

**K971092 QA-ES**Apr 23, 1997  
28 days to decisionK971092 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k971092/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 26, 1997
Decision date	Apr 23, 1997
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Smith</b>
Location	Crofton, MD, US
Contact	E.J. Smith
Website	<a href="http://www.si.edu/">http://www.si.edu/</a>
510(k) history	5 submissions · 5 cleared · 1997-1998

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971092/> 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