	ASTM D412 (Method A); aging per ASTM D573	Meets ASTM D6319 minimum tensile strength and ultimate elongation before and after aging.	Tensile strength (pre/post): Pass; Ultimate elongation (pre/post): Pass.
Tensile Strength - Before Aging	ASTM D412 (Method A)	≥ 14 MPa (minimum)	Median 38.8 MPa (range 33.1–41.6 MPa) - Pass
Tensile Strength - After Aging	ASTM D412 (Method A) / ASTM D573	≥ 14 MPa (minimum)	Median 39.8 MPa (range 31.7–52.6 MPa)- Pass
Ultimate Elongation - Before Aging	ASTM D412 (Method A)	≥ 500% (minimum)	Median 533% (range 505–574%) - Pass
Ultimate Elongation - After Aging	ASTM D412 (Method A) / ASTM D573	≥ 400% (minimum)	Median 437% (range 412-468%) - Pass
Freedom from Holes (Watertight Integrity)	ASTM D5151-19	AQL 2.5 (per sampling plan)	AQL 1.5 - Pass
Residual Powder (Powder-Free)	ASTM D6124-06 (Reaffirmed 2022)	≤ 2.0 mg/glove	0.4 mg/glove - Pass
BIOCOMPATIBILITY			
Biocompatibility Skin Irritation	ISO 10993-23:2021	Not an irritant	Under the conditions of the study, the subject device is not a skin irritant. - Pass

Biocompatibility Skin Sensitization	ISO 10993-10:2010	No evidence of sensitization (non-sensitizer classification)	Under the conditions of the study, the subject device is not a skin sensitizer. - Pass
Biocompatibility Cytotoxicity / Acute Systemic Toxicity	ISO 10993-5 ISO 10993-11:2017	Under the conditions of the studies, non-cytotoxic or if cytotoxic then no acute systemic toxicity	Under the conditions of study, the device extracts did not demonstrate acute systemic toxicity. - Pass

Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that Program insite® Powder-Free, Disposable Nitrile Exam Gloves (K252075) is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Showa® Medical Exam Glove (Green) Powder-free, Disposable Nitrile Glove, K190159.