September 8, 2023

OcuJect, LLC
% Heidi Busz
Senior Regulatory Consultant
Namsa
400 Highway 169 South, Ste 500
Minneapolis, Minnesota 55426

Re: K230372
Trade/Device Name: VitreJect Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QLY, FMF, QNQ
Dated: August 10, 2023
Received: August 11, 2023

Dear Heidi Busz:

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,

CAPT Alan M. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230372

Device Name
VitreJect Syringe

Indications for Use *(Describe)*

The VitreJect Syringe is intended to inject fluids into, or withdraw fluids from, the body.
The VitreJect Syringe is indicated for intracameral and 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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OcuJect LLC
ADVANCED DRUG DELIVERY

510(k) Summary

I. SUBMITTER

OcuJect, LLC
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Phone: (949) 721.6716
Email: llerner@ocuject.com
Primary Contact: Leonid Lerner, MD, PhD
Date prepared: September 8, 2023

II. DEVICE

Name of Device:	VitreJect® Syringe
Common or Usual Name:	Syringe, Piston
Classification Name:	Piston Syringe (21 CFR 880.5860)
Regulatory Class:	II
Product Code:	QLY
Subsequent Code(s):	FMF, QNQ

III. PREDICATE DEVICE

StaClear Syringe, K200242
This predicate has not been subject to a design-related recall.

IV. REFERENCE DEVICE

MiniLoad® Syringe, K212544

V. DEVICE DESCRIPTION

The VitreJect Syringe is designed to provide a means of fluid injection and aspiration. It is a luer-tip piston syringe consisting of a 1 mL hollow barrel with gradient markings and a plunger with an incorporated plunger stopper. The VitreJect Syringe barrel component is available in two configurations, a luer-slip or luer-lock tip, for the fitting of a compatible hypodermic needle. The VitreJect Syringe plunger is available in two configurations: standard dead space or low dead space. It is intended for manual use by health care professionals. The VitreJect Syringe is single use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas. The VitreJect Syringe is suitable for ophthalmic use.

VI. INTENDED USE / INDICATIONS FOR USE

The VitreJect Syringe is intended to inject fluids into, or withdraw fluids from, the body.

The VitreJect Syringe is indicated for intracameral and intravitreal use.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the VitreJect® Syringe are substantially equivalent to the predicate StaClear Syringe (K200242). The intended use of the subject device is identical to the predicate device; both are designed and intended to inject fluids into, or withdraw fluids from, the body. Both the VitreJect® Syringe and the StaClear Syringe are indicated by intravitreal use, whereas the subject device is additionally indicated for intracameral use. The subject device and the predicate device have minor technological differences in device materials, dimensional specifications, connection type, and plunger type/specification. The subject device has the identical design, material, manufacturing process, sterilization method, operation method, and packaging configuration of the MiniLoad® Syringe (K212544). Further, the plunger/syringe interface of the VitreJect Syringe is identical to the MiniLoad® Syringe and the dead space specification of ≤ 0.023 mL with 95% confidence/95% reliability is in alignment with the specification established in the legally marketed MiniLoad® Syringe (K212544).

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

Characteristic	**Subject Device VitreJect® Syringe**	**Predicate Device StaClear Syringe (K200242)**	**Associated Testing Standard**
Applicant	OcuJect, LLC	TriboFilm Research, Inc.	
Proprietary Name	VitreJect®	StaClear	
Device	Syringe, Piston	Identical	
Device Class	II	Identical	
Regulation Number	21 CFR 880.5860	Identical	
Product Code	QLY	Identical	
Subsequent Codes:	FMF *QNQ – low dead space specification identical to MiniLoad Syringe*	Identical *FMI - permanently attached needle*	
Regulation Medical Specialty	General Hospital	Identical	
Intended Use	Intended to inject fluids into, or withdraw fluids from, the body.	Identical	Supported by referenced performance and biocompatibility testing
Indications	The VitreJect® Syringe is intended to inject fluids into, or withdraw fluids from, the body.	Equivalent, the predicate device does not indicate for intracameral use.	ISO 10993-1, ISO 10993-7, ISO 10993-10, USP <788>, USP <789>

