September 14, 2023

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

Re: K230959
Trade/Device Name: VitreJect® Needle; OcuSafe® Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 9, 2023
Received: August 10, 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,

Courtney Evans -S
Digitally signed by Courtney Evans -S
Date: 2023.09.14 23:40:05 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230959

Device Name
VitreJect® Needle
OcuSafe® Needle

Indications for Use *(Describe)*
The VitreJect® Needle is intended for use with a luer-tip syringe for the administration of drugs.
The VitreJect® Needle is indicated for intravitreal use.

The OcuSafe® Needle is intended for use with a luer-tip syringe for the administration of drugs.
The OcuSafe® Needle 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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510(k) Summary

I. SUBMITTER

OcuJect, LLC
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Newport Beach, CA 92660
Phone: (949) 721.6716
Email: llerner@ocuject.com
Primary Contact: Leonid Lerner, MD, PhD
Date prepared: September 14, 2023

II. DEVICE

Name of Device: VitreJect® / OcuSafe® Needle
Common or Usual Name: Needle, Hypodermic, Single Lumen
Classification name: Hypodermic Single Lumen Needle (21 CFR 880.5570)
Regulatory Class: 2
Product Code: FMI

III. PREDICATE DEVICE

SteriCap® Mini Needle and Standard Needle, K212805
The predicate devices have not been subject to a design-related recall.

IV. REFERENCE DEVICE

StaClear Syringe, K200242
Altaviz Needle Kit II, K231261

V. DEVICE DESCRIPTION

The VitreJect® / OcuSafe® Needles are designed to provide a means of fluid injection and aspiration. The devices are single-lumen needles intended for use with a luer-tip syringe. The VitreJect® Needle has a spring-actuated, non-removable sliding cap that protects the needle prior and during its use. The OcuSafe® Needle has a removable cap that is removed prior to the needle's use. They are intended for use by health care professionals for administration of drugs. Their operation is manual. The VitreJect®/OcuSafe® Needles are single use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas. The VitreJect®/OcuSafe® Needles are suitable for ophthalmic use.
The VitreJect® Needle is offered in the following configurations:

-	30G x 5.5mm	30G x 6mm
31G x 4mm	31G x 5.5mm	31G x 6mm
33G x 4mm	33G x 5.5mm	33G x 6mm

The OcuSafe® Needle is offered in the following configurations:

-	-	29G x 13mm
-	-	30G x 13mm
31G x 4mm	-	31G x 13mm
-	33G x 8mm	-

VI. INTENDED USE / INDICATIONS FOR USE

The VitreJect® Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect® Needle is indicated for intravitreal use.

The OcuSafe® Needle is intended for use with a luer-tip syringe for the administration of drugs. The OcuSafe® Needle is indicated for intravitreal use.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The intended use of the subject device is identical to the predicate device; designed and intended to inject fluids into, or withdraw fluids from, the body. The technological characteristics of the VitreJect® / OcuSafe® Needles are substantially equivalent to the predicate SteriCap® Mini Needle / Standard Needle (K212805). The subject device and the predicate device have identical design, material, manufacturing process, sterilization method, operation method, and packaging configuration. The OcuSafe® Needle introduces an additional configuration (31G x 4 mm) and there are minor differences in biocompatibility and performance testing and indications for use as the VitreJect® / OcuSafe® Needles are additionally indicated for intravitreal use.

A comparison of the technological characteristics between the subject and primary predicate devices is illustrated in the table below:

Characteristic	**Subject Device VitreJect®/OcuSafe® Needle**	**Predicate Device SteriCap® Mini Needle / Standard Needle (K212805)**	**Associated Testing Standard**
Applicant	OcuJect, LLC	Identical	-
Proprietary Name	VitreJect® OcuSafe®	SteriCap® -	-
Product Code	FMI	Identical	-
Intended Use	Intended to inject fluids* into, or withdraw fluids from, the body.	Identical	*Namely drugs Supported by referenced performance and biocompatibility

Characteristic	Subject Device VitreJect®/OcuSafe® Needle	Predicate Device SteriCap® Mini Needle / Standard Needle (K212805)	Associated Testing Standard
			testing
Indications	The VitreJect® Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect® Needle is indicated for intravitreal use. The OcuSafe® Needle is intended for use with a luer-tip syringe for the administration of drugs. The OcuSafe® Needle is indicated for intravitreal use.	Equivalent, the predicate device does not identify specific clinical applications: *The SteriCap® Mini Needle and standard needles are intended for use with a luer-tip syringe (e.g. luer-lock or slip-tip luer syringe) for the administration of drugs.*	ISO 10993-1, ISO 10993-7, ISO 10993-10, USP <788>, USP <789>
Intended Users and Environment	Health care professionals in a clinical setting	Identical	-
Principle of Operation	Connects to a luer type syringe to serve as a conduit for the manual advancement and withdrawal of fluid	Identical	ISO 80369-7, ISO 7864, ISO 9626
Functional Construct	Single lumen needle	Identical	ISO 7864, ISO 9626
Design/ Construction	Needle Assembly: Cannula, needle hub, needle cap (spring loaded or removable) Designed to fit standard 6% luer fittings	Identical	ISO 80369-7, ISO 7864, ISO 9626
Device Components and Materials	Cannula: stainless steel Lubricant: silicone Adhesive: polyacrylate Needle Cap: polypropylene Hub: polypropylene Spring (VitreJect®): stainless steel	Identical *Stainless steel spring in SteriCap® model only*	ISO 10993-1, ISO 10993-2, ISO 10993-4, ASTM F756, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-17,

