

**K941435 BIPOLAR U-SHAPE HANDLE, PRONGS, AND CORD**Apr 11, 1995  
383 days to decisionK941435 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k941435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 24, 1994
Decision date	Apr 11, 1995
Days to decision	383 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New Eder Corp.</b>
Location	Elk Grove Village, IL, US
Contact	JAIRO E CANAVERAL
510(k) history	4 submissions · 4 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941435/> 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 29, 2026