

K251254 Ignite RF SystemJan 15, 2026
267 days to decisionK251254 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 23, 2025
Decision date	Jan 15, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inmode , Ltd.
Location	Yokneam, IL
Contact	Suhair Francis
510(k) history	15 submissions · 15 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

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.netDevice record: <https://www.510kdatabase.net/k251254/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026