Characteristic	Subject Device VitreJect®/OcuSafe® Needle	Predicate Device SteriCap® Mini Needle / Standard Needle (K212805)	Associated Testing Standard
			ISO 10993-18, ISO 10993-23 ISO 7864, ISO 9626
Needle Length (Exposed)	VitreJect®: 4 mm / 5.5 mm / 6 mm OcuSafe®: 13 mm 8 mm 4 mm	Equivalent, the predicate Standard Needle is not offered in 4 mm: *SteriCap®:* *4 mm / 5.5 mm / 6 mm* *Standard:* *13 mm / 8 mm*	ISO 7864, ISO 9626
Needle Gauge	VitreJect®: 30G, 31G and 33G. OcuSafe®: 29G, 30G, 31G and 33G.	Identical *SteriCap®: 30G, 31G and 33G.* *Standard Needle: 29G, 30G, 31G and 33G.*	ISO 7864, ISO 9626
Cannula tip configuration	Lancet bevel	Identical	ISO 7864, ISO 9626
Sterilization and Shelf Life	Provided Sterile, Single-Use 100 individual blister-packed devices packaged into a shelf carton Sterilization Method: EO SAL: 10^{-6} Shelf Life: 5 years Ethylene oxide residual were assessed per ISO 10993-7. Endotoxins were tested as recommended in FDA guidance Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices.	Identical *Reduced residual and endotoxin limits for ophthalmic use not applicable.*	AAMI TIR28, ISO 11135-1, ISO 10993-7, USP <85>, USP <161>, ANSI/AAMI ST72, ASTM F1980-16, ISO 7864, ISO 9626, ISO 80369-7, ASTM F88/F88-15, ASTM F1929-15, ASTM D4169-16

Characteristic	Subject Device VitreJect®/OcuSafe® Needle	Predicate Device SteriCap® Mini Needle / Standard Needle (K212805)	Associated Testing Standard
Biocompatibility per ISO 10993-1	Non-cytotoxic	Identical	ISO 10993-5
	Non-sensitizer	Identical	ISO 10993-10
	Non-irritant, Intracutaneous	Identical	ISO 10993-23
	Non-irritant, Ocular	Equivalent, Ocular, Intravitreal Injection and Intraocular Irritation testing not performed on the predicate device.	ISO 10993-10
	Non-irritant, Intravitreal Injection		ISO 13485
	Non-irritant, Intraocular		ISO 13485
	Non-pyrogenic	Identical	USP <151>, ISO 10993-11
	Non-toxic	Identical	ISO 10993-11
	Non-hemolytic	Identical	ISO 10993-4, ASTM F756
			ISO 10993-3

VIII. PERFORMANCE DATA

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

- Dimensional and Physical Properties Verification
  - ISO 7864, ISO 80369-7
- Bond and Material Strength Verification
  - ISO 7864, ISO 80369-7
- Needle quality
  - ISO 9626, ISO 7864
- Color coding
  - ISO 6009, ISO 7864
- Luer connector
  - ISO 80369-7
- Particulate testing
  - USP <788>, USP <789>
- Biocompatibility (ISO 10993-1)

VitreJect® and OcuSafe® Needles are categorized as externally communicating devices with limited (<24 hours) direct tissue and indirect blood/tissue path contact. OcuJect, LLC

completed the following biological safety tests:

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

The test article extracts showed no evidence of cytotoxic effect, were not considered a sensitizer, showed no evidence of erythema and edema, were not considered an irritant to the ocular tissue of the rabbit, were not considered inflammatory to intraocular tissues of the rabbit, were not considered an irritant to the intraocular tissues of the rabbit, did not show evidence of systemic toxicity, were not considered pyrogenic, and were not considered hemolytic. The biological safety testing demonstrates the subject device is biocompatible for its intended use.

IX. SUBSTANTIAL EQUIVALENCE

The VitreJect® and OcuSafe® Needles are 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 is additionally indicated for intravitreal use.
- The subject device and predicate device are substantially equivalent with only minor technological differences in configuration/size offering, biocompatibility and performance testing.
- To support intravitreal use, the subject device was tested for compliance with intraocular requirements for ethylene oxide residuals, endotoxin, particulate matter according to USP <789> (using both the light obscuration and microscopy test methods), and intraocular irritation testing and passed.
- Biocompatibility testing and performance testing demonstrate the additional configuration/size offering and additional indication do not raise new or different questions of safety and effectiveness.

The biocompatibility testing data and particulate test data in conjunction with the performance test data demonstrating compliance with ISO 7864, ISO 9626, and ISO 80369-7 demonstrate that the VitreJect® and OcuSafe® Needles meet the established safety and performance characteristics of the device and demonstrate substantial equivalence.

X. CONCLUSIONS

The VitreJect® and OcuSafe® Needles met the established safety and performance characteristics

for a hypodermic single-lumen needle. Suitability of the subject devices for the additional configuration/size offering and additional indication of intravitreal use was evaluated through biocompatibility and performance testing. These differences do not raise any new or different questions of safety or effectiveness. Testing demonstrates the VitreJect® and OcuSafe® Needles are as safe and effective as the predicate device and will perform as intended.

The VitreJect® and OcuSafe® Needles are biocompatible for the intended use and demonstrate equivalent performance to the predicate device. The VitreJect® and OcuSafe® Needles are substantially equivalent to the SteriCap® Mini Needle and Standard Needles cleared under K212805.