July 27, 2020

TriboFilm Research, Inc.
% Beryl Jeanne
Regulatory Consultant
Namsa
400 Highway 169 South, Suite 500
Minneapolis, Minnesota 55426

Re: K200242
Trade/Device Name: StaClear Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QLY, FMF, FMI
Dated: June 24, 2020
Received: June 25, 2020

Dear Beryl Jeanne:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For CAPT Alan Stevens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200242

Device Name
StaClear Syringe

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.

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K200242 510(k) Summary

510(k) Number	K200242	
Preparation Date	June 21, 2020	
Submitter	TriboFilm Research, Inc. 625 Hutton Street, Suite 105 Raleigh, NC 27606 Phone: +1-919-838-2844 Fax: +1-919-838-6787 E-mail: info@tribofilmresearch.com	
Primary Contact	Jackson Thornton, PhD Director of Research TriboFilm Research, Inc. 625 Hutton Street, Suite 105 Raleigh, NC 27606	
Subject Device	Trade Name	StaClear Syringe
	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
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.	
Device Description	The StaClear Syringe is a single-use piston syringe consisting of a 0.25 mL graduated barrel, plunger, plunger stopper, needle, needle shield, and plunger cap. The needle is a 31-gauge needle, 5/16in in length, which is permanently attached to the syringe body. It is intended for use by health care 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. The StaClear syringe is suitable for ophthalmic use.	
Predicate Device	Trade Name	Sterile Single-use Syringe with Needle
	Applicant	JiangXi HongDa Medical Equipment Group Ltd.
	510(k) Number	K163161

	Clearance Date	March 20, 2017
	Common Name	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	FMF; FMI
	Regulation Medical Specialty	General Hospital
	510(k) Review Panel	General Hospital
Reference Device	Trade Name	BD Insulin Syringe
	Applicant	Becton, Dickinson & Company
	510(k) Number	K024112
	Clearance Date	01/09/2003
	Device	Syringe, Piston
	Regulation Numbers	21 CFR 880.5860
	Device Class	Class II
	Product Codes	FMF
	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 in the device materials, syringe volume, connector type, needle gauge, needle length, biocompatibility tests completed, and performance testing completed. Biocompatibility testing and performance testing demonstrate these differences do not raise questions of safety and effectiveness. 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	Predicate Device	Associated Testing Standard
Device Name	StaClear Syringe	Sterile Single-Use Syringe with Needle	-
Applicant	TriboFilm Research, Inc.	JiangXi HongDa Medical Equipment Group Ltd.	-
510(k) Number	K200242	K163161	-
Intended Use	The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body.	Identical	All listed Performance and Biocompatibility testing listing within this 510(k) Summary support the safety and effectiveness of the device as compared to the predicate.
Indications for Use	The StaClear Syringe is indicated for intravitreal use.	Equivalent, the predicate device does not identify specific indications for use.	ISO 10993-15, Intravitreal Injection Irritation testing, USP <788>, USP <789>
Mechanism of Action	Manual	Identical	ISO 7886-1
Sterilization information	Provided Sterile, single-use Sterilization Method: Ethylene Oxide SAL: 10^{-6}	Identical	ISO 10993-7, ISO 14937, TIR 56, ISO 11135, ISO 11737-1, ISO 11737-2
Shelf Life	1 year	Unknown The predicate device's shelf life is unknown. This information is not provided in the K163161 510(k) Summary.	ASTM F1980-16, ISO 7886-1, ISO 7864, USP <71>

	Device Materials	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	Equivalent. Both the subject and predicate devices use stainless steel for the needles. Both the subject and predicate devices use polypropylene and polyisoprene for the syringes. The predicate device additionally uses polyethylene for the syringe's plunger, needle shield, and plunger cap. These components are non-patient contacting. The subject device uses a silicone oil crosslinked with inert argon gas plasma for the lubricant. The predicate device uses standard silicone oil as the lubricant.	ISO 10993-1, ISO 10933-2, ISO 10993-4, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-17, ISO 10993-18, ASTM F756
	Syringe Volume	0.25 mL	Equivalent. The subject device's 0.25 mL syringe volume is smaller than the predicate device's syringe volume range of 1 mL to 60 mL.	ISO 7886-1
	Connector Type	Attached needle	Equivalent. The subject device has the needle permanently attached to the syringe body whereas the predicate uses a luer slip and luer lock connector.	ISO 7886-1, ISO 7864, ISO 9626
	Needle Gauge	31 G	Equivalent. The subject device's 31G needle is smaller than the predicate device's needle range of 18G to 30G.	ISO 7864 and ISO 9626
	Needle Length	5/16 in.	Equivalent. The subject device's 5/16 in. needle length is shorter than the predicate device's needle length range of ½ in. to 1½ in.	ISO 7864 and ISO 9626

