December 20, 2024

Congruence Medical Solutions, LLC
Gautam Shetty
Founder, CEO
3000 Falls Road
Suite 200A
Baltimore, Maryland 21211

Re: K243149
Trade/Device Name: Microliter Dosing Syringe (9, 20, 25, 37.5, 50 and 100 microliter models)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QLY, FMF
Dated: December 7, 2024
Received: December 9, 2024

Dear Gautam Shetty:

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.

510(k) Number *(if known)*
K243149

Device Name
Microliter Dosing Syringe (9, 20, 25, 37.5, 50 and 100 microliter models)

Indications for Use *(Describe)*
The Microliter Dosing Syringe is intended to inject fluid into, or withdraw fluid from the body.
The Microliter Dosing 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.

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K243149 510(k) Summary

510(k) Number	K243149	
Preparation Date	December 20, 2024	
Submitter	Congruence Medical Solutions, LLC 3000 Falls Road Suite 200A Baltimore, MD 21211 Email: gs@congruencemed.com Phone: 216-272-5521	
Primary Contact	Gautam Shetty, PhD Founder, CEO Congruence Medical Solutions, LLC 3000 Falls Road Suite 200A Baltimore, MD 21211	
Subject Device	Trade Name	Microliter Dosing Syringe (9, 20, 25, 37.5, 50 and 100 microliter models)
	Common name	Ophthalmic Syringe, Piston syringe
	Regulation name	Syringe, Piston
	Regulation number	21 CFR 880.5860
	Device Class	Class II
	Product Codes	QLY, FMF
	Regulation Medical Specialty	General Hospital
	510(k) Review Panel	General Hospital
Intended Use/Indications for Use	The Microliter Dosing Syringe is intended to inject fluid into, or withdraw fluid from the body. The Microliter Dosing Syringe is indicated for intravitreal use.	
Device Description	The Microliter Dosing Syringe is a single-use, piston syringe-based device consisting of a syringe barrel, plunger stopper, syringe tip cap and incorporates a plunger rod subassembly. It is intended for use by healthcare professionals for general purpose fluid aspiration/injection. Its operation is manual. The Microliter Dosing Syringe is single use only, non-toxic, non-pyrogenic and sterilized by e-beam irradiation. The Microliter Dosing Syringe is suitable for ophthalmic use.	
Predicate Device	Trade Name	StaClear Syringe
	Applicant	TriboFilm Research, Inc.
	510(k) Number	K200242
	Clearance Date	July 27, 2020
	Common Name	Ophthalmic Syringe Syringe, Piston Needle, Hypodermic, Single Lumen
	Regulation Name	Piston syringe; Hypodermic single lumen needle
	Regulation Numbers	21 CFR 880.5860, 21 CFR 880.5570
	Device Class	Class II
	Product Codes	QLY, FMF, FMI
	Regulation Medical Specialty	General Hospital
	510(k) Review Panel	General Hospital
Mechanism of Action	Manual operation	

Technological Characteristics

The technological characteristics of the subject device are substantially equivalent to the predicate device with only minor differences observed in the device materials, syringe volume, connector type, biocompatibility tests completed, and performance testing completed. Biocompatibility testing and other non-clinical testing demonstrate these differences do not raise questions of safety and effectiveness when compared to the predicate device. Refer to Table 1 below for a comparison of technological characteristics between the subject and predicate devices.

