

**K181071 SIRA RFA Electrosurgical Device**Jan 16, 2019  
268 days to decisionK181071 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 23, 2018
Decision date	Jan 16, 2019
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innoblative Designs, Inc.</b>
Location	Chicago, IL, US
Contact	Tyler Wanke
510(k) history	2 submissions · 2 cleared · 2019-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181071/> 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 26, 2026