Cytotoxicity	No evidence of causing cell lysis or toxicity	Identical	ISO 10993-5
Sensitization	No skin sensitization	Identical	ISO 10993-10
Irritation or Intracutaneous Reactivity	Intracutaneous Reactivity: No intracutaneous reactivity	Identical	ISO 10993-15, Intravitreal Injection Irritation testing
	Irritation, Ocular: Not considered irritants to the ocular tissue	N/A. Ocular Irritation and Intravitreal Injection Irritation testing not performed on predicated device.	ISO 10993-15, Intravitreal Injection Irritation testing
	Irritation, Intravitreal Injection: Not considered inflammatory to intraocular tissues		
Acute Systemic Toxicity	No mortality or evidence of systemic toxicity	Identical	ISO 10993-11
Pyrogenicity	Not pyrogenic	Identical	ISO 10993-11
Hemolysis	Not hemolytic	Identical	ASTM F756, ISO 10993-4

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

- There are no differences between the subject device and the predicate device with respect to intended use.
- The subject device is additionally indicated for intravitreal use. This additional indication was evaluated through ocular and intravitreal injection irritation testing, demonstrating that the device is biocompatible for intravitreal use. This difference in indications for use between the subject and predicate device does not raise new or different questions of safety and effectiveness.
- The technological characteristics of the subject device are substantially equivalent to the predicate device with only minor differences in the device materials, syringe volume, connector type, needle gauge, needle length.
- TriboFilm completed performance testing according to the following standards: ISO 7886-1, ISO 7864, and ISO 9626. The StaClear Syringe met the applicable requirements of all three standards. These three standards were utilized by predicate device JiangXi Sterile Single-use Syringe with Needle (K163161) to demonstrate performance. Additionally, TriboFilm completed particulate testing according to the following standards and

	compared results to reference device Becton Dickinson & Co's BD Insulin Syringe (K024112): USP <788> and USP <789>. The StaClear Syringe passed both USP <788> and USP <789>. Therefore, the StaClear Syringe demonstrates it performance characteristics are substantially equivalent to the predicate and references devices. Refer to the *Performance Testing* section below for a full list of performance testing completed. • Tribofilm completed biocompatibility testing in accordance with ISO 10993-1: 2016 to demonstrate the subject device is as safe and effective as the legally marketed predicate device, and that any minor differences in technological characteristics do not raise new or different questions of safety and effectiveness as compared to the predicate device. Refer to the *Biocompatibility Testing* section below for a full list of biocompatibility testing completed.

Non-clinical Testing:	Bench testing was performed to demonstrate the subject is as safe and effective as the proposed subject device. Performance testing was conducted according to TriboFilm's design control system. The following tests were completed: ISO 7886-1: 2017 • Cleanliness • Acidity and Alkalinity • Extractable Metals (performed based on exhaustive extraction with limits set for intraocular lenses ≤ 0.2 µg/device) • Lubricant • Tolerance on Graduations • Stopper Detachment • Dead Space • Air and Liquid Leakage Past Plunger • Plunger Force • Fit of Stopper ISO 7864: 2016 • Cleanliness • Acidity and Alkalinity • Extractable Metals (performed based on exhaustive extraction with limits set for intraocular lenses ≤ 0.2 µg/device) • Tolerance on Length • Tube Defects • Lubricant • Point Defects • Needle Penetration Force • Bond between Tube and Hub • Patency of Lumen ISO 9626: 2016 • Materials • Surface Finish • Cleanliness • Acidity and Alkalinity • Size designation • Dimensions • Stiffness • Resistance to Breakage • Resistance to Corrosion Particulate Testing • USP <788> Particulate Matter in Injections • USP <789> Particulate Matter in Ophthalmic Solutions

Non-Clinical Testing (Biocompatibility)	StaClear Syringe is classified as an externally communicating device with prolonged (> 24 hours to 30 days) tissue contact. TriboFilm completed the following biological safety tests: • Chemical Characterization • 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. 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. Therefore, this biological safety testing demonstrates the subject device is biocompatible for its intended use.
Clinical Testing:	Not Applicable
Conclusion:	In conclusion, the StaClear Syringe is biocompatible for its intended use, demonstrates equivalent performance as the predicate device, and demonstrates better performance than the reference device. TriboFilm Research, Inc. respectfully requests FDA clearance to legally market the StaClear Syringe in the U.S. The modifications to design, dimensions, and materials met the requirements of the standards. The suitability of the device for intravitreal injections was evaluated through biocompatibility and particulate testing. The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The StaClear Syringe is substantially equivalent to the Sterile Single-use Syringe with Needle cleared under K163161 with respect to the intended use, target populations, treatment method, and technological characteristics.