

**K162656 ESU-1 Electrosurgical Generator**Nov 10, 2016  
48 days to decisionK162656 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162656/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 23, 2016
Decision date	Nov 10, 2016
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tva Medical, Inc.</b>
Location	Austin, TX, US
Contact	Katherine Kumar
510(k) history	2 submissions · 1 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162656/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026