

**K212871 Aliya(TM) System, Aliya(TM) Generator, Aliya(TM) Needle, Aliya(TM) Electrode**Jun 17, 2022  
281 days to decisionK212871 · Product code: **OAB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212871/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Sep 9, 2021
Decision date	Jun 17, 2022
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Galvanize Therapeutics, Inc.</b>
Location	San Carlos, CA, US
Contact	Deborah Sheffield
510(k) history	2 submissions · 2 cleared · 2022-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>DuVal &amp; Associates, P.A.</b>
Contact	Lisa L. Pritchard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212871/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026