October 25, 2024

OcuJect, LLC
% Julie Stephens
President
Regulatory Resources Group, Inc.
111 Laurel Ridge Dr
Alpharetta, Georgia 30004

Re: K242956
Trade/Device Name: LDS Needle; OcuSafe® LDS Needle; SteriCap® LDS Safety Needle; VitreJect® LDS Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: QNS, FMI, QYM
Dated: September 25, 2024
Received: September 25, 2024

Dear Julie Stephens:

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)*
K242956

Device Name
LDS Needle; OcuSafe® LDS Needle; SteriCap® LDS Safety Needle; VitreJect® LDS Safety Needle

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

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

The SteriCap® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The SteriCap Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick.

The VitreJect® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect® LDS Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick. The VitreJect® LDS Safety 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.

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By:
OcuJect, LLC
1441 Avocado Ave, Suite 204
Newport Beach, CA 92660 USA
Phone: (678) 523-8977

Contact Person:
Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.
Phone: (678) 513-0693

Date Prepared: September 27, 2024

Device Name and Classification:

Trade Name:	LDS Needle OcuSafe® LDS Needle VitreJect® LDS Safety Needle SteriCap® LDS Safety Needle
Regulation Number:	21 CFR 880.5570
Regulation Name:	Hypodermic Single Lumen Needle
Class:	II
Product Code(s):	QNS, FMI, QYM

Legally Marketed Predicate Device:

Predicate Devices: SteriCap® Safety Needle / VitreJect® Safety Needle, 510(k) # K233343
VitreJect® Needle / OcuSafe® Needle, 510(k) # K230959
SteriCap™ Mini Needle and Standard Needles, 510(k) # K212805
Reference Predicate Device: EZ-Injec LDV Sterile Safety Needle, 510(k) # K210444

Device Description:

The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle 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 Low Dead Space (LDS) needle has a decreased internal volume within the luer taper to reduce fluid volume loss. The LDS Needle and OcuSafe® LDS Needle have a removable cap that is removed prior to the needle's use. The SteriCap® LDS Safety Needle and VitreJect® LDS Safety Needle have a spring-actuated, non-removable sliding cap that protects the needle prior and during its use. They are intended for use by health care professionals for administration of drugs. Their operation is manual. The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Needle / SteriCap® LDS Needle are single use only, non-toxic, non-pyrogenic, and sterilized by ethylene oxide gas. The VitreJect® LDS Safety Needle and OcuSafe® LDS Needle are suitable for intravitreal use.

510(k) Summary

Product Name	Description	Configurations	
LDS Needle	Low Dead Space	31G	4mm
		33G	8mm
		29G; 30G; 31G	13mm
OcuSafe® LDS Needle	Low Dead Space Intravitreal	31G	4mm
		33G	8mm
		29G; 30G; 31G	13mm
VitreJect® LDS Safety Needle	Safety Low Dead Space Intravitreal	31G; 33G	4mm
		30G; 31G; 33G	5.5mm
		30G; 31G; 33G	6mm
SteriCap® LDS Safety Needle	Safety Low Dead Space	31G; 33G	4mm
		30G; 31G; 33G	5.5mm
		30G; 31G; 33G	6mm

Indications for Use:

The LDS Needle is intended for use with a luer-tip syringe for the administration of drugs.

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

The SteriCap® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The SteriCap Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick.

The VitreJect® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect® LDS Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick. The VitreJect® LDS Safety Needle is indicated for intravitreal use.

Comparison of Indications of Use to the Predicate Device

The Indications for Use statement for the LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle [Proposed Devices] **did not change** from devices under the respective previously cleared 510(k)s [Predicate Devices]. The Low Dead Space (LDS) will be added to the trade name, labels and labeling of these needles going forward. The Low Dead Space (LDS) usage is stated in FDA's Product Classification Database within the 21 CFR 880.5570 regulation with Product Code QNS. The OcuSafe® LDS Needle and the VitreJect® LDS Safety Needle maintain "indicated for intravitreal use" in their Indications for Use. The QYM Product Code for Ophthalmic Needle within the 21 CFR 880.5570 regulation is added as an additional Subsequent Product Code.

