

**K161038 PK Morcellator**Oct 7, 2016  
177 days to decisionK161038 · Product code: **GEI** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k161038/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 13, 2016
Decision date	Oct 7, 2016
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161038/> 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 9, 2026