May 9, 2025

Altaviz, LLC
% Sean Griffin
President
Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
Keller, Texas 76248

Re: K243322
Trade/Device Name: Altaviz Intravitreal Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: QLY, FMF
Dated: April 4, 2025
Received: April 7, 2025

Dear Sean Griffin:

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)*
K243322

Device Name
Altaviz Intravitreal Syringe

Indications for Use *(Describe)*
The Altaviz Intravitreal Syringe is intended for use by heath care professionals for general purpose fluid aspiration/injection. It is indicated for general and intravitreal use in adult patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K243322 510(k) Summary

This 510(k) Summary has been prepared in accordance with 21 CFR 807.92.

Applicant

The name and address of the Applicant is:

Altaviz LLC
13766 Irvine Blvd, Suite 143
Irvine, CA 92618

Application Correspondent:

Sean Griffin
President
Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
Keller, TX 76248
Phone: (817) 994-4306

Date Prepared: May 9, 2025

Device

Device Subject to this 510(k):

Trade Name:	Altaviz Intravitreal Syringe
Common Name:	Piston Syringe
Product Code:	QLY (Ophthalmic Syringe), FMF (Syringe, Piston); 21 CFR 880.5860
Classification:	II

Predicate Device

510(k) Number	K941562
Device	1mL Luer-Lok Syringe

Device Description

The Altaviz Intravitreal Syringe is identical to the BD (Becton Dickenson) 1mL Luer-Lok Syringe cleared in K941562 with the exception of the Indications for Use. The Altaviz Intravitreal Syringe is a three-piece sterile, single use, hypodermic syringe with male 6% (Luer) conical lock fittings, which are connectable to a compatible female 6% (Luer) connector. The syringe assembly consists of a lubricated polycarbonate barrel with a graduated scale, a lubricated synthetic rubber stopper and a polypropylene plunger rod. The plunger rod is pulled back to aspirate fluids or depressed to inject or expel fluids. The barrel scale of the Altaviz Intravitreal Syringe incorporates a scale graduated in units of milliliters and is provided sterile by an irradiation sterilization method. The only difference between the Altaviz Intravitreal Syringe and the BD 1mL Luer-Lok Syringe is that the Altaviz Intravitreal Syringe is routinely tested to, and must meet, additional requirements to support intraocular use including endotoxin and particulate matter.

The Altaviz Intravitreal Syringe is provided sterile by irradiation sterilization.

Indications for Use

The Altaviz Intravitreal Syringe is intended for use by heath care professionals for general purpose fluid aspiration/injection. It is indicated for general and intravitreal use in adult patients.

Technological Characteristics

The subject Altaviz Intravitreal Syringe is identical to the predicate BD 1mL Luer-Lok Syringe in terms of materials and performance characteristics. The technological characteristics of the subject device and predicate device are substantially equivalent as they are identical devices.

Substantial Equivalence Discussion

The subject device is substantially equivalent to the predicate device when evaluating intended use and technological characteristics. The subject device is additionally indicated for intravitreal use. This difference in indications for use between the subject and predicate device is addressed through additional biocompatibility, sterility and performance testing, and does not raise new or different questions of safety and effectiveness.

Features and Characteristics	Subject Device Altaviz Intravitreal Syringe	Predicate Device BD 1mL Luer-Lok Syringe	Comparison of Subject Device and Predicate
510(k) Number	K243322	K941562	
Device Code	QLY, FMF	FMF	Identical
Indications for Use/Intended Use	The Altaviz Intravitreal Syringe is intended for use by heath care professionals for general purpose fluid aspiration/injection. It is indicated for general and intravitreal use in adult patients.	The BD 1mL Luer-Lok™ Syringe is intended for use by health care professionals for general purpose fluid aspiration/injection.	Same as predicate with exception of additional indication for intravitreal use.
Syringe Materials			
Barrel	Polycarbonate	Polycarbonate	Identical
Barrel Lubricant	Silicone	Silicone	Identical
Plunger Rod	Polypropylene	Polypropylene	Identical
Stopper	Polyisoprene Rubber	Polyisoprene Rubber	Identical
Stopper Lubricant	Silicone	Silicone	Identical
Mechanism of Action	Manual	Manual	Identical
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Identical
SAL	10^{-6}	10^{-6}	Identical
Shelf Life	5 Years	5 Years	Identical

Non-Clinical Performance Testing

Particulate testing of the subject device according to USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions was performed and passed. Performance testing was also conducted and results confirmed that the Altaviz Intravitreal Syringe complies with the requirements of ISO 80369-7 (Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications) and ISO 7886-1 (Sterile hypodermic syringes for single use - Part 1: Syringes for manual use).

Non-Clinical Biocompatibility Testing

In addition to the biocompatibility testing conducted on the predicate (cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, hemolysis), chemical characterization and toxicological risk assessment of the device was performed to evaluate the subacute toxicity. An ocular study was conducted following intravitreal injection in rabbits and demonstrated that the device was not considered inflammatory to intraocular tissues of the rabbit.

Conclusion

The Altaviz Intravitreal Syringe is substantially equivalent to the predicate device.