Table 1: Comparison of Technological Characteristics

Characteristic	Subject Device Microliter Dosing Syringe	Predicate Device StaClear Syringe (K200242)	Associated Standard, Testing	Comment
Device Name	Microliter Dosing Syringe	StaClear Syringe	-	-
Applicant	Congruence Medical Solutions, LLC	TriboFilm Research, Inc.	-	-
510(k) Number	K243149	K200242	-	-
Intended Use	The Microliter Dosing Syringe is intended to inject fluid into, or withdraw fluid from the body.	The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body.	Performance and Biocompatibility testing results provided herein support the safety and effectiveness of the device as compared to the predicate.	Identical
Indications for Use	The Microliter Dosing Syringe is indicated for intravitreal use.	The StaClear Syringe is indicated for intravitreal use.	ISO 10993-23, Intravitreal Injection Irritation Testing, USP <788>, USP <789>	Identical
Mechanism of Action	Manual	Manual	ISO 7886-1	Identical
Sterilization Information	Provided Sterile, single-use Sterilization Method: Electron-beam irradiation	Provided Sterile, single-use Sterilization Method: Ethylene Oxide	ISO 11137-1, ISO 11137-2, ISO 11737-1, ISO 11737-2, TIR13004	Different
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	ISO 11137-1, ISO 11137-2, ISO 11737-1, ISO 11737-2, TIR13004	Identical

Shelf Life	2 years	1 year	ASTM F1980-21, ISO 7886-1, USP <71>	Different
Device Materials	Barrel – Cyclic olefin polymer Plunger Rod subassembly – Polycarbonate with glass fiber, Polyethylene terephthalate with glass fiber, stainless steel Plunger stopper – chlorinated butyl rubber with fluoropolymer coating Tip Cap – Chlorobutyl rubber with fluoropolymer coating	Barrel - Polypropylene Plunger - Polyethylene Plunger Stopper - Polyisoprene (Nipol IR2200, Zeon Chemicals) Needle – ASTM 304 Stainless Steel Needle Shield - Polyethylene Plunger Cap - Polyethylene Barrel Lubricant - Silicone Oil, crosslinked with inert argon gas plasma	ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-23, ASTM F756	Different
Syringe Volume	0.35mL	0.25mL	ISO 7886-1	Different
Target Dose Volume	± 3µL (95% Confidence Level for all models)	Unknown	ISO 7886-1	Different
Connector Type	Luer lock	Pre-attached needle	ISO 7886-1, ISO 80369-7	Different
Cytotoxicity	No evidence of causing cell lysis or toxicity	No evidence of causing cell lysis or toxicity	ISO 10993-5	Identical
Sensitization	No skin sensitization	No skin sensitization	ISO 10993-10	Identical
Irritation or Intracutaneous Reactivity	Intracutaneous Reactivity: No intracutaneous reactivity	Intracutaneous Reactivity: No intracutaneous reactivity	ISO 10993-23	Identical
	Irritation, Ocular: Not considered irritants to the ocular tissue	Irritation, Ocular: Not considered irritants to the ocular tissue	ISO 10993-23, Annex D	Identical
	Irritation, Intravitreal Injection: Not considered cause intravitreal irritation	Irritation, Intravitreal Injection: Not considered cause intravitreal irritation	Intravitreal Injection Irritation testing	Identical

Acute Systemic Toxicity	No evidence of system toxicity	No evidence of system toxicity	ISO 10993-11	Identical
Pyrogenicity	Not pyrogenic	Not pyrogenic	ISO 10993-11	Identical
Hemolysis	Not hemolytic	Not hemolytic	ASTM F756, ISO 10993-4	Identical
Particulate Testing	Conforms to USP <788> and USP <789> requirements	Conforms to USP <788> and USP <789> requirements	USP <788>, USP <789>	Identical
Endotoxin Testing	≤ 0.2 EU/device or ≤ 0.2 EU/mL	Unknown. The K200242 510(k) Summary did not contain information about endotoxin testing	USP <85>	No data available for predicate

Substantial Equivalence Discussion:
The subject device is substantially equivalent to the predicate device when evaluating intended use and technological characteristics.