510(k) Summary

Proposed Device 510(k) #: K242956	Predicate Devices 510(k) #: K233343; K230959; K212805
LDS Needle OcuSafe® LDS Needle SteriCap® LDS Safety Needle VitreJect® LDS Safety Needle	Needle OcuSafe® Needle SteriCap® Safety Needle VitreJect® Safety Needle
The LDS Needle is intended for use with a luer-tip syringe for the administration of drugs. The OcuSafe® LDS Needle is intended for use with a luer-tip syringe for the administration of drugs. The OcuSafe® LDS Needle is indicated for intravitreal use. The SteriCap® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The SteriCap Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick. The VitreJect® LDS Safety Needle is intended for use with a luer-tip syringe for the administration of drugs. The VitreJect® LDS Safety Needle has an integrated passive needle cap/shield that covers the needle prior to use and automatically activates to cover the needle immediately after use. A lock mechanism can be manually activated to lock/unlock the needle cap. The locked needle cap minimizes risk of accidental needle stick. The VitreJect® LDS Safety Needle is indicated for intravitreal use.	Same **No Changes**

Technological Characteristics:

The technological characteristics of the LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle [Proposed Devices] **did not change** from devices under the respective previously cleared 510(k)s [Predicate Devices]. The proposed devices and the predicate devices have the identical design, materials, manufacturing process, sterilization method, operation method, and packaging configuration.

A comparison of the technological characteristics between the Proposed Devices and Predicate Devices are illustrated in the following table:

510(k) Summary

Comparison of Technological Characteristics to the Predicate Device

Characteristic		**Proposed Device** LDS Needle OcuSafe® LDS Needles SteriCap® LDS Safety Needles VitreJect® LDS Safety Needles	**Predicate Device** Needle OcuSafe® Needles SteriCap® Safety Needles VitreJect® Safety Needles	**Associated Testing Standard**
Applicant		OcuJect, LLC	Identical	-
Trade Name(s)		Needle, OcuSafe®; SteriCap®; VitreJect®	Identical	-
510(k) Numbers		K242956	K233343; K230959; K212805	
Product Code; Regulation; Class		FMI, QNS, QYM; 21 CFR 880.5570; Class II Additional testing per standards to support QYM were performed within 510(k) K230959 and K233343	FMI; 21 CFR 880.5570; Class II	ISO 10993-10 ISO 10993-7 USP <789> USP <85> ISO 7864 ISO 9626 ISO 80369-7
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 manual movement of fluid	Identical	ISO 80369-7, ISO 7864, ISO 9626
Device Components		Needle Assembly: needle, needle hub, spring-loaded needle cap (VitreJect and SteriCap) Designed to fit standard 6% Luer fittings	Identical	ISO 80369-7, ISO 7864, ISO 9626
Material	Needle	Stainless Steel	Identical	ISO 10993-1, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 7864, ISO 9626, ISO 6009, ISO 80369-7 Internal Standards, ISO 23908
	Needle hub	Polypropylene		
	Lubricant	Silicone		
	Spring	Stainless Steel (VitreJect and SteriCap)		
	Adhesive	Polyacrylate		
	Needle cap	Polypropylene		
Needle Length (Exposed)		VitreJect® LDS: 4 mm / 5.5 mm / 6 mm SteriCap® LDS: 4 mm / 5.5 mm / 6 mm OcuSafe® LDS:13 mm / 8 mm / 4 mm LDS Needle: 13 mm / 8 mm / 4 mm	Identical	ISO 7864, ISO 9626
Needle Gauge		VitreJect® LDS: 30G, 31G and 33G. SteriCap® LDS: 30G, 31G and 33G OcuSafe® LDS: 29G, 30G, 31G and 33G LDS Needle: 29G, 30G, 31G and 33G	Identical	ISO 7864, ISO 9626
Connection		Luer-slip Luer-lock	Identical	ISO 7864, ISO 80369-7
Needle Color Coding		Conforms to ISO 6009	Identical	ISO 6009
Needle tip configuration		Lancet bevel	Identical	ISO 7864, ISO 9626
Sterilization and Shelf Life		Provided Sterile, Single-Use 100 individual blister packed devices packaged into shelf carton Sterilization Method: EO SAL: 10^{-6} Shelf Life: 5 years	Identical	AAMI TIR28, ISO 11135, ISO 10993-7, USP <85>, USP <161>, ANSI/AAMI ST72, ASTM F1980-16, ISO 7864,

