

**K964736 BERGEN 610 BIPOLAR COAGULATOR**Feb 27, 1997  
94 days to decisionK964736 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k964736/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 25, 1996
Decision date	Feb 27, 1997
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bergen Mfg.</b>
Location	New Port Richey, FL, US
Contact	ROGER OOSTEN
510(k) history	4 submissions · 4 cleared · 1986-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964736/> 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 July 4, 2026