

**K213831 Olympus PK Electrosurgical Instruments, PK J-hook,  
PK Spatula, PK Needle**Jan 4, 2022  
27 days to decisionK213831 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213831/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 8, 2021
Decision date	Jan 4, 2022
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gyrus Acmi, Inc.</b>
Location	Westborough, MA, US
Contact	Dolan Mills
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/k213831/>. 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 13, 2026