

K253826 Aliya® EX SystemMay 7, 2026
157 days to decisionK253826 · Product code: **OAB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Energy Direct Current Thermal Ablation System (OAB)
Date received	Dec 1, 2025
Decision date	May 7, 2026
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Aliya® EX Generator; Aliya® Needle; Aliya® Electrode; INUMI™ Flex Needle

APPLICANT

Company	Galvanize Therapeutics, Inc.
Location	San Carlos, CA, US
Contact	Deborah Sheffield
510(k) history	3 submissions · 3 cleared · 2022-2026

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