

**K163373 PK AIM**Dec 12, 2016  
11 days to decisionK163373 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163373/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 1, 2016
Decision date	Dec 12, 2016
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gyrus Acmi, Inc.</b>
Location	Westborough, MA, US
Contact	Graham A.L. Baillie
Website	<a href="https://www.olympusmedical.com">https://www.olympusmedical.com</a>
510(k) history	42 submissions · 42 cleared · 2007-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163373/> 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 14, 2026