U.S. FOOD & DRUG ADMINISTRATION

June 17, 2022

Galvanize Therapeutics, Inc.
% Lisa Pritchard
VP of Regulatory, Quality, Clinical & Engineering
DuVal & Assoicates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K212871
Trade/Device Name: Aliya(TM) System, Aliya(TM) Generator, Aliya(TM) Needle, Aliya(TM) Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OAB
Dated: September 6, 2021
Received: September 9, 2021

Dear Lisa Pritchard:

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

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10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2022.06.17 15:54:04 -04'00'

Long Chen, Ph.D.
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

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)*
K212871

Device Name
Aliya(TM) System

Indications for Use *(Describe)*
The Aliya System is indicated for the 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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Ex. 2149-003 **CX-2845.3**

510(k) Summary – K212871

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

Date Summary Prepared: June 15, 2022

Submitter Information

Company: Galvanize Therapeutics, Inc.
1531 Industrial Road
San Carlos, CA 94070
Ph: 650-268-4252
Fax: NA

Contact: Deborah Sheffield
Sr. Vice President, Regulatory & Quality Affairs
Deb@GalvanizeTherapeutics.com
Ph: 650-268-4252

Name of the Device

Trade Name: Aliya™ System

Common Name: Low energy soft tissue ablation device

Classification Name: Low Energy Direct Current Thermal Ablation System

Review Panel: General & Plastic Surgery (SU)

Regulation: 878.4400

Class: Class II

Product Code: OAB

Predicate Device: NanoKnife™ System (K183385)
AngioDynamics, Inc.

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Equivalence Claimed to Predicate Device

The predicate device is classified as follows:

Regulation Number	21 CFR 878.4400
Regulation Name	Electrosurgical cutting and coagulation device and accessories
Product Code	OAB
Regulatory Class	II

Predicate Trade Name, 510(k) Number and Manufacturer:

Trade Name	NanoKnife System
510(k) Number	K183385
Manufacturer	AngioDynamics, Inc.

Based on the information and rationale presented and supported by the collective content of this 510(k), the Aliya System is equivalent to the legally marketed predicate, the NanoKnife System.

Intended Use/Indications for Use

The Aliya System has the same intended use as the predicate in that it was designed for the ablation of soft tissue.

The Aliya System has the same Indication for Use statement as the predicate with one exception. The omitted words reflect a minor design difference in the number of outputs between the two systems that has no impact on the intended use.

Subject Indications for Use

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

Device Description

The Aliya System is designed to ablate soft tissue through the delivery of pulsed electric fields (PEF) energy to target tissue. The high frequency, short duration energy delivered to the target tissue to induce programmed cell death (apoptosis) while maintaining the cellular matrix.

The Aliya System consists of an Aliya Generator, an Aliya Ablation Device and a cardiac monitor.

Generator: The Aliya Generator is a transportable non-sterile electrical device compatible for use in the operating room environment. It consists of hardware, software, a display touch screen user interface, a power supply cord and a foot switch. It features controls to initiate and stop treatment as well as indicators to monitor the treatment and provide alerts to the user.

The Aliya Generator creates high frequency short duration energy, which is delivered to the target tissue via the Aliya Ablation Device. The Generator interfaces with the commercially available Ivy Biomedical Model 7600 cardiac monitor (Cardiac Monitor), which is provided with

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the Aliya System and is used in accordance with its cleared indications. The Cardiac Monitor uses a 4-lead configuration, which detects the R-wave of the electrocardiogram (ECG) signal and sends a trigger signal to the Generator for precise synchronization of energy output to the patient. This ensures reliable energy delivery synchronization with the patient's cardiac cycle thereby reducing risk of cardiac rhythm disturbances.

The Generator software includes an algorithm that interprets trigger signals from the Cardiac Monitor. The algorithm will only allow the initiation and delivery of energy output when the patient's heart rate is within acceptable limits.

Aliya Ablation Device: The Aliya Ablation Device is a monopolar electrosurgical instrument comprising the Aliya Needle and the Aliya Electrode. Both the needle and electrode are designed for sterile, single use. The Aliya Needle consists of a 19 gauge, 20cm needle with a 1 cm exposed tip and a nested stylet (which is removed once the Aliya Electrode is in position). The Aliya Electrode consists of a 21 cm probe that connects with the needle, a 3-meter cable, and a plug that connects with the Aliya Generator. When connected to the Aliya Generator, the Aliya Ablation Device delivers PEF energy to the target zone at the distal 1 cm of the needle.

Comparison of Subject and Predicate Device Characteristics

The principle of operation (i.e., delivery of pulsed electric fields (PEF) energy to surgically ablate soft tissue via programmed cell death) of the subject device is identical to the predicate device. Some subject device waveform characteristics (e.g., frequency, number of activations, monopolar biphasic, etc.) vary from the predicate device. Both devices utilize a cardiac monitor to synchronize ablation timing with the patient's heart rate. The predicate device requires two to six sterile 19-Gauge electrodes (probes) positioned in a parallel array with equal depth placement while the subject device utilizes one sterile 19-Gauge electrode (needle) which can be repositioned as needed to obtain the desired treatment effect. Both devices utilize Computed Tomography (CT) and/or ultrasound for visualization during placement. The dimensions, needle tip geometry and the markings of the predicate and subject device (electrodes) are very similar. While both devices (generators) are transportable, the predicate device is larger in size compared to the subject device.

