

**K192545 Potenza**Feb 20, 2020  
157 days to decisionK192545 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 16, 2019
Decision date	Feb 20, 2020
Days to decision	157 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jeisys Medical Incorporated</b>
Location	Seoul, KR
Contact	Wonchel Choi
510(k) history	3 submissions · 3 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192545/> 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