



November 21, 2025

Staclear, Inc.  
Jackson Thornton  
Director of Technology  
7250 ACC Blvd.  
Raleigh, North Carolina 27617

Re: K251849

Trade/Device Name: Staclear Syringe (SC250AN); Staclear Syringe (SC250LS); Staclear Syringe (SC250LL)  
Regulation Number: 21 CFR 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: Class II  
Product Code: QLY, FMF, FMI  
Dated: October 28, 2025  
Received: October 28, 2025

Dear Jackson Thornton:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Shruti N. Mistry -S**

Shruti Mistry, M.S.

Assistant Director

DHT3C: Division of Drug Delivery and General  
Hospital Devices, and Human Factors

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251849

?

Please provide the device trade name(s).

?

Staclear Syringe (SC250AN);  
Staclear Syringe (SC250LS);  
Staclear Syringe (SC250LL)

Please provide your Indications for Use below.

?

The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body. The StaClear Syringe is indicated for intravitreal use.

Please select the types of uses (select one or both, as applicable).

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

?



## 510(k) Summary - K251849

Prepared in accordance with 21 CFR 807.92  
StaClear Syringe – Tray Packaging Configuration

### I. Submitter Information

#### Submitter:

StaClear, Inc.  
7250 ACC Blvd.  
Raleigh, NC 27617  
United States

#### Contact:

Jackson Thornton, Ph.D.  
Director of Technology  
StaClear, Inc.  
Phone: 1-919-838-6716  
Email: info@staclear.com

**Date prepared:** 28 October 2025

### II. Device Information

Trade Name:	StaClear Syringe (SC250AN); StaClear Syringe (SC250LS); StaClear Syringe (SC250LL)
Common Name:	Piston Syringe
Classification Name:	Ophthalmic Syringe
Regulation Number:	21 CFR 880.5860
Regulatory Class:	II
Product Code:	QLY
Additional Product Code:	FMF, FMI

### III. Predicate Device

K243936 StaClear Syringe (SC250AN, SC250LS, SC250LL)

The predicate device has not been subject to a design-related recall.

### IV. Device Description

The StaClear Syringe is a sterile, single-use, manually operated piston syringe intended for general-purpose aspiration and injection of fluids by trained healthcare professionals. It is suitable for



ophthalmic applications, including intravitreal injections. The syringe functions using standard positive-displacement mechanics, in which movement of the plunger creates pressure differentials to aspirate or expel fluid.

The StaClear Syringe is offered in the following configurations:

- **SC250AN:** Consisting of a 0.25 mL graduated barrel, plunger, plunger stopper, needle, needle shield, and optional plunger cap.
- **SC250LS:** Consisting of a 0.25 mL graduated barrel with an ISO 80369-7-compliant luer-slip connector, plunger, and plunger stopper.
- **SC250LL:** Consisting of a 0.25 mL graduated barrel with an ISO 80369-7-compliant luer-lock connector, plunger, and plunger stopper.

All three configurations were previously cleared under K243936. This submission introduces no changes to the device's design, dimensions, materials, or intended use. The only modification is the addition of a rigid PETG tray sealed with a Tyvek lid as an alternative sterile barrier packaging configuration.

The device's intended use, design, materials, sterilization method (EO), and labeled shelf life (5 years) remain unchanged.

## V. Intended Use / Indications for Use

The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body. The StaClear Syringe is indicated for intravitreal use.

## VI. Comparison of Technological Characteristics with the Predicate Device

The subject StaClear Syringe is identical to the predicate in terms of:

- Intended use
- Technological characteristics
- Design and materials
- Syringe dimensions and configurations
- Sterilization method (ethylene oxide) and SAL ( $10^{-6}$ )
- Shelf life (5 years)

The only modification is the addition of a validated PETG tray with Tyvek lid packaging configuration for bulk packaging.

Comparisons of the technological characteristics between the subject and predicate device are illustrated in the table below:



**TABLE 1: TECHNOLOGICAL COMPARISON OF SUBJECT AND PREDICATE DEVICE**

Attribute	Predicate Device (K243936)	Subject Device	Comparison
Device Name	StaClear Syringe	StaClear Syringe	Identical
Model(s)	SC250AN, SC250LS, SC250LL	SC250AN, SC250LS, SC250LL	Identical
Regulation Number	21 CFR 880.5860	21 CFR 880.5860	Identical
Product Code(s)	QLY, FMF, FMI	QLY, FMF, FMI	Identical
Device Classification	Class II	Class II	Identical
Intended Use / Indications for Use	"The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body. The StaClear Syringe is indicated for intravitreal use."		Identical
Mechanism of Action	Manual	Manual	Identical
Single Use	Yes	Yes	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical
SAL	10 <sup>-6</sup>	10 <sup>-6</sup>	Identical
Shelf Life	5 years	5 years	Identical
Syringe Volume	0.25 mL	0.25 mL	Identical
Connector Type	Attached needle (AN), Luer-slip (LS), Luer-lock (LL)		Identical
Materials	Polypropylene (barrel), polypropylene (plunger)*, polyisoprene (stopper), 304 stainless steel (needle, SC250AN only), TriboLink-Si (barrel lubricant)		Identical
Primary Sterile Barrier System	Tyvek pouch (SC250LS, SC250LL); Self-contained (SC250AN)	PETG tray sealed with Tyvek lid (all models)	New validated configuration; no change to syringe design
Sterile Barrier Validation	ISO 11607-1 for Tyvek pouch; Bacterial aerosol and USP <71> sterility testing for self-contained fluid path (SC250AN)	Validated per ISO 11607-1 using the same standards and methods as Tyvek pouch: ASTM D4169, F1980, F88, F1929, F2096, F1886	Equivalent; validated per ISO 11607-1 using equivalent ASTM methods

TABLE 1: TECHNOLOGICAL COMPARISON OF SUBJECT AND PREDICATE DEVICE			
Attribute	Predicate Device (K243936)	Subject Device	Comparison
<i>Open Tray Sterility</i>	Not applicable	ISO 11737-2 sterility confirmed under simulated aseptic handling conditions	New validated attribute
<i>Inner Packaging</i>	SBS inner box	Same	Identical
<i>Shipping Case</i>	Corrugated outer case	Same	Identical
<i>Performance Standards</i>	ISO 7886-1, ISO 7864 (SC250AN), ISO 9626 (SC250AN), ISO 80369-7 (SC250LS, SC250LL), USP <788>, USP <789>		Identical
<i>Biocompatibility</i>	ISO 10993 (cytotoxicity, sensitization, irritation, systemic toxicity, hemolysis, pyrogen)		Identical
<i>Endotoxin</i>	USP <85> – meets intraocular limits		Identical

*\*Note: The plunger shaft was previously misidentified as polyethylene in K243936. The correct material is polypropylene, as documented in the device master record and supplier specification.*

These comparisons demonstrate that the only change is to the sterile barrier packaging. No other technological characteristics differ from the predicate device.

## VII. Summary of Performance Data

All verification and validation activities were conducted in accordance with StaClear’s QMS and 21 CFR 820.30. Testing included:

### Packaging integrity and sterile barrier testing per ISO 11607-1

- Distribution simulation: ASTM D4169
- Accelerated aging: ASTM F1980
- Seal strength: ASTM F88
- Dye penetration: ASTM F1929
- Bubble leak: ASTM F2096
- Visual inspection: ASTM F1886/F1886M

### Sterilization validation

- The EO sterilization process was previously validated per ISO 14937.
- Equivalence of sterilization conditions was confirmed for the tray packaging configuration.
- EO residuals were within intraocular exposure limits per ISO 10993-7.

### Open tray sterility

- Sterility was evaluated per ISO 11737-2 following a 6-hour aseptic hold after tray opening.
- No microbial growth was observed under worst-case simulated use conditions.



### Labeling Compliance

- Labeling includes the prescription device statement (Rx only), UDI, ISO 15223-1 symbols, manufacturer identification, and applicable warnings.
- New tray warning: **“Tray must be opened in an aseptic environment (ISO Class 5 Laminar Flow Hood or equivalent). Use within 6 hrs of opening. Discard remaining syringes if removed from the aseptic environment or after 6 hrs.”**

No new or different questions of safety or effectiveness compared to the predicate were raised by the packaging modification. All verification and validation activities were conducted under StaClear’s Design Control procedures in compliance with 21 CFR 820.30.

### VIII. Conclusions

The subject StaClear Syringe, when packaged in a Tyvek-lidded PETG tray, is substantially equivalent to the predicate device cleared under K243936.

The packaging change does not impact the device’s intended use, design, performance, or sterilization method. All verification and validation testing confirmed that the tray packaging maintains the sterile barrier, supports the labeled shelf life and complies with FDA labeling requirements and recognized consensus standards.

The packaging change raises no new or different questions of safety or effectiveness compared to the predicate and is being submitted under the Traditional 510(k) pathway in accordance with 21 CFR 807.87.