

**K042031 OPUS SPEEDSTITCH SUTURE DEVICE**Oct 19, 2004  
83 days to decisionK042031 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k042031/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Jul 28, 2004
Decision date	Oct 19, 2004
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Opus Medical, Inc.</b>
Location	Albuquerque,, NM, US
Contact	LAURA N KASPEROWICZ
510(k) history	13 submissions · 13 cleared · 2001-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042031/> 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