Characteristic		Subject Device VitreJect® Syringe	Predicate Device StaClear Syringe (K200242)	Associated Testing Standard
		The VitreJect® Syringe is indicated for intracameral and intravitreal use.	The StaClear Syringe is intended to inject fluids into, or withdraw fluids from, the body. The StaClear Syringe is indicated for intravitreal use.	
Intended Use Population, Users and Environment		Adults Only (greater than 21 years of age) Clinicians in a clinical setting.	Unknown Identical	
Principle of Operation		Manual advancement and withdrawal of the plunger within the barrel	Identical	ISO 7886-1
Device Components		Barrel Plunger	Identical syringe components StaClear Syringe has permanently attached needle whereas VitreJect Syringe is a luer-tip syringe.	ISO 10993-1, ISO 10993-2, ISO 10993-4, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-17, ISO 10993-18, ISO 10993-23, ASTM F756 ISO 7886-1
Materials	Barrel	Polypropylene random copolymer	Equivalent, Polypropylene	
	Plunger	Polyethylene (HDPE) – plunger and stopper Blue Ink Titanium Dioxide	Equivalent, Polyethylene – plunger Polyisoprene – plunger stopper	
	Lubricant	Non-silicone (oleamide) slip agent mixed into Polypropylene barrel	Equivalent, Silicone oil, cross-linked with inert argon gas plasma	
Barrel Volume		1 mL	Equivalent, 0.25mL	
Barrel Length		Luer-Slip (LDS) – 84.7 mm Luer Lock (LDS & STD) – 86 mm	Equivalent, StaClear Syringe specification unknown.	
Barrel Outside Diameter		~ 6.4 mm	Equivalent, StaClear Syringe specification unknown.	

Characteristic	Subject Device VitreJect® Syringe	Predicate Device StaClear Syringe (K200242)	Associated Testing Standard
Barrel Inside Diameter	~ 4.6 mm	Equivalent, StaClear Syringe specification unknown.	
Barrel Color	Transparent and Clear	Equivalent, StaClear Syringe specification unknown.	
Barrel Printing	Black ink	Equivalent, StaClear Syringe specification unknown.	
Plunger Length	Luer-Slip (LDS) – 94.3 mm Luer Lock (LDS) – 96.3 mm Luer Lock (STD) – 85.3 mm	Equivalent, StaClear Syringe specification unknown.	
Plunger Color	Blue	Equivalent, StaClear Syringe specification unknown.	
Plunger Type	Low dead space (LDS) Standard (STD)	Equivalent, StaClear Syringe specification unknown.	ISO 7886-1
Graduation	ISO 7886-1 compliant *Full scale capacity testing as well as 0.05 mL fill volume to support dosing accuracy for ophthalmic use.*	Identical	ISO 7886-1
Tip Type	Luer-slip Luer-lock	Equivalent, Permanently attached needle	ISO 7886-1 ISO 80369-7
Dead Space Specification	≤ 0.023 mL with 95% confidence / 95% reliability	Equivalent, StaClear Syringe specification unknown	ISO 7886-1
Sterilization and Shelf Life	Provided Sterile, Single-Use 100 individual blister packed devices packaged into shelf carton Sterilization Method: EO	Equivalent, Provided Sterile, Single-Use 100 single-use syringes, EO sterile fluid path, in shelf carton Sterilization Method: EO SAL: 10-6	AAMI TIR28 ISO 11135-1 ISO 10993-7 USP <85> ANSI/AAMI ST72 ASTM F1980-16 ISO 7886-1