Performance Testing

The following testing was conducted to confirm that the Aliya System meets specifications and that it performs equivalent to the predicate NanoKnife System. Performance testing was completed in accordance with applicable standards.

Verification Activity	Result
System Electromechanical Safety Testing	Pass

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Verification Activity	Result
System Electromagnetic Compatibility Testing	Pass
System Ablation Tissue Effects – Ex Vivo Testing	Pass
Aliya Ablation Device – Electrical Test	Pass
Aliya Ablation Device – Mechanical Test	Pass
Aliya Ablation Device – Dimensional Inspection	Pass
Aliya Ablation Device – Packaging and Transit Test	Pass
Aliya Ablation Device – Shelf Life	Pass
Aliya Ablation Device – Biocompatibility	Pass
Aliya Ablation Device - Sterilization	Pass
Aliya Generator – System and Software Verification	Pass
Aliya Generator – Hardware Verification	Pass
Aliya Generator – Packaging and Transit Verification	Pass

Device safety and performance were evaluated against the following published consensus standards as necessary per the subject device intended use and technological characteristics.

Standard ID	Title
ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 24971:2020	Medical devices. Guidance on the application of ISO 14971
ASTM F 88/F88-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO/IEC 17025:2017	General requirements for the competence of testing and calibration laboratories
ISTA 3A:2018	Packaged Products for Parcel Delivery System Shipment 70kg (150lbs) or Less
ISO 10993-1:2018	Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process

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Standard ID	Title
ANSI/AMI/ISO 10993-5:2009 (R)2014	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third edition 2010-08-01	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11 Third edition 2017-09	Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.
IEC 60601-1:2005 /A1:2012 Edition 3.1	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
AAMI/ANSI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R) 2012 & A2:2010/(R)20120 (Consolidated Text), Edition 3.1	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
AAMI/ANSI/IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and test
IEC 60601-2-2: 2017 Edition 6.0	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
IEC60601-2-27: 2011 Edition 3.0	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 61000-4-2 2008	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measuring techniques - Electrostatic discharge immunity test
IEC 61000-4-3: 2006, A1: 2007, A2: 2010	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques -Radiated, radio-frequency, electromagnetic field immunity test
IEC 61000-4-4: 2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test.
IEC 61000-4-5: 2005	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
IEC 61000-4-6: 2013	Electromagnetic compatibility (EMC) - Part 4- 6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

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Standard ID	Title
IEC 61000-4-8: 2009	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
IEC 61000-4-11: 2004	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
CISPR 11: 2009, A1:2010	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
IEC 61000-3-2: 2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current <= 16 A per phase)
IEC 61000-3-3 2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection
IEC 62304 Edition 1.1 2015-06, Consolidated Version	Medical device software – Software life cycle processes
ANSI/AAMI/ISO 11135:2014/Amd 1:2018	Sterilization of health care products – Ethylene Oxide – Requirements for development, validation, and routine control of a sterilization process for medical devices
AAMI TIR28:2016	Product adoption and process equivalency for ethylene oxide sterilization
ANSI/AAMI/ISO 10993-7:2008 / AC:2009 / Amd 1:2019	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 11737-2 Third edition, 2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ANSI/AAMI/ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

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To address the recommendations contained in the FDA Guidance document "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", an animal study was conducted in accordance with 21 CFR Part 58, Good Laboratory Practice. The purpose of the testing was to evaluate safety and performance of the Aliya System under clinically relevant operating conditions. The study was completed using three different study physicians and six healthy porcine in accordance with the operating instructions in the User Manual and IFU. Treatment was applied to the liver, kidney, and skeletal muscle in all animals. To visualize the treatment sites, all animals underwent a baseline and post procedure CB-CT (Cone Beam Computer Tomography) scanning procedure. Animals were survived up to 28 days depending on their treatment group assignment.

In addition, Galvanize performed ex-vivo tissue ablation performance testing following the FDA guidance document Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, dated August 15, 2016. The performance comparison testing and evaluation between the bipolar monophasic NanoKnife system predicate device and the monopolar biphasic Aliya System subject device was conducted using liver, kidney, and muscle tissue.

Conclusion

Results of the successful testing of the Aliya System demonstrate that the technological differences in the Aliya System compared to the predicate device do not raise any new questions of safety or effectiveness and therefore support substantial equivalence to the predicate NanoKnife System. The subject Aliya System is substantially equivalent to the predicate NanoKnife System (K183385). Both devices share the same Intended Use and similar Indications for Use. Testing demonstrates that the technological differences do not raise any new questions of safety or effectiveness. Testing therefore supports the Aliya System substantial equivalence to the predicate NanoKnife System.

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