May 22, 2024

Galvanize Therapeutics, Inc.
Dongbo Wang
Senior Director of Regulatory Affairs
3200 Bridge Parkway
Redwood City, California 94065

Re: K233884
Trade/Device Name: 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: May 20, 2024
Received: May 20, 2024

Dear Dongbo Wang:

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.

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,

Long H. Chen -S Digitally signed by Long H. Chen -S
Date: 2024.05.22 08:59:39 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
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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.

Submission Number *(if known)*

K233884

Device Name

INUMI™ Flex Needle

Indications for Use *(Describe)*

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

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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K233884 – 510(k) Summary

Date of 510(k) Summary Preparation: 11 April 2023

Submitter Information

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

Contact: Dongbo Wang
Senior Director of Regulatory Affairs
dwang@galvanizetx.com
Phone: 650-268-4252

Subject Device

Device Trade Name:	INUMI™ Flex Needle
510(k) Number:	K233884
Common Name:	Low energy soft tissue ablation device
Regulation Number:	21 CFR §878.4400
Regulation Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	OAB low energy direct current thermal ablation system
Review Panel:	General & Plastic Surgery (SU)

Primary Predicate Device

Device Trade Name:	Aliya™ System
510(k) Number	K212871
Manufacturer:	Galvanize Therapeutics

Device Description

The INUMI™ Flex Needle (subject device) is an endoscopically compatible soft tissue ablation device that is used as part of the 510(k)-cleared Aliya™ System (K212871). The subject device has a 160 cm working length, and is compatible with endoscope working channels with a minimum of 2.0 mm diameter.

Proposed Indications for Use statement

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

Comparison to Primary Predicate Device

Characteristic	INUMI™ Flex Needle Subject Device	Aliya™ System Primary Predicate Device	Comparison
510(k) number	TBD (K233884)	K212871	N/A
Classification Regulation	21 CFR §878.4400 Electrosurgical cutting and coagulation device and accessories.	21 CFR §878.4400 Electrosurgical cutting and coagulation device and accessories.	Identical
Product Code	OAB low energy direct current thermal ablation system	OAB low energy direct current thermal ablation system	Identical
Indications for Use statement	The INUMI™ Flex Needle is intended for use as part of the Aliya™ System for surgical ablation of soft tissue.	The Aliya™ System is indicated for the surgical ablation of soft tissue.	Identical, for surgical ablation of soft tissue, subject device specifies compatibility with the Aliya System
Intended use	Ablation of soft tissue	Ablation of soft tissue	Identical
Type of Use	Prescription	Prescription	Identical
Energy Source	Galvanize Aliya™ Generator (K212871) – Pulsed Electric Field	Galvanize Aliya™ Generator (K212871) – Pulsed Electric Field	Identical
Energy Polarity	Monopolar	Monopolar	Identical
Electrode	Aliya™ Electrode (K212871)	Aliya™ Electrode (K212871)	Identical
Access	Endoscopic	Percutaneous	Different

Comparison of Indications for Use statement with the Primary Predicate Device

The Indications for Use statements are identical in that both devices (predicate and subject devices) are indicated for the surgical ablation of soft tissue. The Indication for Use statement for the subject device adds the specificity for the compatibility with the Aliya System. The additional language defining compatibility does not alter or expand the intended use, it is a technical limitation on compatible devices.

Comparison of Technological Characteristics with the Primary Predicate Device

The subject device and the primary predicate device utilize the same generator and electrode to achieve soft tissue ablation. The main difference in technological characteristics is the form of access – endoscopic for the subject device and percutaneous for the predicate device.

Performance Testing (bench)

Performance testing has been completed to demonstrate (in part) substantial equivalence of the subject device to the predicate device. The testing performed is summarized, below:

Biocompatibility

Biocompatibility testing was performed for patient-contacting components of the INUMI™ Flex Needle in accordance with ISO 10993-1 requirements, as well as the FDA Guidance Document Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process,” September 2023.

Sterilization

The INUMI™ Flex Needle was validated per ISO 11135:2014 to achieve a sterility assurance level of 10^{-6} using ethylene oxide sterilization.

Shelf-Life/Package Validation

Shelf-Life and Package Validation were performed to ensure that the devices maintain package integrity and sterility. Applicable standards were used: ASTM F1980-21, ISTA 3A 2018, ASTM F2096-11, ASTM F1929-15, ASTM F88/F88M-21.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was completed for the applicable components of the INUMI™ Flex Needle. The results demonstrated compliance to all applicable standards, including IEC 60601-1 and IEC 60601-1-2.

Capacitive Couple Testing

Capacitive coupling testing was done per FDA Guidance on Premarket Notifications (510(k)) Submissions for Electrosurgical Devices for General Surgery according to the applicable clauses of IEC 60601-2-18.

Mechanical and Electrical Performance Testing

Mechanical and Functional testing was completed to confirm that the performance of the INUMI™ Flex Needle conforms to the predefined mechanical and electrical specifications after sterilization and accelerated aging.

Ex Vivo Characterization of Thermal Effects on Tissue

The temperature-time history was measured consistent with the recommendations of the FDA Guidance on Premarket Notification (510(k)) Submission for Electrosurgical Devices for General Surgery in three types of ex-vivo porcine tissue - liver, kidney, and muscle. Comparative testing was performed with the subject device and the primary predicate device.

Performance Testing (animal)

Comparative Ablation Performance

Porcine model was utilized to characterize tissue destruction with subject device and the primary predicate device in the liver, kidney, and longissimus dorsi skeletal muscle in accordance with the FDA guidance on Premarket Notification [510(k)] for Electrosurgical Devices for General Surgery.

Endoscopic Performance

A chronic porcine GLP study was conducted to evaluate the performance of the endoscopic use of subject device regarding navigation, access, and ablation of target tissues.

Conclusion

The subject INUMI™ Flex Needle and the legally marketed predicate Aliya™ System (K212871) share the same Intended Use and consistent Indications for Use. Both performance testing (bench) and performance testing (animal) support a determination of substantial equivalence to the legally marketed predicate device.