

K230663 DensityAug 14, 2023
157 days to decisionK230663 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 10, 2023
Decision date	Aug 14, 2023
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jeisys Medical, Inc.
Location	Littleton, CO, US
Contact	Bora Kim
510(k) history	15 submissions · 15 cleared · 2008-2024

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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230663/> 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