

**K242630 Aerin Console**Dec 10, 2024  
98 days to decisionK242630 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242630/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 3, 2024
Decision date	Dec 10, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aerin Medical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Teri Feeley
510(k) history	9 submissions · 9 cleared · 2015-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242630/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026