- The intended use is equivalent to the predicate device.
- The technological characteristics of the subject device are substantially equivalent to the predicate device with only minor differences; these minor differences do not introduce or increase safety risk.
- Congruence completed performance testing according to the ISO 7886-1 standard and USP <789> for subvisible particulate testing. The Microliter Dosing Syringe met the applicable requirements of ISO 7886-1 and USP <789>. These standards were also used by the predicate device TriboFilm StaClear. In addition, endotoxin testing according to USP <85> was performed with the Microliter Dosing Syringe to establish conformance to the limits recommended for ophthalmic devices in FDA guidance. The Microliter Dosing Syringe test results demonstrate its performance characteristics are substantially equivalent to the predicate device. Refer to the *Non-clinical Testing* section below for a list of performance testing completed.
- Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 to demonstrate that the Microliter Dosing Syringe is as safe and effective as the legally marketed predicate device, and that any minor differences in technological characteristics do not raise questions of safety and effectiveness as compared to the predicate device (K200242). Refer to the *Biocompatibility Testing* section below for a list of the biocompatibility testing completed.
- The differences between the predicate device (K200242) and the subject device for device volume, device materials, syringe volume and shelf-life do not introduce new or different questions of safety and effectiveness when compared to the predicate device based on successful completion of biocompatibility testing, non-clinical testing and performance testing conducted to support substantial equivalence.
- Adequate performance testing has been completed to support that the differences in connector types do not raise new or different questions of safety and effectiveness between the subject device and the predicate device. Substantial equivalence is also claimed despite difference in sterilization method (electron beam irradiation for Microliter Dosing Syringe compared to ethylene oxide sterilization for predicate device (K200242)), based on having an identical Sterility Assurance Level (SAL) of 10-6 and based on successful completion of biocompatibility testing, non-clinical testing and performance testing conducted with devices treated with electron beam irradiation.

Non-clinical testing	Bench testing was performed to demonstrate the subject device is as safe and effective as the predicate device. The following tests were completed: ISO 7886-1 • Cleanliness • Acidity and Alkalinity • Extractable Metals • Tolerance on Graduations • Dead Space • Air and Liquid Leakage Past Plunger • Plunger Force • Fit of Stopper Particulate Testing: • USP <788> Particulate Matter in Injections • USP <789> Particulate Matter in Ophthalmic Solutions Endotoxin Testing: • USP <85> Bacterial Endotoxins Test
Non-clinical Testing (Biocompatibility)	A chemical characterization of the device was done to evaluate the subacute/subchronic and genotoxicity endpoints. The toxicological risk assessment demonstrated an acceptable level of risk of systemic exposure to the extractable compounds when classifying the Microliter Dosing Syringe as externally communicating device with prolonged contact (>24 hours to 30 days) with patient tissue contact through the injectable fluid. The following biological safety tests were also completed: • Cytotoxicity • Sensitization • Irritation, Ocular • Irritation, Intravitreal Injection • Intracutaneous Reactivity • Acute Systemic Toxicity • Pyrogenicity • Hemolysis The test article extract did not show evidence of causing cell lysis or toxicity, was not considered a sensitizer, was not considered an irritant to the ocular tissue of the rabbit, was not considered inflammatory to intraocular tissues of the rabbit, did not show evidence of erythema and edema, did not show evidence of mortality or systemic toxicity, was not considered pyrogenic, and was not considered hemolytic. Therefore, this biological safety testing demonstrates the subject device is biocompatible for its intended use.
Clinical Testing	Not applicable - "N/A"
Conclusion	In conclusion, the Microliter Dosing Syringe is biocompatible for its intended use, demonstrates equivalent performance as the predicate device, and conforms to limits for endotoxins in single-use ophthalmic devices recommended in FDA guidance. The suitability of the device for intravitreal injection was evaluated through biocompatibility, intravitreal injection irritation testing, particulate and endotoxin testing. Test results confirm that the differences between the predicate and the subject device do not raise new questions of safety or effectiveness, supporting conclusion of substantial equivalence. The Microliter Dosing Syringe is substantially equivalent to the predicate device – StaClear Syringe (K200242) with respect to the intended use, target populations, treatment method, and technological characteristics.