

**K981888 SMOKE-EVAC**Oct 15, 1998  
139 days to decisionK981888 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k981888/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	May 29, 1998
Decision date	Oct 15, 1998
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bio-Medical Devices, Inc.</b>
Location	Irvine, CA, US
Contact	NICK HERBERT
510(k) history	7 submissions · 7 cleared · 1994-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981888/> 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 22, 2026