510(k) Summary

Characteristic	**Proposed Device** LDS Needle OcuSafe® LDS Needles SteriCap® LDS Safety Needles VitreJect® LDS Safety Needles	**Predicate Device** Needle OcuSafe® Needles SteriCap® Safety Needles VitreJect® Safety Needles	**Associated Testing Standard**
			ISO 9626, ISO 80369-7, ASTM F88/F88-15, ASTM F1929-15, ASTM D4169-16
Biocompatibility per ISO 10993-1	Non-cytotoxic	Identical	ISO 10993-5
	Non-sensitizer	Identical	ISO 10993-10
	Non-irritant, Intracutaneous Reactivity	Identical	ISO 10993-10
	Non-irritant, Ocular	Identical	
	Non-irritant, Intravitreal Injection	Identical	
	Non-irritant, Intraocular	Identical	
	Non-pyrogenic	Identical	ISO 10993-11, USP <151>
	Non-toxic	Identical	ISO 10993-11
	Non-hemolytic	Identical	ISO 10993-4 ASTM F756-17

The minor difference for the LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle is that a low dead space specification was established that is less than or equal to 5µL (≤ 0.005 mL)]. The “Low Dead Space (LDS)” specification was confirmed by testing using 58 samples for the 95% confidence and 95% reliability. The “Low Dead Space (LDS)” designation will be added to the trade name, labels and labeling of the LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle [Proposed Devices].

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 biocompatibility categorized as an externally communicating device with limited (<24 hours) direct tissue and indirect blood path contact with the testing completed to demonstrate the needle devices are biocompatible for the intended use. Biocompatibility endpoints included Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity, Acute systemic toxicity, Material mediated pyrogenicity, Indirect hemolysis, Direct hemolysis, Particulates, Occular Irritation, and Intravitreal Injection Irritation. Performance and safety testing included dimensional and physical properties verification, bond and material strength verification, needle quality, color coding, luer connector, particulate testing, sharps injury prevention features. The ethylene oxide sterilization cycle was validated based on the principles of ISO 11135. The residual levels meet the requirements of ISO 10993-7. LAL testing for each lot ensures the devices meet the acceptance criteria of 20 EU/device (for LDS Needle / SteriCap® LDS Safety Needle) or ≤ 0.2 EU/device (for the OcuSafe® LDS Needle / VitreJect® LDS Safety Needle with the intravitreal indication for use). The shelf-life was validated using industry-standard accelerated aging technique and assured functional performance of the device as well as packaging and sterile barrier integrity. The shelf-life validation included anticipated stress associated with transportation and handling. Packaging integrity was validated using the bubble leak test method and seal strength. The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle [Proposed Devices] **did not change** from devices under the respective previously cleared 510(k)s [Predicate Devices].

510(k) Summary

Substantial Equivalence Conclusions:

The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle [Proposed Devices] met the established safety and performance characteristics for a hypodermic single-lumen needle. The addition of the “low dead space (LDS)” specification to the trade name, labels and labeling did not raise any new or different questions of safety, performance or effectiveness when compared to the predicate device. The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle are as safe and effective as the respective predicate devices previously cleared under the 510(k)’s [Predicate Devices] and will perform as intended.

The LDS Needle / OcuSafe® LDS Needle / VitreJect® LDS Safety Needle / SteriCap® LDS Safety Needle are substantially equivalent to the Needle / OcuSafe® Needle / VitreJect® Safety Needle / SteriCap® Safety Needle previously cleared under 510(k) #: K233343; K239059; and K212805.