

K213696 ETHICON Megadyne Electrosurgical GeneratorJan 21, 2022
59 days to decisionK213696 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 23, 2021
Decision date	Jan 21, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megadyne Medical Products, Inc.
Location	Murray, UT, US
Contact	Sharon Sussex
510(k) history	50 submissions · 48 cleared · 1990-2024

REGULATORY CONSULTANT

Consulting firm	Ethicon Endo-Surgery, Inc.
Contact	Rubina Dosani

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/k213696/> 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