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

Re: K231261
Trade/Device Name: Altaviz Needle Kit II
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI, GAA
Dated: May 1, 2023
Received: May 2, 2023

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 (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: 2023.07.27 12:34:46 -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)*
K231261

Device Name
Altaviz Needle Kit II

Indications for Use *(Describe)*

The Altaviz Needle Kit II is a convenience kit that includes:

A 29G injection needle that is a sterile medical device for single use intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Either an 18G or a 19G 5 micron filter needle that is a sterile medical device for single use intended to draw up fluids into a syringe.

The Altaviz Needle Kit II 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 - K231261

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 Alton Parkway, Suite 143
Irvine, CA 92618

Application Correspondent:

Sean Griffin
President
Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
Keller, TX 76248
Phone: (817) 805-8392

Date Prepared: July 27, 2023

Device

Device Subject to this 510(k):

Trade Name:	Altaviz Needle Kit II
Common Name:	Needle Convenience Kit
Product Code:	FMI (Needle, Hypodermic, Single Lumen; 21CFR Section 880.5570), GAA (Needle, Aspiration and Injection, Disposable; 21CFR Section 878.4800)
Classification:	II

Predicate Device

510(k) Number	Device
K222681	Altaviz Needle Kit
K970370	TSK Steriject 29G Hypodermic Needle (Additional Predicate)

Device Description

The Altaviz Needle Kit II is a convenience kit with a tray that is made of polyethylene terephthalate glycol (PETG) and a coated paper lid. The original version of this kit, the Altaviz Needle Kit, was cleared on December 5, 2022 (K222681), and the only difference between the Altaviz Needle Kit and the Altaviz Needle Kit II is the 29G injection needle included.

The tray of the Altaviz Needle Kit II is designed to securely store two separately packaged and previously sterilized needles: a single-use 29G injection needle and either a sterile 18G or 19G 5 micron filter needle. The tray lid provides protection and helps secure the needles during transport. No changes to the primary packaging of the needles or additional sterilization occurs prior to inclusion in the Altaviz Needle Kit II.

The 29G needle is a sterile hypodermic single lumen needle, for single use consisting of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polycarbonate designed to be connected with a male connector (nozzle) of a piston syringe.

The 18G or 19G 5 micron filter needle is a sterile medical device for single use consisting of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) made of polycarbonate or ABS (respectively) designed to be connected with a male connector (nozzle) of a piston syringe. The filter needle is used to draw up fluids into a syringe.

Indications for Use

The Altaviz Needle Kit II is a convenience kit that includes:

A 29G injection needle that is a sterile medical device for single use intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Either an 18G or a 19G 5 micron filter needle that is a sterile medical device for single use intended to draw up fluids into a syringe.

The Altaviz Needle Kit II is indicated for intravitreal use.

Physical and Performance Characteristics

The Altaviz Needle Kit II is a convenience kit of currently distributed and routinely used needles that have been combined for the convenience of the end user for use in the injection of intravitreal fluids. The Altaviz Needle Kit II components (needles) are identical to the separately distributed versions and have not been changed. The included 29G injection needle is commonly used to inject intravitreal fluids and the included 5 micron filter needle is commonly used to draw up medication into a syringe prior to injection.

Comparison of Technological Characteristics with the Predicate Device

Features and Characteristics	**Proposed Altaviz Needle Kit II**	**Primary Predicate Altaviz Needle Kit**	**Comparison of Proposed Device and Predicate**
510(k) Number	K231261	K222681	
Device Code	FMI, GAA	FMI, GAA	Same as Predicate
Intended Use	Used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	Used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin	Same as Predicate
Indications for Use	The Altaviz Needle Kit II is a convenience kit that includes: A 29G injection needle that is a sterile medical device for single use intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. Either an 18G or a 19G 5 micron filter needle that is a	The Altaviz Needle Kit II is a convenience kit that includes: A 29G injection needle that is a sterile medical device for single use intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. Either an 18G or a 19G 5 micron filter needle that is a	Same as Predicate Additional testing to intraocular acceptance criteria for the TSK 29G needle has been performed.

	sterile medical device for single use intended to draw up fluids into a syringe. The Altaviz Needle Kit II is indicated for intravitreal use.	sterile medical device for single use intended to draw up fluids into a syringe. The Altaviz Needle Kit II is indicated for intravitreal use.	
Mechanism of Action	Manual	Manual	Same as Predicate
Where Used	Hospital, surgical setting	Hospital, surgical setting	Same as Predicate
Kit Components	TSK Steriject 29G Hypodermic Needle Either an 18G or a 19G 5 micron filter needle	Terumo K-Pack II 29G Thin Wall Needle Either an 18G or a 19G 5 micron filter needle	Same as Predicate with exception of supplier of injection needle
Packaging/ How Supplied	A convenience kit containing previously sterilized devices	A convenience kit containing previously sterilized devices	Same as Predicate
Materials of Construction	Needle kit tray: polyethylene terephthalate glycol (PETG) 29G Needle: stainless steel and polypropylene 18G or 19G filter needle: stainless steel and polycarbonate or ABS (respectively)	Needle kit tray: polyethylene terephthalate glycol (PETG) 29G Needle: stainless steel and polypropylene 18G or 19G filter needle: stainless steel and polycarbonate or ABS (respectively)	Same as Predicate
Sterility	Contains Sterile (previously sterilized) devices. No additional sterilization performed prior to including in the Altaviz Needle Kit II	Contains Sterile (previously sterilized) devices. No additional sterilization performed prior to including in the Altaviz Needle Kit	Same as Predicate

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 specifically indicated for intravitreal use while the standard hypodermic needle has a broad indication for all parts of the body. To support intravitreal use, ethylene oxide residuals, endotoxin, and particulate matter (see Performance Data) were tested to ensure compliance with intraocular requirements. An evaluation of biocompatibility for intravitreal injection was also conducted to ensure that the proposed device is safe for intravitreal injections.

The technological characteristics of the 29G injection needle included in the subject device are substantially equivalent to the additional predicate device in that they are identical devices. The 18G or 19G 5 micron filter included in the Altaviz Needle Kit II is a previously marketed class 1 device provided with the 29G injection needle for convenience of the user.

Performance Data

Particulate testing of the kit components (needles) according to USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions was performed and passed. In addition, intraocular irritation testing according to ISO 10993-10 was performed and passed. Ethylene oxide residuals were assessed per ISO 10993-7. Endotoxins were also tested as recommend in FDA guidance Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices.

Conclusion

The Altaviz Needle Kit II is substantially equivalent to the predicate device.