

**K233884 INUMI™ Flex Needle**May 22, 2024  
166 days to decisionK233884 · Product code: **OAB** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233884/>**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	Dec 8, 2023
Decision date	May 22, 2024
Days to decision	166 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233884/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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