

**K123319 GYRUS ACMI BICOAG HEMOSTASIS PROBE**Dec 14, 2012  
49 days to decisionK123319 · Product code: **KNS** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k123319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Oct 26, 2012
Decision date	Dec 14, 2012
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Surgical Technologies America</b>
Location	Southborough, MA, US
Contact	NEIL KELLY
510(k) history	12 submissions · 12 cleared · 2012-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123319/> 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 26, 2026