

**K081129 ENSEAL POWERTIP,NSEAL-514D,-525D,-535D,-545D,-514RD,-525RD,-535RD,-545RD, ETRIO-314D,-325D,-335D,-345D, ENSEAL UNIVERSAL**Jul 28, 2008  
98 days to decisionK081129 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k081129/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 21, 2008
Decision date	Jul 28, 2008
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surgrx, Inc.</b>
Location	Mountain View, CA, US
Contact	LINDA OLESON
510(k) history	12 submissions · 12 cleared · 2003-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081129/> 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 June 24, 2026