

K250065 DENSITYJul 8, 2025
179 days to decisionK250065 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 10, 2025
Decision date	Jul 8, 2025
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DENZA; DENSITY Noir

APPLICANT

Company	Jeisys Medical Incorporated
Location	Seoul, KR
Contact	Jeongwook Lee
510(k) history	3 submissions · 3 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	E & M
Contact	Sanghwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250065/> 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 14, 2026