May 7, 2026

Galvanize Therapeutics, Inc.
Elodie Trouche
Regulatory Affairs Manager
3200 Bridge Pkwy.
Redwood City, California 94065

Re: K253826
Trade/Device Name: Aliya® EX System; Aliya® EX Generator; Aliya® Needle; Aliya® Electrode; INUMI™ Flex Needle
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: OAB
Dated: April 8, 2026
Received: April 9, 2026

Dear Elodie Trouche:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.07 11:48:58 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253826

Please provide the device trade name(s).

Aliya® EX System;
Aliya® EX Generator;
Aliya® Needle;
Aliya® Electrode;
INUMI™ Flex Needle

Please provide your Indications for Use below.

The Aliya® EX System is indicated for surgical ablation of soft tissue.

The Aliya® Needle is intended for use as part of the Aliya® System and Aliya EX® System for surgical ablation of soft tissue.

The Aliya® Electrode is intended for use as part of the Aliya® System and Aliya EX® System for surgical ablation of soft tissue.

The INUMI™ Flex Needle is intended for use as part of the Aliya® System and Aliya EX® System for surgical ablation of soft tissue.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253826 - 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary.

Date Summary Prepared: May 6, 2026

Submitter Information

Manufacturer: Galvanize Therapeutics, Inc.
3200 Bridge Pkwy,
Redwood City, CA 94065
Phone: 650-268-4252

Contact: Deborah Sheffield
Chief Regulatory Officer
dsheffield@galvanizetx.com

Subject Device

Device Trade Name:	Aliya® EX System, Aliya® EX Generator, Aliya® Needle, Aliya® Electrode; INUMI™ Flex Needle
Common Name:	Low energy direct current thermal ablation device
Regulation Number:	21 CFR §878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	OAB
Device Class:	II
Review Panel:	General & Plastic Surgery

Predicate Devices

Device Trade Name:	Aliya® System, Aliya® Generator, Aliya® Needle, Aliya® Electrode
510(k) Number:	K212871
Manufacturer:	Galvanize Therapeutics, Inc.
Device Trade Name:	INUMI™ Flex Needle
510(k) Number	K233884
Manufacturer:	Galvanize Therapeutics, Inc.

Device Description

The Aliya EX System (subject device) is an electrosurgical system that delivers high frequency, short duration electrical pulses known as Aliya Pulsed Electric Field (aPEF) through the Aliya Needle (K212871) or INUMI Flex Needle (K233884) to ablate soft tissue. The delivery needle is connected to the Aliya EX Generator using the Aliya Electrode (K212871). The Aliya EX Generator can deliver two energy settings: G10 and G20 resulting in two different lesion sizes which are listed in the device labeling.

The INUMI™ Flex Needle is an endoscopically compatible soft tissue ablation device for use as part of the Aliya® EX System. The INUMI Flex Needle has a 160 cm working length, and is compatible with endoscope working channels with a minimum of 2.0 mm diameter. The device is provided sterile for single use.

Proposed Indications for Use statement

Aliya EX System: The Aliya® EX System is indicated for the surgical ablation of soft tissue.

Aliya Needle: The Aliya® Needle is intended for use as part of the Aliya® System and Aliya® EX System for surgical ablation of soft tissue.

Aliya Electrode: The Aliya® Electrode is intended for use as part of the Aliya® System and Aliya® EX System for surgical ablation of soft tissue.

INUMI Flex Needle: The INUMI™ Flex Needle is intended for use as part of the Aliya® System and Aliya® EX System for surgical ablation of soft tissue.

Comparison of Subject and Predicate Device Characteristics

Aliya EX System: The predicate Aliya System includes the Aliya 2.5 Generator that provides one factory preset energy setting of 3000 V maximum to create an ablation zone of ~10mm in diameter. The Aliya EX System generator provides two factory preset energy settings: 1) the G10 setting creates a ~10mm diameter ablation zone like the predicate, and 2) a new G20 setting that creates an ~20mm diameter ablation zone. The Aliya EX Generator also includes device enhancements to improve product use, including 1) a foot switch latching feature in the software that delivers the full energy cycle after the foot switch is held down for 15 seconds to reduce physician fatigue, 2) a serial port for Galvanize to retrieve generator performance data during service, 3) current control (vs. voltage control for the Aliya 2.5 Generator) to enhance predictability and consistency of tissue ablation at different impedances , and 4) a boot application to facilitate the main application startup code.

INUMI Flex Needle: The subject and predicate INUMI Flex Needles are identical product and have the same intended use for surgical ablation of soft tissue when used as part of a compatible Aliya System. The INUMI labeling was updated to specify compatibility with the Aliya EX System. The additional language defining compatibility does not alter or expand the intended use of the needle.

Performance Testing (Bench) – Aliya EX System

The following performance testing was completed to support demonstration of substantial equivalence of the subject Aliya EX System to the predicate Aliya System.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was completed. The results demonstrated compliance of the subject device to all applicable standards, including IEC 60601-1 and IEC 60601-1-2 and IEC 60601-4-2.

Software Verification and Validation (V&V) and Cybersecurity

Software V&V testing and cybersecurity testing was performed in alignment with the following FDA guidance document.

- *Off-The-Shelf Software Use in Medical Devices*, issued August 11, 2023
- *Content of Premarket Submissions for Device Software Functions*, issued June 14, 2023
- *Content of Premarket Submissions of Management of Cybersecurity in Medical Devices*, issued June 27, 2025

Ex Vivo Characterization of Thermal Effects on Tissue

The temperature-time history was measured consistent with the recommendations of FDA's Guidance *Premarket Notification (510(k)) Submission for Electrosurgical Devices for General Surgery*, issued March 9, 2020, in three types of ex-vivo porcine tissue - liver, kidney, and muscle. Comparative testing was performed with the subject and predicate generator used with the Aliya Needle and INUMI Flex Needle.

Performance Testing (Animal)

A porcine model was used to characterize tissue destruction with the subject Aliya EX System with the Aliya EX Generator and the predicate Aliya System with the Aliya 2.5 Generator in the liver, kidney, and longissimus dorsi skeletal muscle, in accordance with the FDA's guidance *Premarket Notification (510(k)) for Electrosurgical Devices for General Surgery* issued March 9, 2020.

Conclusion

Aliya EX System: The subject Aliya EX System has the same intended use as the predicate Aliya System for surgical ablation of soft tissue. The bench and animal performance testing demonstrate that the differences in technological characteristics do not raise different questions of safety or effectiveness and the Aliya EX System is as safe and as effective as the predicate Aliya System. Thus, the subject Aliya EX System meets FDA's criteria for substantial equivalence to the predicate Aliya System (K212871) per 21 CFR § 807.100 (b)(2).

INUMI Flex Needle: The subject and predicate INUMI Flex Needles are identical products and have the same intended use for surgical ablation of soft tissue when used as part of an Aliya System. The subject INUMI Flex Needle updated IFU adds compatibility with the Aliya EX System. The additional language defining compatibility does not alter or expand the intended use of the needle. Thus, the subject INUMI Flex Needle meets FDA's criteria for substantial equivalence to the predicate INUMI Flex Needle (K233884) per 21 CFR § 807.100 (b)(2).