

**K251996 ENTire IRE System**Jan 14, 2026  
201 days to decisionK251996 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k251996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 27, 2025
Decision date	Jan 14, 2026
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Entire Medical , Ltd.</b>
Location	Herzliya, IL
Contact	Daniela Heimlich
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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

**CLINICAL EVIDENCE - NCT06187194****Efficacy and Safety of Irreversible Electroporation for Chronic Symptomatic Tonsillar Hypertrophy Treatment**

Status	Completed
Enrollment	24 patients (actual)
Study sites	1 site
Condition studied	Tonsillar Hypertrophy
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 2, 2025
Sponsor	ENTire Medical Ltd. (Industry)

**Primary outcome**

Change of Tonsil(s) Size at 3 Months Compared to the Baseline.

**Secondary outcome**

Change in Snore VAS at 3-months Post-treatment Compared to Baseline

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT06187194](https://clinicaltrials.gov/study/NCT06187194)