April 3, 2025

StaClear, Inc.
Jackson Thornton
Director of Research
7250 ACC Blvd.
Raleigh, NC 27617

Re: K243936
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: November 5, 2024
Received: January 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shruti N. Mistry -S

Shruti Mistry
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

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.

Submission Number *(if known)*

K243936

Device Name

StaClear Syringe (SC250AN);
StaClear Syringe (SC250LS);
StaClear Syringe (SC250LL)

Indications for Use *(Describe)*

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

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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7250 ACC Blvd.
Raleigh, NC 27617. USA
Phone: +1(919)838-6716
E-mail: info@staclear.com

510(k) SUMMARY

I. SUBMITTER

StaClear, Inc.
7250 ACC Blvd.
Raleigh, NC 27617
Phone: 1-919-838-6716
Email: info@staclear.com
Primary Contact: Jackson Thornton, Director of Research
Date prepared: March 26, 2025

II. DEVICE

Device Name:	StaClear Syringe
Common/Usual Name:	Piston Syringe
Classification Name:	Ophthalmic Syringe
Regulatory Class:	2
Product Code:	QLY
Subsequent Product Code:	FMF; FMI

III. PREDICATE DEVICE

K200242 StaClear Syringe

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

IV. DEVICE DESCRIPTION

The StaClear Syringe is a single-use piston syringe intended for use by healthcare professionals for general-purpose fluid aspiration/injection. Its operation is manual. The StaClear Syringe is single use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas. It uses standard syringe components with a low-particulate gas plasma crosslinked silicone coating called TriboLink-Si. The StaClear Syringe is suitable for ophthalmic use.

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 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.

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.

StaClear

7250 ACC Blvd.
Raleigh, NC 27617. USA
Phone: +1(919)838-6716
E-mail: info@staclear.com

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the StaClear Syringe are substantially equivalent to the predicate device. The intended use and indications for use of the subject device are identical to the predicate device.

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

STACLEAR SYRINGE SUBSTANTIAL EQUIVALENCE COMPARISON					
Attribute	**Predicate Device K200242**	**Subject Device**			**Comparison**
Device Name	StaClear Syringe Attached Needle	StaClear Syringe Attached Needle	StaClear Syringe Luer Slip	StaClear Syringe Luer Lock	Different models based on connector type
Model	SC250	SC250AN	SC250LS	SC250LL	Change model suffix to designate: AN = Attached Needle, LS = Luer Slip, LL = Luer Lock
Device	Ophthalmic Syringe; Syringe, Piston				Identical
Device Class	Class II				Identical
FDA Product Code	QLY; FMF; FMI	QLY; FMF; FMI	QLY; FMF	QLY; FMF	The luer-tip models do not include a needle, so the FMI designation is not required.
Intended Use/Indication 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				Identical
Single-Use Only	Yes				Identical
Provided Sterile	Yes				Identical, endotoxin meets intraocular limits
Sterilization Method	Ethylene Oxide				Identical, EO/ECH residuals meet intraocular standards
SAL	10^{-6}				Identical
Shelf Life	1 year	5 years	5 years	5 years	Testing supports that performance characteristics and sterility are maintained over 5 years.
Syringe Volume	0.25 mL				Identical
Connector Type	Attached Needle	Attached Needle	Luer Slip	Luer Lock	Compliant with established performance standards: ISO 7886-1, ISO 7864, ISO 9626, ISO 80369-7. Compliant with additional testing and reduced acceptance levels for ophthalmic use.

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STACLEAR SYRINGE SUBSTANTIAL EQUIVALENCE COMPARISON						
Attribute	**Predicate Device K200242**	**Subject Device**			**Comparison**	
Needle Gauge	31 G	31 G	None	None	Luer configurations do not have an attached needle.	
Needle Length	5/16 in.	5/16 in.	None	None	Luer configurations do not have an attached needle.	
MATERIALS						
Barrel	Polypropylene				Luer configurations have different barrel connector types but the same barrel material/dimensions for the fluid-path contacting surfaces.	Final, finished device is biocompatible for intended use per ISO 10993-1 as an external communicating device with prolonged tissue contact.
Plunger	Polyethylene				Identical	
Plunger Stopper	Polyisoprene				Identical	
Needle	304 Stainless Steel	304 Stainless Steel	None	None	Luer configurations do not have an attached needle or glue.	
Needle Lubricant	Silicone Oil	Silicone Oil	None	None	Luer configurations do not have an attached needle.	
Needle Shield	Polyethylene	Polyethylene	None	None	Luer configurations do not have a needle shield.	
Plunger Cap	Polyethylene				Identical	
Barrel Lubricant	TriboLink-Si				Identical	
PACKAGING						
Primary Package	LLDPE Bag (10 self-contained syringes)	LLDPE Bag (20 self-contained syringes)	Tyvek Pouch (1 unit)	Tyvek Pouch (1 unit)	LLDPE Bag for the attached needle model contains self-contained syringe units, so the sterile barrier is maintained between the needle shield and plunger cap. Tyvek Pouch packaging maintains sterility within the Tyvek Packaging.	Packaging where the sterile barrier is maintained within self-contained syringe units challenged using bacterial aerosol followed by sterility tests per USP <71>.
Inner Box	SBS				Identical	

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STACLEAR SYRINGE SUBSTANTIAL EQUIVALENCE COMPARISON				
Attribute	**Predicate Device K200242**	**Subject Device**	**Comparison**	
Shipping Case	Cardboard		Identical	Packaging where the sterile barrier is maintained within a Tyvek pouch complies with established requirements per ISO 11607-1:2019.
PERFORMANCE				
Syringe Performance	ISO 7886-1		Identical	
Particulate Testing	USP <788>, USP <789>		Identical	
Luer Connector Performance	None	ISO 80369-7	Attached needle configurations are identical so testing is not applicable. Luer configurations are compliant with established performance standards	
Needle Performance	ISO 7864, ISO 9626	None	Attached needle configurations are identical. Luer configurations do not have an attached needle so testing is not applicable	

VII. PERFORMANCE DATA

The following non-clinical testing was performed to confirm the safety and effectiveness of the StaClear Syringe as compared to the predicate device. Performance testing was performed as per the design control system.

- ISO 7886-1:2017
  - Cleanliness
  - Acidity and Alkalinity
  - Extractable Metals (IOL limits per ISO 11979-5)
  - Lubricant
  - Tolerance on Graduations
  - Stopper Detachment
  - Dead Space
  - Air and Liquid Leakage Past Stopper
  - Plunger Force
  - Fit of Stopper

7250 ACC Blvd.
Raleigh, NC 27617. USA
Phone: +1(919)838-6716
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- ISO 7864:2016 (SC250AN only)
  - Cleanliness
  - Acidity and Alkalinity
  - Extractable Metals (IOL limits per ISO 11979-5)
  - Tolerance on Length
  - Tube Defects
  - Lubricant
  - Point Defects
  - Needle Penetration Force
  - Bond Between Tube and Hub
  - Patency of Lumen
- ISO 9626:2016 (SC250AN only)
  - Materials
  - Surface Finish
  - Cleanliness
  - Limits for Acidity and Alkalinity
  - Size Designation
  - Outside Diameter
  - Stiffness
  - Resistance to Breakage
  - Resistance to Corrosion
- ISO 80369-7:2021 (SC250LS and SC250LL only)
  - Materials
  - Dimensional Requirements
  - Fluid Leakage
  - Air Leakage
  - Stress Cracking
  - Separation Force
- ISO 80369-7:2021 (SC250LL only)
  - Unscrewing Torque
  - Resistance to Overriding
- Particulate Testing
  - USP <788> Particulate Matter in Injections
  - USP <789> Particulate Matter in Ophthalmic Solutions
- Biocompatibility (ISO 10993-1)
  - StaClear Syringe is categorized as an external communicating devices with prolonged tissue contact (prolonged due to repeated/chronic treatment for intravitreal injections).
- Sterility and Shelf Life
  - StaClear Syringe is sterilized to SAL 10-6 using a validated ethylene oxide sterilization cycle. The sterilization residual levels meet the requirements of ISO 10993-7 for IOL. Bacterial endotoxin testing per USP <85> with limits set for IOL is conducted for each lot.
  - After distribution simulation per ASTM D4169 and 5-year accelerated aging per ASTM F1980, testing demonstrates the device maintains performance per ISO 7886-1, ISO

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E-mail: info@staclear.com

7864, ISO 9626, and/or ISO 80369-7, and maintains sterility per USP <71> or a sterile barrier per ISO 11607-1 after 5-years of aging.

VIII. SUBSTANTIAL EQUIVALENCE

The StaClear Syringe is substantially equivalent to the predicate when evaluating intended use and technological characteristics.

- The subject device has the identical intended use and indications for use as the predicate device.
- The subject device has identical materials, manufacturing process flow, sterilization process, and principle of operation as the predicate device.
- The technological characteristics of the subject device are substantially equivalent to the predicate device with only minor differences in device design (connector type) and packaging configuration.
- Performance testing demonstrates that the subject device is as safe and effective as the legally marketed predicate device and does not raise new or different questions of safety and effectiveness compared to the predicate device.

IX. CONCLUSIONS

StaClear Syringe meets the established safety and performance characteristics of an ophthalmic syringe. Performance testing according to ISO 7886-1, ISO 7864, ISO 9626, ISO 80369-7, and particulate testing per USP<788> and USP <789> demonstrate the StaClear Syringe is as safe and effective as the predicate device and will perform as intended.

StaClear Syringe is biocompatible for its intended use and demonstrates equivalent performance to its predicate device. The StaClear Syringe SC250AN, SC250LS, and SC250LL models are substantially equivalent to the predicate StaClear Syringe SC250 model cleared under K200242.