Characteristic	Subject Device VitreJect® Syringe	Predicate Device StaClear Syringe (K200242)	Associated Testing Standard
	SAL: 10-6 Shelf Life: 5 years	Shelf Life: 1 year	ISO 80369-7 ISO 11607-1 ASTM F88/F88-15 ASTM F1929-15 ISTA 3A
Biocompatibility per ISO 10993-1	Non-cytotoxic	Identical	ISO 10993-5
	Non-sensitizer	Identical	ISO 10993-10
	Non-irritant, Intracutaneous Reactivity	Identical	ISO 10993-23
	Non-irritant, Ocular	Identical	ISO 10993-10
	Non-irritant, Intravitreal Injection	Identical	ISO 13485
	Non-irritant, Intraocular	Equivalent, Test not applicable to StaClear Syringe, which is not indicated for intracameral use.	ISO 13485
	Non-pyrogenic	Identical	ISO 10993-11, USP <151>
	Non-toxic	Identical	ISO 10993-11
	Non-hemolytic	Identical	ASTM F756, ISO 10993-4
Performance Data	Meets ISO 7886-1	Identical	ISO 7886-1
	Meets ISO 80369-7	Equivalent, Test not applicable to StaClear Syringe, which has a permanently attached needle.	ISO 80369-7
	Meets USP <788>	Identical	USP <788>
	Meets USP <789>	Identical	USP <789>

VIII. PERFORMANCE DATA

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

- ISO 7886-1
  - Freedom from Extraneous Matter
  - Lubricant Quantification
  - Tolerance on Graduations

  - Plunger Stopper Detachment
  - Barrel Flange to Plunger Distance
  - Dead Space
  - Freedom from Leakage
  - Piston Operational Force
  - Plunger Fit

- ISO 80369-7
  - Luer Connector

- Particulate Testing
  - USP <788> Particulate Matter in Injections
  - USP <789> Particulate Matter in Ophthalmic Solutions

- Biocompatibility (ISO 10993-1)

VitreJect Syringe is categorized as an externally communicating device with prolonged (>24 h to 30 d) tissue/blood path indirect contact (fluid path). OcuJect, LLC completed the following biological safety tests:

  - Chemical Characterization
  - Cytotoxicity
  - Sensitization
  - Irritation, Intracutaneous Reactivity
  - Irritation, Ocular
  - Irritation, Intravitreal Injection
  - Irritation, Intraocular
  - Acute Systemic Toxicity
  - Pyrogenicity
  - Hemolysis

The results of the *in vitro* and *in vivo* studies were acceptable. A chemical characterization study was performed to identify and quantitate the extractables and/or leachables that may be released from the test article. A toxicological risk assessment was then conducted on the chemical characterization testing data to address the biological endpoints of systemic toxicity (subacute/subchronic) and genotoxicity and summarize the biological safety of the VitreJect Syringe. 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.

IX. SUBSTANTIAL EQUIVALENCE

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

- The subject device has the identical intended use as the predicate device.

- The subject device and the predicate device are indicated for intravitreal use. The subject device is additionally indicated for intracameral use. This additional indication was evaluated through intraocular injection irritation testing, demonstrating that the VitreJect Syringe is biocompatible for intracameral use. This difference in indication for use does not raise new or different questions of safety and effectiveness.
- The subject device and predicate device are substantially equivalent with only minor technological differences in device materials, dimensional specifications, connection type, plunger type. OcuJect completed performance testing according to ISO 7886-1, ISO 80369-7, USP <788> and USP <789> and the VitreJect Syringe met the applicable requirements. The ISO 7886-1, USP <788> and USP <789> standards were also utilized by the StaClear Syringe to demonstrate performance. The VitreJect Syringe demonstrates its performance characteristics are substantially equivalent to the predicate and reference device.
- Biocompatibility testing demonstrates the subject device is as safe and effective as the legally marketed predicate device, and that minor differences in technological characteristics do not raise new or different questions of safety and effectiveness compared to the predicate device.

The biocompatibility testing data and particulate test data in conjunction with the performance test data in compliance with ISO 7886-1 demonstrate that the VitreJect Syringe met the established safety and performance characteristics of the device and demonstrate substantial equivalence.

X. CONCLUSIONS

The VitreJect Syringe met the established safety and performance characteristics for a piston syringe. Suitability of the subject device for the additional indication of intracameral and intravitreal use was evaluated through endotoxin, biocompatibility, and particulate testing. The additional indication for intracameral administration routes does not raise any new or different questions of safety or effectiveness. Testing demonstrates the VitreJect Syringe is as safe and effective as the predicate device and will perform as intended. The VitreJect Syringe is substantially equivalent to the StaClear Syringe cleared under K200242.