FDA 510(k) Premarket Notification

K261202 ENTire IRE System

CLEARED

May 29, 2026
46 days to decision

K261202 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k261202/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**MCRA, LLC**
Contact	Glenn Stiegman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov