

**K261202 ENTire IRE System**May 29, 2026  
46 days to decisionK261202 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k261202/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 13, 2026
Decision date	May 29, 2026
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entire Medical , Ltd.</b>
Location	Herzliya, IL
Contact	Hila Wachsler-Avrahami
510(k) history	2 submissions · 2 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>MCRA, LLC</b>
Contact	Glenn Stiegman

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261202/> 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 June 5, 2026